DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Establishment Registration and Product Listing for Tobacco Products

Docket No. FDA-2025-N-7130

Preliminary Regulatory Impact Analysis
Initial Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

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Executive Summary

This proposed rule prescribes the format, content, and procedures for establishment registration and tobacco product listing. If finalized, this proposed rule would also extend registration and listing requirements to owners and operators of foreign establishments that engage in the "manufacture, preparation, compounding, or processing" of a tobacco product where, currently, only domestic owners and operators are required to register and list their tobacco products. In addition, since registered establishments are subject to Food and Drug Administration (FDA or Agency) inspections by statute, this rule will extend FDA's inspections of establishments to foreign establishments. While the specific benefits are difficult to quantify, having complete and accurate tobacco product establishment registration and product listing information for both domestic and foreign establishments can help FDA accomplish several important statutory, regulatory, and public health objectives, such as identifying establishments operating in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act), facilitating the recall of non-compliant tobacco products that have entered commercial distribution, or refusing adulterated or misbranded tobacco products imported or offered for import. We quantify costs to be incurred by both domestic and foreign establishments from the time used to enter and submit their registration and tobacco product listing information and also from the time it takes for their managers to accompany FDA inspections. The 20-year annualized total costs to domestic and foreign establishments and FDA range from $6.80 million to $26.55 million at a 7 percent discount rate, with a primary estimate of $15.57 million. Costs incurred by domestic establishments are $0.013 million (primary estimate at 7% discount rate), representing 0.1% of total costs. Costs incurred by foreign establishments are $0.37 million (primary estimate at 7% discount rate), representing 2.4% of total costs; FDA costs account for the remaining 97.5% of total costs. This proposed rule would not affect the total amount of user fees set by statute nor the size of the federal budget.

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I. Introduction and Summary

A. Introduction

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 14192, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4).

Executive Orders 12866 and 13563 direct us to assess all benefits and costs of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits. Rules are economically significant under Executive Order 12866 if they have an annual effect on the economy of $100 million or more; or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities. The Office of Information and Regulatory Affairs (OIRA) has determined that this proposed rule is a significant regulatory action under Executive Order 12866.

Executive Order 14192 requires that any new incremental costs associated with certain significant regulatory actions "shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations." This proposed rule, if finalized as proposed, is expected to be an Executive Order 14192 regulatory action.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the additional costs per entity of this rule are small, we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (Section 202(a)) requires us to prepare a written statement, which includes estimates of anticipated impacts, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year." The current threshold after adjustment for inflation is $187 million, using the most current (2024) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Overview of Benefits, Costs, and Transfers

Section 905 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C § 387e) requires owners and operators of domestic establishments, upon first engaging in the manufacture, preparation, compounding, or processing of a tobacco product, to immediately

register their establishment, and to register annually thereafter.[1] It also requires owners and operators who register their establishments to submit, at the time of registration, a list of all tobacco products it manufactures, prepares, compounds, or processes.[2] Changes to the product list are to be reported twice a year. Section 905 also requires foreign establishments to register in accordance with regulations promulgated by FDA. This proposed rule would prescribe the format, content, and procedures for registration and product listing of domestic establishments and extend those requirements to foreign establishments engaged in the manufacture, preparation, compounding, or processing of a tobacco product that is imported or offered for import into the United States.

Table 1 presents estimated annualized total costs associated with the provisions in this proposed rule for both domestic and foreign establishments as well as for FDA. The 20-year annualized total costs range from $6.80 million to $26.55 million at a 7 percent discount rate, with a primary estimate of $15.57 million. The annualized total costs range from $6.81 million to $26.55 million at a 3 percent discount rate, with a primary estimate of $15.57 million. Estimated costs to establishments are derived from registration and listing activities and from inspection costs. Total annualized costs to domestic tobacco product establishments are estimated at $13,574 and $13,429 per year using a discount rate of 7 and 3 percent respectively (primary estimate), over a period of 20 years. Total annualized costs to foreign tobacco product establishments are estimated at $370,215 and $377,071 per year using a discount rate of 7 and 3 percent respectively (primary estimate). Annualized costs to FDA are approximately $15.18 million, also using a discount rate of 7 percent and 3 percent (primary estimate). These costs include costs to FDA associated with conducting both domestic and foreign inspections.

The proposed establishment registration and product listing requirements would generate several categories of benefits including several increased efficiencies in FDA enforcement and compliance activities, faster public health response, enhanced deterrence and compliance, reduced availability of unauthorized products, and reduced public health burden. We describe these benefits qualitatively due to data limitations and modeling constraints. To illustrate the potential economic benefits of the proposed rule, we provide an example of the potential reduction in illegal imported e-cigarette products.

[1] See Section 905(b), (c).
[2] See Section 905(i). The product listing includes additional information, such as a copy of all consumer information and other labeling as well as a representative sample of advertising for certain listed tobacco products.

Table 1. Summary of Benefits, Costs, and Distributional Effects of the Proposed Rule (millions of 2024 dollars)

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized $/year					7%		
						3%		Not Quantified
	Annualized Quantified					7%		
						3%		
	Qualitative							
Costs	Annualized Monetized $/year	$15.57	$6.80	$26.55	2024	7%	2027-2046	Costs incurred by domestic establishments are $13,574 (primary estimate at 7% discount rate) representing 0.1% of total costs. Estimated foreign establishment costs are $370,215 at 7 percent discount rate representing 2.4% of total costs. FDA costs account for the remaining 97.5% of total costs.[1]
		$15.57	$6.81	$26.55	2024	3%		
	Annualized Quantified					7%		
						3%		
	Qualitative							
Transfers	Federal Annualized Monetized $/year					7%		
						3%		
	From/To	From:			To:			
	Other Annualized Monetized $/year					7%		
						3%		
	From/To	From:			To:			
Effects	State, Local or Tribal Government: Small Business: none Wages: none Growth: none							

[1] This rule would not affect the total amount of user fees set by statute nor the size of the federal budget.

In line with Executive Order 14192, in Table 2 we estimate present and annualized values of costs, cost savings, and net costs over a perpetual time horizon. We estimate that this proposed rule would generate $12.56 million in annualized net costs at a 7 percent discount rate (primary estimate), discounted relative to year 2024 over a perpetual time horizon. The majority of these net costs are FDA costs.

Table 2. Executive Order 14192 Summary Table (millions of 2024 dollars, discounted over a perpetual time horizon relative to year 2024 at a 7 percent discount rate)

	Primary Estimate	Low Estimate	High Estimate
Present Value of Costs[1]	$179.40	$77.52	$307.14
Present Value of Cost Savings	$0	$0	$0
Present Value of Net Costs	$179.40	$77.52	$307.14
Annualized Costs	$12.56	$5.43	$21.50
Annualized Cost Savings	$0	$0	$0
Annualized Net Costs	$12.56	$5.43	$21.50

[1] This rule would not affect the total amount of user fees set by statute nor the size of the federal budget.

II. Preliminary Economic Analysis of Impacts

A. Background

The Family Smoking Prevention and Tobacco Control Act (the TCA) (Pub. L. 111–31) was enacted on June 22, 2009, amending the FD&C Act. Section 101(b) of the TCA amends the FD&C Act by adding new chapter IX, which provides FDA with tools to regulate tobacco products and imposes certain obligations on owners and operators of tobacco product establishments. Among the amendments are provisions that relate to tobacco product establishment registration and listing of tobacco products.

Cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco were immediately covered by FDA's tobacco product authorities in chapter IX of the FD&C Act (21 U.S.C. 387 through 387u, including registration and listing requirements under 387e) when the TCA went into effect in 2009.

On May 10, 2016, FDA published a final rule entitled "Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products" (81 FR 28974) (Deeming Rule), which became effective on August 8, 2016. Under this rule, all products that meet the statutory definition of "tobacco product" set forth in section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)), including components and parts, but excluding accessories of deemed tobacco products, are now subject to chapter IX of the FD&C Act,[3] including registration and listing requirements in section 905.

[3] The deemed products include cigars, pipe tobacco, water pipe tobacco, electronic nicotine delivery systems (ENDS) (including e-cigarettes), and other novel tobacco products such as certain dissolvable products and gels. On August 9, 2023, the U.S. District Court for the District of Columbia issued an order vacating this rule "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). The court gave a definition that specified what constituted a premium cigar for the purposes of its ruling. On January 24, 2025, the U.S. Court of Appeals for the District of Columbia Circuit affirmed the district court's order, in part, and

The Consolidated Appropriations Act, 2022 (Pub. L. 117–103), 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 (e.g., products containing synthetic nicotine) are subject to chapter IX of the FD&C Act without needing to be deemed by regulation.

In 2020, FDA replaced the legacy FDA Unified Registration and Listing System (FURLS) Tobacco Registration and Listing Module (TRLM) system with a scalable tobacco registration system to handle large data processing and storage, the Tobacco Registration and Listing Module Next Generation (TRLM NG). TRLM NG makes the process of submitting registration and listing information more efficient for industry while providing faster access to this information for both FDA and industry.

The current registration and listing electronic system is an online application that can be accessed from the TRLM NG website. This online system allows users to view and update their registration and listing information from any location and at any time. This system also makes registration and listing information more accessible for both FDA and industry. For example, when an establishment wants to view its establishment registration and product listing data, TRLM NG allows the establishment to do so via one website. This system reduces the number of duplicate data submissions. For example, TRLM NG allows establishments to distinguish the items that need to be updated from those that do not need to be updated, thereby eliminating any confusion that previously led to duplicate data submissions.

This proposed rule covers registration and listing requirements for owners and operators of both domestic and foreign establishments engaged in the manufacture, preparation, compounding, or processing of tobacco products. In codifying the already effective, self-implementing requirements of the TCA applicable to owners and operators of domestic establishments, the proposed rule explains who would be required to register and list, when they would be required to register and list, and how they would be required to register and list. The proposed rule also describes the type of tobacco product listing information that owners or operators would be required to submit to FDA. The proposed regulations generally would require the electronic submission of the registration and listing information. In addition, the rule would require owners or operators of such establishments to maintain a historical file of consumer information, labeling, and advertisements, as well as information related to the distribution of free samples of smokeless tobacco products.

