Report to Congress

Tobacco Regulation Activities

FY 2025

Submitted Pursuant to Public Law 117-103

Executive Summary

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), enacted in 2009, amended the Federal Food, Drug, and Cosmetic Act to authorize the Food and Drug Administration (FDA or Agency) to oversee the manufacture, marketing, distribution, and sale of tobacco products and to protect the public from the harmful effects of tobacco product use. In addition, the Tobacco Control Act directed FDA to establish the Center for Tobacco Products to implement this law.

The Consolidated Appropriations Act of 2022 (Public Law 117-103), signed into law on March 15, 2022, (1) provided appropriations to federal agencies, (2) modified or established various programs to address a wide range of policy areas, and (3) requires yearly reporting by FDA on specific information and data related to its tobacco regulation activities. This report to Congress satisfies this annual reporting requirement by providing information and data about the funding, application review, regulatory work, and compliance and enforcement efforts of FDA in fiscal year 2025.

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Acronym List

APPH	Appropriate for the Protection of the Public Health
CMP	Civil Money Penalty
CTP	Center for Tobacco Products
ENDS	Electronic Nicotine Delivery System
EX REQ	Exemption from Substantial Equivalence
FDA	Food and Drug Administration
FD&C Act	Federal Food, Drug, and Cosmetic Act
FY	Fiscal Year (October 1 to September 30)
HHS	Department of Health and Human Services
HTP	Heated Tobacco Product
MRTPA	Modified Risk Tobacco Product Application
NTSO	No-Tobacco-Sale Order
OII	Office of Inspections and investigations
PMTA	Premarket Tobacco Product Application
SE	Substantial Equivalence
Tobacco Control Act	The Family Smoking Prevention and Tobacco Control Act
TPSAC	Tobacco Products Scientific Advisory Committee

I. Background

Tobacco product use is the leading preventable cause of disease, disability, and death in the United States. Each year, an estimated 490,000 Americans die prematurely from smoking or from exposure to second-hand smoke.[1] More than 16 million people in the United States live with a serious illness caused by smoking.[2]

In 2009, the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) was enacted, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) and granted authority to the Food and Drug Administration (FDA or Agency) to regulate tobacco products. This new authority gave FDA comprehensive tools to protect the public from the harmful effects of tobacco product use.

FDA works to protect Americans from tobacco-related death and disease by regulating the manufacture, distribution, and marketing of tobacco products and by educating the public, especially young people, about tobacco products and the dangers posed to themselves and others from use of these products.

FDA executes regulatory and public health activities to support the following objectives:

- Reducing initiation of tobacco product use;
- Decreasing the harms of tobacco products; and
- Encouraging cessation among tobacco product users.

On March 15, 2022, the President signed the Consolidated Appropriations Act of 2022 (Public Law 117-103) into law. As a result, the FD&C Act now includes specific language that makes clear that FDA regulates tobacco products containing nicotine from any source, including synthetic nicotine.

Division P, Title I, Subtitle B, section 112 of the Consolidated Appropriations Act of 2022, excerpted below, requires yearly reporting by FDA on specific information and data related to tobacco regulation activities.

> (b) REQUIRED INFORMATION.—

[1] Office of the Surgeon General (2024). *Eliminating Tobacco-Related Disease and Death: Addressing Disparities: A Report of the Surgeon General*, available at https://www.hhs.gov/sites/default/files/2024-sgr-tobacco-related-health-disparities-full-report.pdf.

[2] U.S. Department of Health and Human Services. The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General. Atlanta: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014.

Each report submitted under subsection (a) shall contain the following information for the previous fiscal year:

(1) Total annual user fee collections.

(2) Total amount of fees obligated.

(3) The amount of unobligated carryover balance from fees collected.

(4) The amount obligated by the Center for Tobacco Products for each of the following activities:

(A) Compliance and enforcement.
(B) Public education campaigns.
(C) Scientific research and research infrastructure.
(D) Communications.
(E) Leadership, management oversight, and administrative services.
(F) Related overhead activities.

(5) The numbers of applications, categorized by class of tobacco product and review pathway under sections 905, 910, and 911 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387e; 387j; 387k), that were—

(A) submitted;
(B) pending;
(C) accepted;
(D) refused to file;
(E) withdrawn;
(F) denied;
(G) authorized for marketing under an order;
(H) issued a deficiency letter or environmental information request letter; or
(I) referred to the Tobacco Products Scientific Advisory Committee.