This proposed rule also implements section 905(h) of the FD&C Act to now require registration and product listing by owners or operators of foreign establishments engaged in the manufacture, preparation, compounding, or processing of a tobacco product that is imported or offered for

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reversed and remanded the case back to the district court "so that the district court can invite briefing on the appropriate definition of 'premium cigars.'" *Cigar Ass'n of Am. v. FDA*, No. 23-5220, Document #2096141 (D.C. Cir. Jan. 24, 2025.). That litigation is pending.

import into the United States. An owner or operator of such foreign establishment must 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. Similar to domestic establishments, foreign establishments will also be required to report changes in their product listing twice a year.

B. Potential Need for Federal Regulatory Action

Both domestic and foreign establishments manufacture, prepare, compound, or process tobacco products that are offered for sale or distribution in the United States. Section 905 of the FD&C Act requires the owners and operators of domestic establishments engaged in the manufacture, preparation, compounding, or processing of a tobacco product to register their establishments with FDA and submit product listings. Section 905 also applies to owners or operators of foreign establishments engaged in such functions, but section 905(h), specific to foreign establishments, requires the Secretary of Health and Human Services to promulgate regulations to implement the provision. This creates significant gaps in Agency information.

Without this rule, domestic establishments would continue to incur registration, tobacco product listing, and inspection costs while foreign establishments would not, placing domestic establishments at a disadvantage as compared to foreign establishments that manufacture, prepare, compound, or process tobacco products offered for importation into, and sale or distribution in the United States. By extending registration and listing requirements to include foreign establishments, FDA will also have more complete information from both domestic and foreign establishments about the tobacco products being offered for sale or distribution in the United States.

A complete and accurate tobacco product establishment registration and product listing information system for both domestic and foreign establishments can help FDA accomplish several important statutory, regulatory, and public health objectives, such as identifying establishments operating in violation of the FD&C Act or facilitating the recall of non-compliant tobacco products that have entered U.S. commercial distribution. The system would also help FDA schedule inspections of registered establishments and help facilitate communication between the Agency and tobacco product establishments.

FDA relies on having complete and accurate establishment registration and product listing information for tobacco products to accomplish its public health objectives. FDA has established its own central information system because no individual tobacco firm or organization has sufficient financial incentive to create and maintain such a system for the entire industry. While having such a system would make it easier to uncover and solve problems (such as when there is a recall of non-compliant tobacco products that have entered U.S. commercial distribution), the private costs to create such a system and include both domestic and foreign establishments would

probably be prohibitive for any single firm or third-party organization. We estimate that an effective system of information would require several thousand domestic and foreign participants covered under this rule to regularly gather information, provide it to a central system, verify the information, and make it available for regulatory purposes. The private transactions cost to bring all the participants together voluntarily and get them to agree to create such a system would be extraordinarily high. Because the provision of information by some participants would make it available for all, there would be a tendency for some establishments to benefit from the information system without contributing to it. Nevertheless, increased information and participation in the registration system also increases the effectiveness of the entire system.

As a part of FDA's central information system, this proposed regulation addresses the need for information on: which domestic and foreign establishments manufacture, prepare, compound, or process a tobacco product or tobacco products that enter commercial distribution in the United States; what types of tobacco product each establishment handles; and how each establishment can be contacted.

C. Purpose of the Proposed Rule

Under section 905 of the FD&C Act (21 U.S.C. 387e), every person who owns or operates any domestic establishment engaged in the "manufacture, preparation, compounding, or processing" of a tobacco product, including repackagers/relabelers, are required to register and list. Currently, domestic establishments are required to submit registration and product listing information and FDA has issued guidance to help tobacco establishments implement this provision.[4] Section 905 also applies to owners or operators of foreign establishments engaged in such functions, but section 905(h), specific to foreign establishments, requires the Secretary of Health and Human Services to promulgate regulations to implement the provision. This creates significant gaps in Agency information. This proposed rule would extend registration and listing requirements to foreign establishments that engage in the "manufacture, preparation, compounding, or processing" of a tobacco product. Registered foreign establishments would be subject to inspection under section 905(g) and 905(h) of the FD&C Act (21 U.S.C 387e(g) and 21 U.S.C 387e(h)).

For the purposes of the proposed rule, the term "manufacture" would include assembling, processing, homogenizing, mixing, formulating, labeling, or packaging. This proposed rule clarifies that persons who engage in the manufacture of tobacco products include specification developers, third-party manufacturers, and bulk tobacco product manufacturers. For the purposes of this proposed rule, references to manufacturers or manufacturing hereinafter are inclusive of

[4]Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/registration-and-product-listing-owners-and-operators-domestic-tobacco-product-establishments.

this definition and the requirements of the proposed rule would apply to owners and operators of establishments that perform manufacturing, preparation, compounding, or processing functions.

FDA is also proposing corresponding changes to the forms currently used by domestic establishments, which will be used by all registrants to submit registration and listing information and proposing that all registration and listing information be submitted electronically, unless a waiver has been granted by FDA for the registrant. Registrants would be permitted to request a waiver from the electronic registration requirement by submitting a written request to FDA explaining why it is not reasonable for the registrant to submit a registration electronically to FDA.

Under sections 905 and 909 of the FD&C Act, FDA is also proposing recordkeeping requirements for a historical file of consumer information, labeling and advertisements for all tobacco products listed, as well as recordkeeping requirements for information about the distribution of free samples of smokeless tobacco products.

Consequently, this proposed rule would allow FDA to better protect the public health by helping to ensure that owners and operators of domestic and foreign establishments that manufacture tobacco products sold, distributed, and/or imported into the United States, are complying with federal law, including FDA's premarket authorization requirements. Information that would be required by the rule would enable FDA to better pursue enforcement actions against non-compliant tobacco products that have entered commercial distribution or await entry into commercial distribution, at the border or otherwise, and in doing so better protect the public health. FDA currently inspects foreign establishments only to support premarket tobacco product application (PMTA) review per 21 CFR 1114.27.

On February 13, 2025, the President signed Executive Order 14212 titled "Establishing the President's Make America Healthy Again Commission." The E.O. sets forth that "[i]t shall be the policy of the Federal Government to aggressively combat the critical health challenges facing our citizens, including the rising rates of mental health disorders, obesity, diabetes, and other chronic diseases. To do so, executive departments and agencies (agencies) that address health or healthcare must focus on reversing chronic disease." On September 9, 2025, the Make America Healthy Again Commission released the Strategy Report titled "Make Our Children Healthy Again," which outlines a strategy of increased enforcement against illegal ENDS products.

Tobacco use is the leading preventable cause of death and disease in the United States, including preventable chronic disease. Accordingly, this rule would support FDA's efforts to advance Administration priorities by helping FDA identify tobacco products sold, distributed, and/or imported into the United States, and the establishments that manufacture them, that do not comply with federal law, and by enabling FDA to better pursue enforcement actions against non-compliant tobacco products.

D. Baseline Conditions

The costs of the requirements in this proposed rule are in addition to the costs of meeting the registration requirements of the 2016 Deeming Rule (81 FR 28973 to 29106). Costs that were attributable to the Deeming Rule and thus already addressed in the 2016 Deeming Rule FRIA are not included in the costs of this proposed rule. Costs of the registration and listing requirements in the Deeming Rule were directed to owners and operators of domestic establishments engaged in the manufacture, preparation, compounding, or processing of deemed tobacco products. The costs to establishments associated with deemed tobacco products already addressed in the 2016 Deeming Rule FRIA are from the requirement for: 1) annual registration by owners and operators of domestic establishments engaged in the manufacture, preparation, compounding, or processing of newly deemed tobacco products; 2) immediate registration of new owners and operators and new establishments; 3) product listing requirements for registered establishments; and 4) biannual reporting of changes in the product listing. Establishments submit their registration annually by December 31st each year. In addition, section 905(i)(3) requires that certain changes to previously submitted product listing information be reported to FDA twice each year (21 U.S.C. 387e(i)(3)).

1. Baseline Industry Characterization

According to FDA's establishment registration data in the TRLM NG database as of August 2025, there are 900 currently registered active domestic establishments. Registration and listing information is provided and periodically updated by regulated entities. Due to the nature of the database, we are unable to construct historical trends.[5] For this reason, we use an estimate of all active establishment registrations from FDA's registration database as of August 2025 and build variability around this estimate to provide a range of actively registered establishments on an annual basis.

To address annual variability, we estimate a low number (minus 15%) and high number (plus 15%) of domestic establishments ranging between 765 and 1,035 respectively. The number of establishments in the database could be an underestimate of the number of establishments that are in fact required to register; for this analysis, FDA estimates that 1-20 domestic establishments may not currently be included in the TRLM NG data. The proposed rule would clarify requirements for these domestic establishments, prompting initial establishment registration and product listing. Also, the tobacco industry has traditionally been characterized by substantial entry and exit of small businesses. As a result, over time we can expect the number of future establishment first-time registrations to vary.

Table 3 presents the number of establishments subject to the rule. When applicable, we use number of establishment estimates prepared for the Paperwork Reduction Act (PRA) Analysis, included in section IX in the preamble for this proposed rule hereinafter referred to as the PRA

[5] For additional information about the TRLM NG database, please see: https://trlm-ng-rlsite.fda.gov/home

Analysis.[6] According to TRLM NG data used for the PRA Analysis, on average, there are 37 new domestic establishments entering the market each year that would be subject to new registration and listing requirements under this rule. Thus, we calculate entry and exit rates of 4% (=37/900 currently active registrants) each year. We assume domestic establishments who are not currently registered would have the same entry and exit rate as currently registered domestic establishments and therefore estimate 4% would be entering the market each year. We therefore estimate a total of 37 (=37 + 4% x 10) new domestic registrants entering the market in each subsequent year after the first year. We assume that foreign tobacco product establishment entry and exit rates are the same as in the United States. We request comments on this assumption.

The number of foreign tobacco product establishments covered by this proposed rule would include all foreign establishments that manufacture, prepare, compound, or process a tobacco product or tobacco products imported or offered for import into the United States. Using information provided by FDA's import compliance systems covering calendar year 2024 for tobacco products, we estimate that 3,253 foreign establishments would be subject to new registration and listing requirements in the first year following the effective date. To address variability, we estimate a low number (minus 15%) and high number (plus 15%) of foreign establishments ranging between 2,785 and 3,720 respectively. Using the 4% entry rate, we expect that there would be 134 (=4% x 3,253) new foreign establishments entering the market in each subsequent year.

Table 3. Number of Establishments Subject to the Rule

	Primary	Low	High
Domestic Manufacturers			
Number of registrants estimated from TRLM NG data	900	765	1,035
First year registrants	47	32	63
Subsequent year registrants	37	31	44
Foreign Manufacturers			
First year registrants	3,253	2,785	3,720
Subsequent year registrants	134	114	153

Note: Product across table may not be exact due to rounding.

As of January 2026, there are approximately 22 million active product listings in the TRLM-NG system. We do not expect new tobacco product categories would be covered by the rule that are not currently covered; however, we do expect that there will be new product listings associated with establishments that are newly registering under the rule, particularly product listings from foreign establishments.[7]

[6] Establishment Registration and Product Listing for Tobacco Products (Proposed Rule).

[7] The listing requirements established in Section 905 apply to all tobacco products regardless of marketing authorization status. For example, 905 does not state that only products subject to a marketing order should be listed. As such, there are a large number of products listed in TRLM NG that may lack a marketing order.

To provide a broad characterization of the industry, we present general information on the tobacco market's retail value, import value, and domestic value of shipments. According to data from Euromonitor, the retail value of all tobacco products sold in the United States during 2024 is $129.4 billion.[8] This retail value includes sales of all tobacco product categories, both domestic and imported. Using FDA import line data for 2024, we estimate the value of tobacco product imports as approximately $3.8 billion.[9] According to 2024 Census data, tobacco manufacturers' value of shipments (NAICS code 312260) is reported as $66.2 billion. This NAICS code does not include manufacturers of e-liquids and e-cigarettes. Data on the value of shipments for these manufacturers are not currently available, and we request comments on potential sources or methods for obtaining this information.

2. Baseline Regulatory Environment

Under the current baseline, domestic tobacco manufacturers must register annually with FDA and list their regulated products using the TRLM-NG system. FDA currently uses registration and listing information to plan for domestic inspections under 905(g) in order to assess compliance with the requirements of the FD&C Act and implementing regulations in effect. As an example of ongoing compliance and enforcement efforts, CTP has issued more than 700 warning letters to firms for manufacturing, selling, and/or distributing new tobacco products without marketing authorization.[10] A small number of warning letters (17) were issued to foreign firms who sold unauthorized tobacco products online to U.S. customers. The proposed rule would extend registration and listing requirements to owners and operators of foreign establishments. FDA also posts a searchable database of the submitted registration and listing information as a means of providing public access to the information, which is required by Section 905(f) of the FD&C Act. The system enables FDA to track regulated tobacco products, monitor industry activities, conduct targeted inspections, verify compliance, identify unauthorized products, and take enforcement actions against non-compliant manufacturers.[11]

However, under the current baseline, foreign manufacturers of regulated tobacco products including electronic nicotine delivery systems (ENDS) are not required to register their establishments with FDA or list their products, limiting FDA's visibility into which foreign firms are producing products intended for the U.S. market and what specific products are being imported or offered for import. As a result, FDA lacks a comprehensive, authoritative reference against which to review shipments of tobacco products before arrival. This information gap allows unauthorized products to be imported and makes it difficult to identify responsible

[8] Euromonitor International Limited 2025 © All rights reserved. Total retail value includes taxes.
[9] The estimated value of imported tobacco products is derived from data on tobacco product shipments from CY 2024 prepared by U.S. Food & Drug Administration – Import Compliance Systems Branch – Minneapolis District Office., prepared on October 17 2025.
[10] https://www.fda.gov/tobacco-products/compliance-enforcement-training/advisory-and-enforcement-actions-against-industry-unauthorized-tobacco-products
[11] FDA Center for Tobacco Products. Compliance and Enforcement Report. 2013-2018: https://www.fda.gov/media/131943/download?attachment. Viewed on 1/13/2026.

manufacturers or track repeat violators across shipments. Enforcement therefore relies heavily on labor-intensive, downstream actions at ports of entry or other locations after products have already entered U.S. commerce.

This baseline enforcement challenge is illustrated by a recent joint FDA–CBP operation in which the agencies seized nearly five million unauthorized e-cigarette units, with an estimated retail value of approximately $86.5 million. According to the report, many of the seized shipments were imported from abroad, lacked required premarket authorization, and contained vague and misleading product descriptions with incorrect values, in an apparent attempt to evade duties and the review of products for import safety concerns.[12] While the operation demonstrates FDA's and CBP's enforcement capabilities, it also highlights the reactive nature of the current system: illegal products are identified only after they are shipped to the United States, requiring substantial inspection, seizure, and follow-up resources, and allowing repeat violators to continue attempting entry by "port shopping" or under new importer identities. Requiring foreign manufacturers to register their establishments and list their products would address (at least in part) these baseline limitations by improving transparency, accountability, and risk-based targeting for inspections.

E. Benefits of the Proposed Rule

1. *Non-Quantified Benefits*

This proposed rule prescribes the format, content, and procedures for establishment registration and tobacco product listing. This proposed rule addresses FDA's fundamental need to know where and what tobacco products are being manufactured, prepared, compounded, or processed, and which tobacco products are offered for importation, sale, or distribution in the United States, which is important for effective regulation and consumer protection. This proposed rule, if finalized, would enhance public health protections by improving market transparency, enabling faster responses to public health risks, supporting compliance efforts, preventing illegal product entry, and providing data to inform policy decisions. Key non-quantified benefits include, but are not limited to, the following:[13]

A More Comprehensive Manufacturer Inventory

The requirements in this proposed rule would provide FDA with a more comprehensive inventory of manufacturers and their products, enabling better monitoring of product availability in the market. This improved market visibility would strengthen FDA's ability to understand the full scope of the tobacco market and would equip FDA with more complete

[12] United States Department of Health and Human Services (US DHHS) Press Release, September 10, 2025. "CBP Seize $86.5 Million Worth of Illegal E-Cigarettes in Largest-Ever Operation" available at https://www.hhs.gov/press-room/hhs-fda-cbp-seize-record-4-7-million-illegal-e-cigarettes-chicago-operation.html Viewed on January 5th, 2026.

[13] This list does *not* serve as a guide to avoiding double-counting in cases of quantification being feasible. As these benefits may be interrelated, any future quantification should account for potential correlation to avoid overstating total impacts.

information about which products are being manufactured, imported, or distributed within the United States. The creation of a more complete, authoritative inventory of domestic and foreign manufacturers and products would address current manufacturer traceability limitations into who is producing and shipping tobacco products to the U.S. market, providing FDA with the foundational data needed for effective oversight.

Increased Efficiency

We expect that benefits from this proposed rule would allow FDA to deploy the Agency's inspectional resources more efficiently and effectively to ensure that tobacco product manufacturers and the products that they commercially market are in compliance with the requirements of the FD&C Act. Such increased efficiency would include the Agency's increased knowledge of foreign establishments and the tobacco products that they manufacture and import or offer for import into the United States. The improved ability would allow for surveillance, investigations, and import screening based on known establishments and listed products and would reduce reliance on random or reactive enforcement, delivering enforcement efficiency gains from more targeted inspections, import refusals, and follow-up actions. By improving the ability to link products to specific foreign manufacturers, the policy would also reduce opportunities for repeat violations through port shopping or misdeclaration, thereby strengthening deterrence and improving long-term compliance.

Protection Against Illegal or Unregulated Products

Requiring registration and product listing for foreign manufacturers, as set forth in the proposed rule, would improve FDA's ability to detect illicit or non-compliant products that are commercially distributed, imported, or offered for import into the United States. FDA's ability to detect illicit or unauthorized tobacco products through inspection planning, investigations, pre-arrival import screening, and manufacturer traceability would be significantly enhanced. Linking information about foreign manufacturers and their products would also help strengthen protection mechanisms against those circumventing proper regulatory review and prevent dangerous, harmful, or illegal tobacco products from reaching U.S. consumers. Ultimately, this would help reduce consumer exposure to illegal and unauthorized tobacco products and support FDA's mission to protect public health.

Faster Public Health Response

With detailed information about foreign manufacturers and their tobacco products readily available, FDA would be able to respond more quickly to potential health risks and emerging safety concerns. In the event of harmful products or contaminated ingredients, this rapid response capability would strengthen FDA's ability to prevent the distribution of non-compliant tobacco products, reducing the duration of public health threats and minimizing consumer exposure to avoidable risks. Ultimately, this would help reduce consumer exposure to adulterated and misbranded tobacco products and support FDA's mission to protect public health.

Support for Compliance and Enforcement

The registration and product listing requirements in the proposed rule would make it easier for FDA to ensure accountability and compliance of foreign manufacturers with the requirements

of the FD&C Act and applicable regulations, including marketing and tobacco product standards requirements and marketing restrictions. This enhanced oversight would support FDA's efforts to enforce regulations consistently across both domestic and foreign producers. Registration and listing information would enable FDA to more efficiently identify unregistered foreign establishments and adulterated or misbranded tobacco products, including unauthorized electronic nicotine delivery system (ENDS) products, to take enforcement action, including detention and refusal when imported or offered for import into the United States. Consistent enforcement across domestic and foreign producers would create regulatory parity that supports compliant manufacturers while ensuring non-compliant entities face appropriate oversight. This would also improve FDA's ability to identify repeat violators, issue targeted enforcement actions, and apply import refusals consistently, thereby delivering market-integrity benefits from improved compliance and deterrence of repeat violators. Beyond these direct enforcement benefits, inspections themselves may generate additional positive effects by improving establishment compliance, deterring future violations, enhancing product quality and safety, and providing establishments with clearer understanding of regulatory requirements through FDA inspections.