(6) The number and titles of draft and final guidance documents and proposed and final regulations issued on topics related to the process for the review of tobacco product applications, whether such regulations and guidance documents were issued as required by statute or by other legal or regulatory requirements, and whether the issuance met the deadlines set forth by the applicable statute or other requirements.

(7) The number and titles of public meetings related to the review of tobacco product applications by the Center for Tobacco Products or other offices or centers within the Food and Drug Administration.

(8) The number of pre-submission meetings relating to applications under section 910 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387j), including the number of meeting requests received, the number of meetings held, and the median amount of time between when such meeting requests were made and when the requests were granted or denied.

(9) The number of full-time equivalent employees funded pursuant to fees collected under section 919 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387s), including identification of the centers and offices within the Food and Drug Administration in which such positions are located.

(10) The number of inspections and investigations conducted at domestic and foreign establishments required to register under section 905 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387e).

(11) The total number of compliance and enforcement actions issued or taken with respect to tobacco products, including warning letters, civil money penalties (CMPs), no-tobacco sale orders (NTSOs), and other enforcement actions (including seizures, injunctions, and criminal prosecution).

This report satisfies these congressional reporting requirements.

II. User Fees

FDA's tobacco regulatory activities are solely funded by tobacco user fees, and these fees are authorized by Congress to remain available until expended. Congress authorized, in the FD&C Act, the amount of tobacco user fees FDA may assess and collect. The fees increased each year from fiscal year (FY) 2009 to FY 2019. Beginning in FY 2019 and in subsequent years, FDA is authorized to assess and collect $712M.

The FD&C Act authorizes FDA to assess and collect tobacco user fees from domestic manufacturers and importers of the following six classes of products: cigarettes, cigars, snuff, chewing tobacco, pipe tobacco, and roll-your-own tobacco. Currently, manufacturers and importers of e-cigarettes do not pay user fees, and activities to address e-cigarettes comprise a sizable portion of the workload of FDA's Center for Tobacco Products (CTP).

Ongoing litigation regarding the regulatory status of premium cigars[3] impacted tobacco user fee collections in FY 2025. FDA's total annual tobacco user fee collections in FY 2025 were $698.8M, of which $696M was collected from FY 2025 tobacco invoices and $2.8M was collected from prior cohort tobacco invoices. Prior to the premium cigar litigation, FDA historically collected 99.8 percent of the $712M. The Agency is continuing to evaluate the evolving legal and practical implications of this ruling.

FDA's FY 2025 tobacco-related obligations (in millions), which are listed by the applicable program area of CTP, are included in Table 1 below. The total amount of tobacco user fees obligated in FY 2025 was $663.9M. The carryover balance from FY 2025 to FY 2026 was $374M.[4] This carryover balance is significantly higher than in past years as a result of the mandatory Department of Health and Human Services' (HHS) cost efficiency initiative, in which CTP reduced FY 2025 planned spending in alignment with the Department's priorities. Those unspent user fees have been carried over and are available to spend in FY 2026.

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[3] In August 2023, the U.S. District Court for the District of Columbia issued an order vacating FDA's Deeming Rule insofar as it applies to premium cigars. This order means that premium cigars are not subject to the requirements of Chapter IX of the FD&C Act, including the requirement to pay user fees. *Cigar Ass'n of Am. v. FDA*, No. 16-cv-01460, Dkt. No. 277 (D.D.C. Aug. 9, 2023). The Court has defined "premium cigars" as (1) are wrapped in whole tobacco leaf; (2) contain a 100 percent leaf tobacco binder; (3) contain at least 50 percent (of the filler by weight) long filler tobacco; (4) are handmade or hand rolled; (5) have no filter, nontobacco tip, or nontobacco mouthpiece; (6) do not have a characterizing flavor other than tobacco; (7) contain only tobacco, water, and vegetable gum with no other ingredients or additives; and (8) weigh more than six pounds per 1,000 units. (D.D.C. Apr. 15, 2026).

[4] The carryover exists in part due to tobacco industry user fees being collected at the end of each quarter; therefore, fourth quarter collections are not available for obligation until the first quarter of the following fiscal year.