Data for Policymaking and Research
Currently not available anywhere else, the information gathered through product listing and extending registration and product listing to foreign establishments would provide essential data for research, market trend analysis, and evidence-based policymaking. This data, along with information on domestic establishments, would support FDA's efforts to develop effective tobacco policies, evaluate their impact over time, and make informed decisions about regulatory actions.

Reduced Public Health Burden
Over time, better oversight of foreign manufacturers and their products would contribute to broader efforts to reduce tobacco product use and related diseases. This comprehensive approach has the potential to decrease healthcare costs, improve population health, and reduce the overall public health burden associated with tobacco product use.

Enhanced Consumer Information
Product listing ensures that the public has access to additional information about tobacco products. This proposed rule would expand the list of establishments that file product listing information, thus increasing information available to the public. This transparency would empower adult consumers to make more informed decisions about tobacco product use and support public health education efforts.

Access to Product Information
Collecting product listing information, such as volume and nicotine concentration, would allow for easier comparison between different tobacco products, including imported tobacco products. This information, currently not available anywhere else, would facilitate both regulatory assessments and informed decision making by adult consumers, supporting FDA's

efforts to evaluate product risks and helping consumers understand the potential health impacts of different tobacco products.

Improved Transparency
Prescribing the format, content, and procedures for registration of domestic and foreign establishments that manufacture, prepare, compound, or process tobacco products and listing of tobacco products manufactured by such establishments would significantly enhance transparency in the tobacco market. Registration and listing would enable efficient compilation and analysis of market-wide data, allowing improved public understanding of the scope of the tobacco market through consistent and complete information about foreign manufacturers and their products.

In summary, registration and listing would provide FDA with a more comprehensive domestic and foreign manufacturer inventory and verified foreign manufacturer data, enabling more effective pre-arrival screening, earlier identification of unauthorized shipments, reduced reliance on post-arrival seizures, and upstream enforcement that prevents illegal products from entering U.S. commerce. For the industry, this rule would establish regulatory parity between domestic and foreign manufacturers, creating equal regulatory requirements regardless of location. For the public, the rule would provide transparent and enhanced manufacturer and product information currently unavailable elsewhere, while establishing manufacturer accountability across the entire regulated tobacco product market.

2. *Illustrative Benefits Analysis: Preventing Illegal Imports*

To illustrate the potential magnitude of benefits from reducing illegal product entry, the analysis draws on a recent joint enforcement action announced by HHS, FDA, and U.S. Customs and Border Protection (CBP). In 2025, the agencies reported the seizure of approximately 4.7 million unauthorized e-cigarette units with an estimated retail value of $86.5 million during a single operation at the Chicago port of entry. All seized products lacked the required FDA premarket authorization and reportedly contained vague and misleading product descriptions with incorrect values in an apparent attempt to evade detection, and the vast majority originated from foreign manufacturers. This enforcement action provides an observable benchmark for the scale of illicit market activity that may be affected by improved foreign establishment registration and product listing.[14]

Requiring foreign establishment registration and product listing is not expected to eliminate all illegal imports. Rather, these requirements would improve FDA's and CBP's ability to identify unregistered manufacturers and unlisted and unauthorized products before entry and to target high-risk shipments more effectively, thereby preventing a portion of illicit imports from

[14] Data limitations and modeling constraints, preclude reliable quantification and monetization of enforcement cost savings, behavioral and health outcomes, and longer-term compliance and deterrence effects within the scope of this analysis.

entering U.S. commerce. Because the effectiveness of these requirements in reducing illegal imports cannot be estimated with precision *ex ante*,[15] the analysis evaluates an illustrative example in which registration and listing assists in preventing an illegal shipment that is comparable in scale to 10 percent, 25 percent, and 50 percent of the Chicago seizure.

Under these scenarios, inputs that might be used in a hypothetical benefits assessment, expressed in terms of avoided retail sales of unauthorized products, would be approximately:

- 10 percent reduction: $8.65 million
- 25 percent reduction: $21.63
- 50 percent reduction: $43.25 million

These values are calculated as the corresponding fractions of the $86.5 million retail value associated with the seized products and are intended to illustrate how these requirements for establishment registration and product listing may improve enforcement efficiency in preventing illegal imports. These estimates should be interpreted as partial estimates that reflect only one component of the proposed rule's potential effects. Our retail value calculation does not account for other important outcomes that we discussed earlier but couldn't put a dollar amount on, such as money saved on enforcement efforts, improvements to public health, and better market integrity and fair competition.

F. Costs of the Proposed Rule

The following list shows cost conventions used throughout the cost analysis which include time estimates for certain activities, domestic and foreign wages, and compliance costs incurred by foreign producers.

1. Estimated Time for Certain Activities

Estimated costs of this rule are based on the time that tobacco product establishments would require to complete certain activities. Establishment registration and product listings can be submitted online via TRLM NG.[16] 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 answering a few questions. In estimating time for submitting registration and product listings, we

[15] The term "*ex ante"* means "in a way that is based on forecasts rather than actual results."
[16] TRLM NG can be found at: www.fda.gov/tobacco-products/manufacturing/tobacco-registration-and-listing-module-next-generation-trlm-ng-instructions

use time estimates prepared for the PRA Analysis, included in section IX in the preamble for this proposed rule.[17]

In the PRA Analysis, FDA estimated the time it would take establishments to submit the initial registration and product listing, the amount of time it would take to resubmit a registration each year, and the amount of time needed for submitting updates to product listings twice each year. Generally, according to the PRA Analysis, we estimate that initial establishment registration for domestic establishments will take 1.83 hours (110 minutes), and initial product listing will take 0.42 hours (25 minutes) under the proposed rule. We assume that 2.25 hours (135 minutes = 110 minutes + 25 minutes) includes time to research and learn FDA's requirements and gather and prepare the information needed for submitting a registration and product listing. Once the initial registration and listing takes place, the yearly registration confirmation and twice-yearly updates to product lists are simplified as all information previously entered is maintained in the system. The PRA Analysis also estimates that annual registration renewal and biannual product listing updates will take an additional 0.33 hours (20 minutes).

For registered domestic establishments estimated from the TRLM NG data, we only include the marginal change in time to complete the registration and listing requirements under this rule. We assume that these registrants previously took 1.6 hours (100 minutes) for initial establishment registration and listing. We thus assume that initial registration and listing of any new fields for these registrants would take 0.23 hours (1.83 hours - 1.6 hours).

We estimate that it would take foreign establishments more time to complete registration and product listing if they are not fluent in English and if they do not have internet access. For estimating costs associated with meeting the requirements of this proposed rule, we adjust time estimates for foreign establishments to account for potential differences in time due to differences in English language proficiency and internet accessibility for all foreign establishments engaged in the manufacture, preparation, compounding, or processing of a tobacco product that is imported or offered for import into the United States. To account for language proficiency differences, we use information from a report titled "Education First English Proficiency Index" (EF EPI).[18] This report ranks countries by the average level of English language skills amongst adults using data collected via English tests available over the internet. To account for country differences in internet accessibility, we use 2024 internet user percentage estimates by country.[19] As explained in more detail below, we combine estimated weights for English proficiency and internet access into a single composite estimate of 1.43 hours for foreign establishments as equivalent to one hour for domestic establishments.

[17] Establishment Registration and Product Listing for Tobacco Products (Proposed Rule).
[18] 2024 EF English Proficiency Index – A Ranking of 116 Countries and Regions by English Skills. Retrieved on 2025-4-18. http://www.ef.edu/epi/
[19] https://databank.worldbank.org/source/world-development-indicators

Table 4 shows establishment counts from countries scaled according to the country's English Proficiency Index (EPI). We estimate that for every hour used by an establishment with high to very high EPI score, that establishments in countries with low and very low EPI score would require two to three hours respectively. Similarly, we estimate that for each hour used by an establishment with high to very high EPI score, that establishments in countries with a moderate EPI score would require one and a half hours. To calculate the percent establishment distribution by proficiency level (column A), we used FDA's Import Compliance Systems data to count unique establishments by country and grouped them according to their respective country's EPI score. We estimate 1.76 proficiency weighted hours as the sum of the product of the establishment percentage (A) and the hourly equivalent (B) across all proficiency index ranges.

Table 4. Proficiency Weighted Hours According to English Proficiency Indices

Proficiency Level	English Proficiency Index	Percent Establishments (A)	Hourly Multiplier Equivalent (B)	Proficiency Weighted Hours (A x B)
Very High	>= 600	11.9%	1	0.119
High	550-599	2.1%	1	0.021
Moderate	500-549	19.7%	1.5	0.296
Low	450-499	66.3%	2	1.326
Very Low	<= 449	0.0%	3	0.000
Sum		100%		**1.761**

Note: Product across table may not be exact due to rounding.

Table 5 shows the estimated number of establishments from countries scaled according to their country's internet access. We estimate that for every hour used by an establishment with high to very high internet access, establishments with moderate, low, and very low internet usage would require 1.5, two and three hours respectively. We estimate that for every hour used by an establishment with high to very high internet usage, that establishment in countries with low and very low internet usage would require two and three hours, respectively. To calculate the percent establishment distribution by internet access (column A), we used FDA's Import Compliance Systems data to count unique establishments by country and grouped them according to their respective country's internet access. We estimate 1.09 internet weighted hours as the sum of the product of the establishment percentage (A) and the hourly equivalent (B) within each internet access index range.

Table 5. Internet Weighted Hours According to Internet Access

Internet Use Level	Percent Population Use	Percent Establishments (A)	Hourly Multiplier Equivalent (B)	Internet Weighted Hours (A x B)
Very High	>= 90	14.9%	1	0.149
High	70-89	72.5%	1	0.725
Moderate	50-69	6.6%	1.5	0.098
Low	30-49	6.1%	2	0.121
Very Low	< 30	0.0%	3	0.000
Sum		100%		**1.093**

Note: Product across table may not be exact due to rounding.

The average of both weighted sums of 1.76 hours to account for differences in English proficiency and of 1.09 hours to account for differences in internet usage give us a single estimate of 1.43 hours (= (1.76 hours + 1.09 hours)/2) for foreign establishments as equivalent to one hour for domestic establishments. We acknowledge that there is uncertainty associated with using this data and request comments on our time estimates.

2. Wages

We use the Bureau of Labor Statistics mean hourly wage in the tobacco manufacturing industry for management occupations and office and administrative support occupations.[20] We double the mean hourly wages to account for benefits and overhead (Table 6). Foreign wage rate estimates for foreign tobacco manufacturing establishments are from historical occupational and industry-level wages in the 20 foreign countries exporting the largest amount of tobacco products to the United States by total dollar value (see Appendix). We use these wage estimates to calculate a single weighted average wage rate for estimating costs to foreign manufacturers.

We estimate that for every hour or fraction of an hour spent filling out 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 the registration information along with the product listing and labeling information to FDA. These estimates are approximate, and some establishments may require more or less time. We acknowledge that there is uncertainty associated with this estimate and request comments on this issue (Table 7).

[20] May 2024 National Industry-Specific Occupational Employment and Wage Estimates for NAICS 312200 - Tobacco Manufacturing https://data.bls.gov/oes/#/industry/312200

Table 6. Mean Hourly Wage for Domestic and Foreign Occupations

Occupation (SOC code)	Mean Hourly Wage	Wage Plus Benefits and Overhead	Source
Domestic Manufacturers			
Management Occupations (11-0000)	$76.92	$153.84	Bureau of Labor Statistics
Office and Administrative Support Occupations (43-0000)	$27.10	$54.20	
Foreign Manufacturers			
Management Occupations	$7.54	$15.08	See Appendix
Office and Administrative Support Occupations	$2.93	$5.86	

Table 7. Domestic and Foreign Weighted Mean Hourly Wage (U.S. $2024)

	Manager	Administrative Support	Weighted (25% manager and 75% admin)
Domestic	$153.84	$54.20	**$79.11**
Foreign	$15.08	$5.86	**$8.17**

3. Costs to Domestic and Foreign Establishments

a. First Year Costs

First year costs for domestic establishments total approximately $19,340, covering both registrants estimated from TRLM NG data (900 establishments and 37 new registrants[21]) and estimated first year registrants (10 establishments). Registrants estimated from TRLM NG data would face costs of $18.46 per establishment for learning new requirements and initial compliance. First year registrants would incur higher costs of $178.00 for initial registration and listing, plus $26.37 for renewal requirements. These costs reflect the one-time nature of learning new procedures and the ongoing burden of maintaining compliance with updated requirements.

Foreign establishments would face first-year costs of approximately $97,949 across the estimated 3,253 establishments, with each establishment incurring $26.23 for initial registration and listing activities and $3.89 for renewal requirements. Table 8 presents estimated first year costs to both domestic and foreign establishments. We request comments on these estimates.

[21] We estimate that 37 establishments entering the market each year in absence of the rule would only face impacts due to changes in form burden under the rule.

Table 8. First Year Costs

Activity	Hours	Hourly wage	Cost per entity	No. of establishments			Total cost		
				Primary	Low	High	Primary	Low	High
Domestic Manufacturers									
Initial registration and listing									
Registrants estimated from TRLM NG data	0.23	$79.11	$18.46	937	796	1,078	$17,296.08	$14,693.36	$19,898.80
First year registrants	2.25	$79.11	$178.00	10	1	20	$1,779.98	$178.00	$3,559.95
Renewal registration and listing for first year registrants	0.33	$79.11	$26.37	10	1	20	$263.70	$26.37	$527.40
Total first year costs							**$19,339.76**	**$14,897.73**	**$23,986.15**
Foreign Manufacturers									
Initial registration and listing for first year registrants	3.21	$8.17	$26.23	3,253	2,785	3,720	$85,310.72	$73,037.30	$97,557.90
Renewal registration and listing for first year registrants	0.48	$8.17	$3.89	3,253	2,785	3,720	$12,638.62	$10,820.34	$14,453.02
Total first year costs							**$97,949.34**	**$83,857.64**	**$112,010.93**

Notes: Product across table may not be exact due to rounding. As explained in section II.F.a, we estimate an average of 1.43 hours for foreign establishments as the hourly equivalent for 1 hour for domestic establishments.

b. Annual (Recurring) Costs

Beginning in year two, annual costs are estimated at $13,016.20, including $690.57 for change in form burden for subsequent year registrants, $7.59 for initial activities of domestic establishments newly entering the market each year, $10.84 for first year registrants continued renewal activities each year, and $12,307.20 for on-going inspection-related costs for first year registrants and registrants that enter the market in each subsequent year.[22] The recurring costs reflect the ongoing administrative burden of maintaining registration and listing compliance, with inspection activities representing the largest cost component due to their time-intensive nature requiring an estimated 16 hours for an establishment's manager to accompany FDA inspections per establishment at management wage rates.

Foreign establishments face significantly higher annual recurring costs of approximately $396,557.71.[23] These costs are driven primarily by recurring inspection activities costing $392,530.90 across 3,253 establishments, followed by $3,507 for new registrants' initial

[22] For the purpose of this regulatory impact analysis, we assume domestic inspections would be conducted biennially for first year registrants or once every two years.

[23] The higher total foreign inspection costs reflect two factors: (1) the significantly larger number of foreign establishments that would be subject to inspection (3,253 foreign establishments due to this rule compared to approximately 10 domestic establishments due to clarifications in this rule), and (2) the higher per-inspection cost for foreign inspections due to travel and logistical requirements. See Table 11 for detailed calculations.

activities, and $519.59 for new registrants' renewal activities.[24] Table 9 presents estimated annual recurring costs to both domestic and foreign establishments. We request comments on these estimates.

Table 9. Annual Recurring Costs Beginning in Year Two

Activity	Hours	Hourly wage	Cost per entity	No. of establishments			Total Cost		
				Primary	Low	High	Primary	Low	High
Domestic Manufacturers									
Change in form burden for subsequent year registrants	0.23	$79.11	$18.46	37	31	44	$690.57	$572.99	$808.91
Initial registration and listing for subsequent year registrants	2.25	$79.11	$178.00	0	0	1	$7.59	$0.76	$15.18
Renewal registration and listing for subsequent year registrants	0.33	$79.11	$26.37	0	0	1	$10.84	$1.08	$21.68
Inspection for subsequent year registrants*	16.00	$153.84	$1,230.72	10	1	20	$12,307.20	$1,230.72	$24,614.40
Total annual costs							**$13,016.20**	**$1,805.55**	**$25,460.17**
Foreign Manufacturers									
Initial registration and listing for subsequent year registrants	3.21	$8.17	$26.23	134	114	153	$3,507.22	$3,002.64	$4,010.71
Renewal registration and listing for subsequent year registrants	0.48	$8.17	$3.89	134	114	153	$519.59	$444.84	$594.18
Inspection for subsequent year registrants*	16.00	$15.08	$120.67	3,253	2,785	3,720	$392,530.90	$336,058.58	$448,882.56
Total annual costs							**$396,557.71**	**$339,506.06**	**$453,487.45**

Note: Product across table may not be exact due to rounding.
*To account for the assumption of biennial inspections (every two years) of domestic and foreign establishments, the costs included in the table are estimated at 50% of the total cost per entity of an inspection.

Other costs associated with other provisions of the proposed rule include requiring manufacturers of tobacco products to establish and maintain records, make reports, and provide information to FDA to assure that their products are not in violation of the FD&C Act. We expect costs for establishing and maintaining records and providing information to FDA to be negligible because, in general, establishing and maintaining records are considered a standard business practice for which costs are internalized by firms. To the extent that FDA requests any number of records from an establishment, the costs of retrieving one or more additional records remain internalized because records retention practices are determined by a firm's business plan. Thus, potential costs to establishments from this requirement, if any, are expected to be small.

4. Costs of requesting waivers from electronic submission

FDA is proposing that submitting registration and listing electronically be mandatory unless a waiver has been granted for the registrant. Registrants would be permitted to request a waiver

[24] For purpose of this regulatory impact analysis, we assume inspections of foreign establishments would be conducted at the same frequency as domestic inspections (i.e., biennially, or once every two years).

from the electronic registration requirement by submitting a written request to FDA explaining why it is not reasonable for the registrant to submit a registration electronically to FDA. FDA tentatively concludes that one reason for why it may not be reasonable for a registrant to submit a registration to FDA electronically may be because a registrant does not have reasonable access to the internet. While we do not know how many establishments would request a waiver from this requirement, we believe that any additional costs from this requirement will be negligible and have provided a hypothetical example of the cost of requesting a waiver below.

Generally, all registration and listing submissions, reviews, and updates would be made electronically in the designated electronic tobacco product registration and listing system. However, FDA recognizes that some owners or operators might be unable to access the internet and the electronic tobacco product registration and listing system. Under the proposed rule, those owners or operators who could not access the electronic tobacco product registration and listing system would be able to request a waiver from electronic submission. The proposed rule states that waivers would be granted only if use of electronic means is not reasonable for the person requesting the waiver. Waiver requests could be granted if the owner or operator does not have an email address, access to a computer, or an internet service provider that can access the electronic tobacco product registration and listing system, or for other circumstances that FDA determines to be reasonable.

We do not account for the costs of requesting waivers in our main costs because most establishments, both in the United States and outside of the United States, have access to the internet, either within their companies or via other public means (e.g., public libraries or internet cafes).

We do not know how many manufacturers would request a waiver from submitting registration and listing information electronically. We assume that the owner or operator of an establishment would request a waiver and file registration and product listing via paper form only when doing so was less costly than filing electronically. As of April 29, 2025, 96% of registration and listing submissions were electronic, while the remaining 4% of the submissions were not initiated directly in TRLM NG and utilized paper and mixed/digital media (i.e., USB or DVD containing pdf or jpeg of material files or excel spreadsheet of product list). Given international shipping costs, we expect that the percent of foreign paper or mixed media submissions would be less than the percent of domestic paper or mixed media submissions. To the extent that any number of manufacturers are granted a waiver from electronic submission, our estimated costs of this rule would be overestimated.