Table 1. CTP's FY 2025 Obligations (in Millions)

FY 2025 Actual Obligations		
	Acquisitions	**Personnel/Operating**
Program Area		
Product Review, Scientific Research, and Research Infrastructure	$ 172.6	$ 120.7
Compliance and Enforcement	$ 75.8	$ 68.0
Public Education Campaigns	$ 59.7	$ 7.3
Communications	$ 10.2	$ 7.3
Leadership, Management Oversight, and Administrative	$ 3.8	$ 32.4
Related Overhead Activities	$ 76.9	$ 29.2
Total	**$ 399.0**	**$ 264.9**
Total Obligations: $663.9		

A. Product Review, Scientific Research, and Research Infrastructure

FDA's product review and scientific research of tobacco products are critical to FDA's implementation of the Tobacco Control Act. Before introducing a new tobacco product to the U.S. market, a company must submit a marketing application and receive authorization. These new product applications are comprehensively evaluated by FDA scientists who determine whether the applicant has demonstrated that the new tobacco product meets the appropriate legal standard for marketing; that standard is referred to as "appropriate for the protection of the public health (APPH)." For additional information about FDA's premarket review of new tobacco products, please see https://www.fda.gov/tobacco-products/products-guidance-regulations/market-and-distribute-tobacco-product.

Additionally, CTP implements a research program that helps inform scientific decisions related to the premarket review of new tobacco products and the review of modified risk tobacco product applications (MRTPAs). Research programs and projects include, but are not limited to, the scientific fields of public health, addiction, behavior, biology, chemistry, medicine, economics, engineering, epidemiology, pharmacology, toxicology, communications, marketing, and statistics. For additional information about FDA's tobacco research efforts, please see https://www.fda.gov/tobacco-products/tobacco-science-research.

B. Compliance and Enforcement

FDA has a comprehensive compliance and enforcement program to evaluate and ensure compliance with the FD&C Act, as amended by the Tobacco Control Act, and implementing regulations, including the *Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Children and Adolescents* final rule.[5] As part of FDA's compliance and enforcement program, the Agency closely monitors tobacco product manufacturers, retailers, distributors, and importers to ensure compliance, including through tobacco inspections by its Office of Inspections and Investigations (OII). For additional information about FDA's tobacco compliance and enforcement efforts, please see https://www.fda.gov/tobacco-products/compliance-enforcement-training.

C. Public Education Campaigns

FDA's distinct tobacco public education campaigns work in concert with its regulatory actions to prevent and reduce tobacco-related disease and death and to improve public health. These campaigns include both educating youth about the risks of tobacco products and educating adults who smoke about the relative risks of tobacco products. For additional information about FDA's tobacco public health education campaigns, please see https://www.fda.gov/tobacco-products/public-health-education/public-health-education-campaigns.

D. Communications

FDA creates and promotes material in which target audiences can seek additional information about the health effects of tobacco product use and find connections to resources for quitting tobacco use. CTP is making investments to build the evidence base for educating adult consumers as well as healthcare providers about the relative

[5] 75 FR 13225 (Mar. 19, 2010), available at https://www.federalregister.gov/documents/2010/03/19/2010-6087/regulations-restricting-the-sale-and-distribution-of-cigarettes-and-smokeless-tobacco-to-protect.

risks of tobacco products, while also understanding the impacts of such messages on unintended populations such as youth or former smokers. For an example of information that FDA provides about the health effects of tobacco product use, please see https://www.fda.gov/tobacco-products/public-health-education/health-effects-tobacco-use. For an example of information that FDA provides about quitting tobacco use, please see https://www.fda.gov/tobacco-products/health-effects-tobacco-use/quitting-smoking-and-other-tobacco-public-health-resources.

E. Leadership, Management Oversight, and Administrative Services

CTP's leadership and management oversight of its tobacco program operations and activities, including the development of regulatory and policy documents, support CTP's programmatic mission. Administrative programs and services include human capital management, information technology project management, financial management, acquisitions, ethics and program integrity, and logistical services.

F. Related Overhead Activities

FDA's overhead activities relate to the following areas: general information technology infrastructure, centralized expenses, General Services Administration rent, other rent and rent-related services, and FDA's headquarters.