As a hypothetical example, we estimate the costs of requesting a waiver and submitting registration and listing information on paper. We assume that both a general operations manager and a legal professional would prepare the waiver. From Table 6, we use the hourly wage rate of a domestic general operations manager of $153.84. For legal professional wages we use the

hourly wage rate of $133.44.[25] We estimate that a manager and a legal professional would require approximately 3 hours to prepare, review, and submit the waiver and registration and listing information on paper on behalf of the manufacturer at a combined hourly wage of $143.64 (average of $153.84 and $133.44). For a domestic manufacturer, one-time costs of submitting a waiver from electronic submission would be $430.92 (Table 10). Similarly, for a foreign manufacturer, one-time costs of requesting a waiver from electronic submission and submitting registration and listing information on paper would be $60.19. We request comments on our calculations and the costs of requesting a waiver from electronic submission and submitting registration and listing information on paper.

As manufacturers request a waiver from electronic submission, there would be annual costs to FDA to review the waivers. We estimate that it would take 1.25 hours for staff to review a waiver submission. Assuming a full-time equivalent FDA employee cost (salary, plus benefits and overhead) of $159.86 per hour, the costs of administering the waiver would be approximately $199.83. Because we estimate that requests for a waiver would be rare, and because of the uncertainty of how many paper submissions the Agency would receive, we do not include the costs in our estimated costs of this rule.

Table 10. Estimated Costs for Requesting a Waiver from Electronic Submission and Submitting Registration and Listing Information on Paper

	Time required (hours)	Wages ($/hour)	Cost per establishment
Domestic	3.00	$143.64	$430.92
Foreign	4.28*	$14.05	$60.19
Costs to FDA	1.25	$159.86	$199.83

Note: Product across table may not be exact due to rounding.
* As explained in section II.F.a, we estimate an average of 1.43 hours for foreign establishments as the hourly equivalent for 1 hour for domestic establishments (1.43 x 3 = 4.28).

5. Costs to FDA

We tentatively project costs to FDA from this proposed rule for conducting additional inspections. These costs represent a social opportunity cost of FDA resources, but they would not affect the total amount of user fees or the size of the federal budget. FDA's tobacco regulatory activities are fully funded by industry user fees, and the annual amount of user fees is set by statute. FDA has the authority to inspect registered establishments to determine each tobacco product's compliance with the requirements of the FD&C Act and applicable regulations; therefore, we estimate the marginal inspection costs to FDA below.

[25] Hourly wage for Legal Occupations of $66.72 as reported in Bureau of Labor Statistics. May 2024 National Industry-Specific Occupational Employment and Wage Estimates for NAICS 541100 - Legal Occupations (23-000) https://data.bls.gov/oes/#/industry/541100. We multiply $66.72 times 2 to account for benefits and overhead to obtain an hourly wage of $133.44.

a. Domestic and Foreign Inspection Costs

Table 11 reports estimated inspection costs to FDA. We expect it would take about 16 hours per inspection, ranging from 8 to 24 hours. Using information provided by FDA subject matter experts on domestic inspections for tobacco product establishments, we estimate an hourly cost of $525. We use a comparison of the hourly cost for work requiring domestic and foreign inspection travel from the Food Safety Modernization Act foreign reinspection fee rates for FY 2026[26] to estimate that the hourly cost for work on foreign inspections is approximately 11% more than the hourly cost for work on domestic inspections. Using this rate, we estimate the cost for each direct hour of work requiring domestic and foreign inspection travel is $525 and $582 per hour, respectively. Total estimated annual costs for domestic and foreign inspection range from $6.48 million to $26.10 million, with a primary estimate of $15.18 million.[27]

Table 11. Inspection Costs to FDA

	Primary	Low	High
Duration of Inspection (hours)	16	8	24
Inspection Cost per Domestic Establishment	$8,393	$4,196	$12,589
Number of Domestic Registrants	10	1	20
Annual Domestic Inspection Costs	$41,963	$2,098	$125,890
Inspection Cost per Foreign Establishment	$9,309	$4,654	$13,963
Number of Foreign Registrants	3,253	2,785	3,720
Annual Foreign Inspection Costs	$15,140,521	$6,481,148	$25,971,136
Total Inspection Costs	$15,182,484	$6,483,246	$26,097,025

Note: Product across table may not be exact due to rounding.

We acknowledge that inspections may lead to additional effects beyond the direct time costs estimated above. If inspections identify violations or areas of non-compliance, establishments may incur additional costs for corrective actions, remediation, or potential enforcement responses. The magnitude and likelihood of these downstream effects would vary significantly depending on each establishment's compliance status and the inspection findings. Due to the uncertainty and establishment-specific nature of these outcomes, we have not quantified these potential effects in this analysis.

b. Tobacco Registration and Listing Module – Next Generation (TRLM NG) Costs

To the extent that FDA's existing TRLM NG would need a system update to process the increasing number of registrations and product listings, FDA may incur additional system

[26] https://www.federalregister.gov/documents/2025/07/30/2025-14414/food-safety-modernization-act-domestic-and-foreign-facility-reinspection-recall-and-importer

[27] Due to efficiency gains from more targeted inspections, the inspection costs could be lower over time.

enhancement costs. Costs of enhancements could include modifying and maintaining a database along with other enhancements to implement the provisions of the proposed rule. While these costs represent an opportunity cost of FDA resources, this rule would not result in changes to overall FDA accounting costs, the size of the federal budget, or the total amount of tobacco industry user fees.

G. Summary of Costs

Table 12 shows a summary of the timing of expected costs to domestic and foreign establishments and costs to FDA over a twenty-year time frame in 2024 U.S. dollars. Only primary estimates are presented. For each year, we present the undiscounted costs.

Table 12. Undiscounted Twenty-year Flow of Costs (2024$)

Year	Costs to Domestic Establishments	Costs to Foreign Establishments	Costs to FDA
1	$19,340	$97,949	$15,182,484
2	$13,016	$396,558	$15,182,484
3	$13,016	$396,558	$15,182,484
4	$13,016	$396,558	$15,182,484
5	$13,016	$396,558	$15,182,484
6	$13,016	$396,558	$15,182,484
7	$13,016	$396,558	$15,182,484
8	$13,016	$396,558	$15,182,484
9	$13,016	$396,558	$15,182,484
10	$13,016	$396,558	$15,182,484
11	$13,016	$396,558	$15,182,484
12	$13,016	$396,558	$15,182,484
13	$13,016	$396,558	$15,182,484
14	$13,016	$396,558	$15,182,484
15	$13,016	$396,558	$15,182,484
16	$13,016	$396,558	$15,182,484
17	$13,016	$396,558	$15,182,484
18	$13,016	$396,558	$15,182,484
19	$13,016	$396,558	$15,182,484
20	$13,016	$396,558	$15,182,484

The total present and annualized values of costs to domestic and foreign establishments and costs to FDA using three and seven percent discount rates are presented in Table 13.

Table 13. Summary of Present and Annualized Values (in millions 2024$)

	Costs to Domestic Establishments	Costs to Foreign Establishments	Costs to FDA
Present Value 7%	$0.14	$3.92	$160.84
Present Value 3%	$0.20	$5.61	$225.88
Annualized Value 7%	$0.01	$0.37	$15.18
Annualized Value 3%	$0.01	$0.38	$15.18

H. Analysis of Regulatory Alternatives to the Proposed Rule

FDA evaluates three regulatory options in the analysis of this rule:

1. Option 1 – Take no action.

We treat the alternative of taking no new action as the baseline for determining the costs and benefits of other alternatives. Under this option, there will be no additional costs or benefits relative to the status quo. Without requiring establishment registration and product listing from foreign establishments, domestic tobacco manufacturers would continue facing unfair competitive disadvantages by bearing registration, listing, and inspection costs while foreign competitors manufacturing for the U.S. market would not. This regulatory gap would leave FDA with incomplete information about tobacco products entering U.S. commerce, hampering the Agency's ability to identify noncompliant tobacco products, facilitate product recalls, schedule inspections, and maintain effective communication with all tobacco product manufacturers.

2. Option 2 – Extend the compliance period.

This alternative extends the compliance date of the rule from 60 days after publication of the final rule to 12 months after publication of the final rule. We assume that the estimated initial costs (or one-time costs) in year 1 in section II.F would occur on year 2 after the rule becomes effective. We also assume that the estimated annual costs would begin in year 3 instead of year 2. Finally, we assume that biennial FDA inspection costs would begin in year 2 instead of year 1.

If a longer compliance period were provided, affected establishments would have additional time to comply with the rule and it would reduce the total costs. It would decrease burden especially for foreign establishments since they would be less familiar with the registration and listing system. However, delaying the compliance date would increase the length of time that foreign firms are not subject to the requirements with which domestic firms must currently comply and would delay benefits in the proposed rule described in Section II.E. above.

3. Option 3 – Proposal to require certain information in the tobacco registration and listing format, content and procedures that are currently optional.

This alternative requires the Data Universal Numbering System (D-U-N-S®) number of a domestic and foreign establishment be included in an establishment’s registration. A D-U-N-S®

number is a nine-digit unique establishment identifier provided by Dun & Bradstreet Credibility Corp. that can be specific for each site. The site-specific number is a widely recognized business identification tool and serves as a useful resource for FDA in identifying and verifying certain business information submitted by a user. Additionally, requiring this information would help FDA determine whether an establishment has been duly registered and to distinguish between registered establishments, especially if they have similar names.

We estimate one-time costs of requiring a D-U-N-S® number in an establishment's registration. For first-year costs, tobacco product manufacturers that currently do not have a D-U-N-S® number will be required to obtain one. We expect most of the manufacturers would already have a D-U-N-S® number, because they use the D-U-N-S® number for credit reporting.[28] Hence, we assume that 5 to 10% of the manufacturers required to submit a D-U-N-S® number would first need to obtain a D-U-N-S® number and, thus, use an average of 7.5% (88 domestic manufacturers and 226 foreign manufacturers).

Both domestic and foreign tobacco product manufacturers may obtain a D-U-N-S® number free of charge either online or by phone. The type of information required by Dun & Bradstreet to get a D-U-N-S® number includes such company information as the name of the business, contact person, e-mail address, physical and mailing address, legal structure, top executive name, and title, SIC (Standard Industrial classification code), number of employees, annual revenues, and parent company name (if applicable).[29]

Dun & Bradstreet usually requires 30 days to provide a D-U-N-S® number upon receiving a complete request. For businesses that are willing to pay a fee of about $229, Dun & Bradstreet can speed up the process and provide a number more quickly.[30] We do not know how many establishments would wait 30 days to obtain a D-U-N-S® number for free, or how many would pay $229 for an expedited number. Our low estimate assumes that no manufacturers would pay $229 and all would wait 30 days to obtain a D-U-N-S® number, our primary estimate assumes that 50% of the manufacturers would pay $229 while 50% of manufacturers would wait 30 days to obtain a D-U-N-S® number free of charge, and our high estimate assumes that all manufacturers would pay $229 for an expedited number. We request comments on this estimate.

Regardless of which service establishments choose, we estimate that the time required to request the number would be 30 minutes or less.[17] In addition, we estimate that the weighted average (or a composite) hourly wage for this labor time would be $79.11 for domestic and $8.17 for foreign manufacturers (Table 7). First-year costs to both domestic and foreign establishments for obtaining a D-U-N-S® number are summarized in Table 14.

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[28] https://www.nfib.com/content/analysis/economy/does-your-small-business-need-a-duns-number/#:~:text=Does%20a%20small%20business%20need,understand%20a%20business'%20credit%20history.
[29] Dun & Bradstreet website. http://www.dnb.com/get-a-duns-number.html
[30] https://fdalisting.com/duns-number/

Table 14. First-Year Costs to Domestic and Foreign Manufacturers for Obtaining a D-U-N-S® Number

	Establishments	Time (Hours)	Composite Wage	One-time Costs		
				Primary	Low	High
Domestic Establishments	88	0.5	$79.11	$11,833.20	$3,485.78	$20,180.63
Foreign Establishments	226	0.5	$8.17	$26,335.43	$922.58	$51,748.28

Note: Product across table may not be exact due to rounding.

The costs of obtaining a D-U-N-S® number would not be the only costs associated with the proposed D-U-N-S® number requirement. We anticipate that the D-U-N-S® number requirement will also result in costs associated with entering the D-U-N-S® number onto the registration site. This cost would be incurred by all domestic and foreign establishments with a D-U-N-S® number, including those that would be required under the proposed rule to obtain a D-U-N-S® number for the first time. In estimating these costs, we assume it will take 1 minute (0.017 hours) of an administrative worker's time to enter the number onto the registration form (Table 15).

Table 15. Costs to Domestic and Foreign Manufacturers from Entering a D-U-N-S® number onto the TRLM- NG site

	Establishments	Time (Hours)	Frequency	Hours/ Year	Wage	One-time Costs	Cost/ Entity
Domestic Establishments	900	0.017	1	15	$79.11	$1,186.65	$1.32
Foreign Establishments	3,013	0.017	1	50	$8.17	$410.04	$0.14

Note: Product across table may not be exact due to rounding.

Table 16 provides a side-by-side summary of total annualized costs to domestic and foreign entities and to FDA under all options. Only primary estimates are presented. All costs are discounted for 20 years using a 7 percent and 3 percent discount rate.

Table 16. Annualized Cost Summary of Regulatory Alternative Options ($Millions)

Option Considered	Domestic entities	Foreign entities	FDA	Discount rate
Proposed Rule	$13,574	$370,215	$15,182,484	7%
	$13,429	$377,071	$15,182,484	3%
Option 2: Extend compliance date	$12,389	$336,955	$13,843,120	7%
	$12,567	$351,760	$14,191,706	3%
Option 3: Proposed rule with DUNS	$14,427	$373,097	$15,182,484	7%
	$14,073	$379,310	$15,182,484	3%

Note: Product across table may not be exact due to rounding.

I. Distributional Effects

The total estimated costs of this rule are expected to be small relative to US tobacco product manufacturer revenues. Given the 2024 value of shipments for domestic tobacco product manufacturers of $66.2 billion, the total annualized costs to domestic manufacturers of $13,574 would represent 0.00002%.[31, 32] Notably, this figure excludes manufacturers of ENDS (such as e-liquids, vapor refills, and electronic cigarette devices), thus the percent of costs over manufacturer revenue is likely to be smaller. Data on the value of shipments for these excluded manufacturers are not currently available, and we request comments on potential sources or methods for obtaining this information.

J. International Effects

Domestic tobacco product manufacturers are already required to register their operations and list their products with FDA. Foreign manufacturers have not previously been subject to these requirements. This proposed rule would require foreign tobacco manufacturers to register and list their products that are offered for U.S. import with FDA, maintain compliance documentation, and submit to inspections beyond current PMTA-related visits (see Section II.C of this analysis). We expect that annualized costs incurred by foreign establishments would be approximately $370,215 at a 7 percent discount rate, representing 2.4% of total costs (see Section II.F for detailed calculations). These expanded requirements fundamentally broaden FDA's international oversight authority and would make it easier for FDA to ensure accountability and compliance of foreign manufacturers and their tobacco products with the requirements of the FD&C Act and applicable regulations, including marketing and tobacco product standards requirements and marketing restrictions (see Section II.E for additional discussion).

III. Initial Small Entity Analysis

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because costs of this rule are small, we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities. This analysis, as well as other sections in this document and

[31] U.S. Census Bureau, Manufacturers' Value of Shipments: Tobacco Manufacturing [A12BVS], retrieved from FRED, Federal Reserve Bank of St. Louis; https://fred.stlouisfed.org/series/A12BVS, January 7, 2026.
[32] The $66.2 billion in tobacco manufacturers' value of shipments from census data corresponds exclusively to NAICS code 312260. This code covers establishments primarily engaged in (1) stemming and redrying tobacco and/or (2) manufacturing cigarettes and other tobacco products.

the preamble of the proposed rule, serves as the Initial Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

A. Description and Number of Affected Small Entities

FDA examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. 601-612). The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities.[33]

This proposed rule affects manufacturers of tobacco products, including ENDS (such as electronic cigarettes and e-liquids). We estimate that there are 910 domestic establishments (manufacturers of tobacco products) that would be affected by this proposed rule.[34] Despite our relative certainty of the total number of affected domestic establishments, we are less certain of the proportion of establishments that are small. We use U.S. Census data for domestic entities to estimate the number of affected domestic small entities. Although U.S. Census data are not ideal for estimating the total number of such entities that would be affected, they offer the best available insight into the proportion that may be small. Manufacturers of tobacco products that would be affected by this proposed rule are designated in the NAICS system as "tobacco product manufacturers." ENDS manufacturers are designated under two separate NAICS codes depending on whether they manufacture devices or liquids. Specifically, manufacturers of e-liquids and vapor refills are designated under NAICS 325998 as "All other chemical product preparation manufacturing"; and manufacturers of electronic cigarette devices are under NAICS 339999 "All other miscellaneous manufacturing." Table 17 shows the Small Business Administration (SBA) size thresholds for small businesses in each of these categories reported in the Statistics of U.S. Businesses (SUSB) data from 2022.[35]

[33] We use the terms entities, establishments and manufacturers interchangeably. We also use the U.S. Census definition for an establishment in this section of the analysis. According to the Census, an establishment is a single physical location at which business is conducted, or services or industrial operations are performed. An establishment is not necessarily equivalent to a company or enterprise, which may consist of one or more establishments. A single-unit enterprise owns or operates only one establishment.

[34] Consistent with section 905 of the FD&C Act (21 U.S.C. § 387e), each establishment engaged in the manufacture, preparation, compounding, or processing of a tobacco product must be registered. A firm that owns or operates multiple establishments is therefore required to register each establishment. This is reflected in the cost analysis, where all costs are estimated and presented on a per-establishment basis.

[35] An important caveat is that NAICS 325998 includes a wide variety of chemical products beyond e-liquids, making it difficult to isolate e-liquid manufacturers specifically. Similarly, NAICS 339999 is an extremely broad catchall category that encompasses diverse products along with electronic cigarette devices.

Table 17. Small Business Administration (SBA) Size Thresholds by NAICS Category

NAICS Code	Description of NAICS Category	SBA Size Standard (Employees)
312230	Tobacco Manufacturing	1,500
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing: Includes establishments producing e-liquids and vapor refills	650
339999	All Other Miscellaneous Manufacturing: Includes establishments making physical electronic cigarette devices and tobacco pipes	550

We used detailed data from 2022 Statistics of U.S. Businesses on U.S. 6-digit NAICS detailed employment sizes and revenues to analyze the potential impacts of this proposed rule on small entities (NAICS codes 312230, 325998, 339999).[36] Of the 910 current and new domestic registrants that may be affected by this rule, we estimate that approximately 855 establishments or 94 percent of the total (910 = 900 registrants estimated from TRLM NG data + 10 first year registrants) may be small according to the Small Business Administration (SBA) size standards. We request comments on these estimates.

B. Description of the Potential Impacts of the Rule on Small Entities

We estimate first year costs (undiscounted) per domestic establishment to be about $18 for currently registered establishments and about $204 for new establishments. Table 18 below itemizes estimated costs per domestic establishment. For currently registered establishments, first-year costs consist of $18.46 for completing new registration and listing fields required under the proposed rule (0.23 hours at a composite wage of $79.11 per hour). For new registrants, first-year costs consist of $178.00 for initial registration and listing (2.25 hours at $79.11 per hour) plus $26.37 for the first annual renewal (0.33 hours at $79.11 per hour), for a total first-year cost of approximately $204.37. Recurring annual costs for all establishments include $26.37 for annual renewal. New registrants entering the market each year also face biennial inspection costs of $1,230.72 per inspection cycle (16 hours at the management wage of $153.84 per hour,

[36] We use 94 percent by dividing aggregated small firm establishment counts by aggregated total firm establishment counts across all three NAICS codes. 2022 SUSB data available from: https://www.census.gov/data/tables/2022/econ/susb/2022-susb-annual.html.
For NAICS descriptions, see https://www.census.gov/naics/?input=312230&year=2022&details=312230, https://www.census.gov/naics/?input=325998&year=2022&details=325998, and https://www.census.gov/naics/?input=339999&year=2022&details=339999.
SBA size classifications available at: https://www.sba.gov/document/support-table-size-standards.

allocated at 50% to reflect biennial frequency). Estimated annualized costs at a 7% discount rate over 20 years are approximately $14.33 per domestic establishment.[37]

Table 18. Itemized Costs per Domestic Establishment

Cost Component	Establishments Affected	Hours	Wage ($/hour)	Cost per Establishment
Initial registration & listing (existing registrants)	Currently registered	0.23	$79.11	$18.46
Initial registration & listing (new registrants)	New entrants	2.25	$79.11	$178.00
Annual renewal (all registrants)	All	0.33	$79.11	$26.37
Biennial inspection (new registrants, 50% annual allocation)	New entrants	8.00	$153.84	$1,230.72
Annualized cost per domestic establishment (7%, 20 years)				**$14.33**

To assess the potential significance of these costs for small entities, we apply a 3% annual revenue threshold to evaluate significant economic impact. Under this threshold, an entity with annual revenues below approximately $478 (= $14.33 ÷ 0.03) would be considered significantly impacted. Average annual receipts for small establishments across all three relevant NAICS codes substantially exceed this level even for the smallest size categories (fewer than 5 employees), where 2022 SUSB average receipts range from approximately $458,000 to $1,059,000 per establishment. Based on this analysis, the likelihood that this rule would impose a significant economic impact on small entities is very low, as estimated annualized compliance costs per establishment fall well below the 3% of annual revenues threshold across all relevant NAICS codes and firm size categories. This finding supports FDA's proposed certification that this rule would not have a significant economic impact on a substantial number of small entities.

C. Alternatives to Minimize the Burden on Small Entities

As described in Section H.2, Regulatory Alternative 2 would reduce costs for all domestic establishments by extending the compliance date of the rule. The number of affected small entities under this alternative would be the same as under the proposed rule. However, annualized costs over 20 years at a 7% discount rate would be approximately $13.08 per

[37] This analysis estimates only the incremental costs attributable to this proposed rule relative to the existing regulatory baseline established by the 2016 Deeming Rule. Inspection costs for currently registered establishments were accounted for in the Final Regulatory Impact Analysis for the 2016 Deeming Rule and are therefore not attributed to this rule.

establishment, which is $1.25 less than under the proposed rule. However, as stated in Section H.2, delaying the compliance date would increase the length of time that foreign firms are not subject to the requirements with which domestic firms must currently comply and would delay benefits in the proposed rule.

IV. References

[1] "Summary: Deeming Tobacco Products to be Subject to the Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations Restricting the Sale and Distribution of Tobacco Products and Required Warning Statements," 10 May 2016. [Online]. Available: https://www.fda.gov/about-fda/economic-impact-analyses-fda-regulations/summary-deeming-tobacco-products-be-subject-food-drug-and-cosmetic-act-amended-family-smoking

Appendix: Wage Rates for Foreign Tobacco Product Manufacturing

To estimate wages in foreign tobacco product manufacturing establishments, we use the Occupational Wages around the World (OWW) Database: Update for 1983-2008.[38] Relying on historical occupational and industry-level wages, we reviewed data for the most recent year available for 15 of the 20 foreign countries that exported the largest amount of tobacco products to the United States by total dollar value. Except for a few countries, the database does not report wages for employees of tobacco product manufacturers. We therefore use reported wages earned by laborers and foremen employed by other manufacturing industries such as chemical products manufacturing as proxy wages. For office and administrative support occupation wage estimates we use production worker wage estimates as proxy wages. We request comments on these assumptions comparing wages for tobacco manufacturing to wages for the manufacture of other chemical products and comparing office and administrative support occupations with production occupations.

We then estimate wages for General and Operations Manager using the ratio of wages for production managers to general managers in the United States according to the Bureau of Labor Statistics.[39] We further use Accountant wages reported in OWW as proxies for the wages of

[38] Freeman, Richard B., and Remco H. Oostendorp (2020). Occupational Wages Around the World 1953-2008 Database [Data file and documentation]. Available from National Bureau of Economic Research website: https://www.nber.org/research/data/occupational-wages-around-world-oww-database.

[39] Bureau of Labor Statistics (2024). May 2024 National Industry-Specific Occupational Employment and Wage

Legal Occupations. For other occupations where the OWW data do not include comparable staff descriptions, we use country-specific general manufacturing industry level wages for specific occupations such as plant and machine operators from the ILOSTAT database[40] (and in the United Arab Emirates, wages from the Federal Competitiveness and Statistics Authority[41]) as proxies.

To account for inflation, we adjust historical wages to their 2022 equivalents based on consumer price indices (CPI) for each country, obtained from the World Bank.[42] In estimating wages for Sweden, Switzerland, Malaysia, Austria, and Zimbabwe, we used a variety of publicly available data sources for respective occupations. These sources are listed below in Table A.1 and are reported in 2024 dollars.

We then used (2024) exchange rates from the U.S. Treasury Department[43] to convert all currency units into U.S. dollars. Finally, we calculate weighted average wages for the occupations for office and administrative support production worker, manager, general manager, and legal staff across the 20 foreign countries, using as weights each country's share of their combined total dollar value of tobacco product exports to the United States. Estimated composite hourly wage rates for all three occupations used in this analysis are represented as the sum of the weighted wage rates (Table A.1). Finally, we adjusted the final production occupation wage of $3.12 by a 94% ratio to obtain a final administrative support wage of $2.93.[44]

Estimates [Online database] for NAICS 312200 and for NAICS 541100 - Legal Occupations. Available from BLS website: https://www.bls.gov/oes/current/oessrci.htm

[40] International Labour Organization. ILOSTAT [Online database]. Available from International Labour Organization website: https://ilo.org/ilostat

[41] UAE Federal Competitiveness and Statistics Authority (FCSA) (2008). Paid Employees in Manufacturing Industry [Data file]. Available from UAE Open Data Portal website: http://data.bayanat.ae/en_GB/dataset/paid-employees-in-manufacturing-industry

[42] https://data.worldbank.org/indicator/FP.CPI.TOTL data downloaded September of 2024.

[43] https://fiscaldata.treasury.gov/datasets/treasury-reporting-rates-exchange/treasury-reporting-rates-of-exchange

[44] We estimate the ratio of 94% by dividing the mean hourly domestic administrative support wages of $27.10 by the mean domestic production wage of $28,86. Wage data obtained from https://data.bls.gov/oes/#/industry/312200.

Table A.1. Weighted Foreign Wage Estimates by Country and by Percent Value of U.S. Tobacco Product Imports from Top Twenty Exporting Countries

Country of Origin Full Name	Base wage rate by occupation and country			Percent Value of Imported Tobacco Products	Wage rates weighted by share of imported tobacco product value (=Base wage x Percent value)		
	Production Occupations	Management Occupations	Legal Occupations		Production Occupations	Management Occupations	Legal Occupations
Dominican Republic (the)	$1.66	$5.55	$1.66	21.4%	$0.35	$1.19	$0.35
China	$1.41	$1.83	$2.96	16.5%	$0.23	$0.30	$0.49
Indonesia	$0.39	$1.36	$0.55	15.7%	$0.06	$0.21	$0.09
Nicaragua	$0.81	$2.69	$2.22	11.0%	$0.09	$0.30	$0.25
Brazil	$1.79	$3.69	$12.31	4.9%	$0.09	$0.18	$0.61
Canada	$16.67	$27.01	$27.74	4.0%	$0.67	$1.09	$1.12
Honduras	$1.51	$3.82	$2.29	3.5%	$0.05	$0.13	$0.08
Turkey	$1.74	$2.60	$3.54	2.9%	$0.05	$0.08	$0.10
India	$0.34	$0.62	$2.40	2.4%	$0.01	$0.02	$0.06
Argentina	$10.12	$33.83	$7.52	2.3%	$0.23	$0.77	$0.17
France	$19.21	$42.26	$34.39	1.4%	$0.27	$0.58	$0.48
Spain	$19.98	$43.95	$31.06	1.1%	$0.23	$0.50	$0.35
United Arab Emirates	$3.78	$20.13	$14.16	1.1%	$0.04	$0.22	$0.16
Germany	$19.85	$43.68	$35.54	1.0%	$0.20	$0.43	$0.35
Sweden [1]	$18.22	$41.81	$47.06	1.0%	$0.18	$0.41	$0.46
Philippines	$1.12	$3.15	$2.66	1.0%	$0.01	$0.03	$0.03
Switzerland [2]	$28.64	$82.34	$103.82	0.8%	$0.22	$0.64	$0.81
Malaysia [3]	$4.85	$21.84	$23.54	0.7%	$0.04	$0.16	$0.17
Austria [4]	$15.12	$43.17	$59.00	0.6%	$0.09	$0.27	$0.37
Zimbabwe [5]	$0.59	$4.01	$3.82	0.6%	$0.00	$0.02	$0.02
Sum				94%	**$3.12**	**$7.54**	**$6.51**

Notes: Product across table may not be exact due to rounding.

(1) Wages obtained from https://statsskuld.se/en/lonestatistik/tobaksarbetare

(2) Wages obtained from Economic Research Institute https://www.erieri.com

(3) Wages obtained from Economic Research Institute https://www.erieri.com and from https://www.salaryexpert.com

(4) Wages obtained from Economic Research Institute https://www.erieri.com and from https://www.salaryexpert.com

(5) Wages obtained from https://worldsalaries.com