III. Numbers of Product Applications

FDA serves a critical public health role by performing a scientific review of new tobacco products[6] before they can be legally marketed. A new tobacco product must be authorized by FDA under one of the following three pathways before marketing:

1. The Premarket Tobacco Product Application (PMTA) pathway, under which an applicant must show, among other things, that permitting the marketing of the tobacco product would be APPH,[7] or

2. The Substantial Equivalence (SE) pathway, under which an applicant must show among other things, that the tobacco product is substantially equivalent[8] to a valid predicate tobacco product,[9] or

3. The SE Exemption (EX REQ) pathway, under which FDA may exempt a product from the requirements of SE.

In addition, before marketing a modified risk tobacco product (i.e., a tobacco product sold or distributed to reduce the harm or risk of tobacco-related disease), a manufacturer must submit an MRTPA and receive an FDA order authorizing the marketing of the product.

[6] A "new tobacco product" is (1) any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007, or (2) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007. See section 910 of the FD&C Act.

[7] The finding of whether the marketing of a tobacco product is appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco products, and taking into account 1) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and 2) the increased or decreased likelihood that those who do not use tobacco products will start using such products. See section 910 of the FD&C Act.

[8] A tobacco product that is "substantially equivalent" is one that FDA has determined either (1) has the same characteristics as the predicate tobacco product or (2) has different characteristics than the predicate tobacco product but the information submitted by the applicant demonstrates that the new product does not raise different questions of public health. See section 905(j) of the FD&C Act.

[9] A "valid predicate tobacco product" is one that was (1) commercially marketed in the United States – other than for test marketing – as of February 15, 2007, or (2) previously found to be substantially equivalent by FDA. See section 905(j) of the FD&C Act.

A. FDA's Tobacco Review Pathways

FDA's tobacco review pathways are described under sections 905, 910, and 911 of the FD&C Act.

Section 905

Under the SE pathway in section 905, manufacturers must submit SE reports to FDA to seek authorization to legally market new tobacco products. FDA has built a science-based process to review these SE reports to determine whether the new products are substantially equivalent to valid predicate products.

SE reports are considered to be either "regular" or "provisional." "Regular SE reports" are those SE reports submitted for a new tobacco product that requires marketing authorization prior to being introduced into interstate commerce. A regular SE report differs from a "provisional SE report," which is an application for a new tobacco product that meets the following criteria: (1) the SE report was submitted by March 22, 2011, and (2) the product was first introduced or delivered for introduction into interstate commerce for commercial distribution in the United States after February 15, 2007, but prior to March 22, 2011.

FDA reviews these SE reports to determine if the new tobacco product is substantially equivalent to a valid predicate product and is in compliance with the requirements of the FD&C Act. If both criteria are met, FDA issues an order permitting the product to be legally marketed in the United States.

In addition, under section 905, the original manufacturer of any new tobacco product may submit an EX REQ. FDA may grant an EX REQ if (1) the new tobacco product is modified by adding or deleting a tobacco additive or by increasing or decreasing the quantity of an existing tobacco additive; (2) the proposed modification is minor and to a tobacco product that can be legally marketed; (3) an SE report is not necessary to ensure that permitting the tobacco product to be marketed would be APPH; and (4) an EX REQ is otherwise appropriate.

Section 910

Under the PMTA pathway in section 910, applicants must demonstrate to FDA, among other things, that the marketing of the new tobacco product would be APPH. This APPH standard requires FDA to consider the risks and benefits to the population as a whole, including users and non-users of tobacco products.

Section 911

Section 911 allows for the submission of MRTPAs. An MRTPA must demonstrate, among other things, that the modified risk tobacco product will significantly reduce harm

and the risk of tobacco-related disease to individual tobacco users and will benefit the health of the population as a whole. A modified risk tobacco product order applies to a specific product, not a tobacco product class.

B. Referrals to the Tobacco Products Scientific Advisory Committee

The Tobacco Products Scientific Advisory Committee (TPSAC) reviews and evaluates safety, dependence, and health issues relating to tobacco products and provides appropriate advice, information, and recommendations to the Commissioner of Food and Drugs. TPSAC provides advice on applications submitted as MRTPAs.[10] Additionally, FDA may choose to solicit advice from TPSAC for other applications, such as PMTAs. For FY 2025, FDA referred one renewal of MRTP orders for the IQOS heated tobacco products (HTPs).[11]

C. Data on Product Applications

Information about FY 2025 product applications, broken down by application type and product class (including cigars, cigarettes, electronic nicotine delivery systems (ENDS), HTPs,[12] other tobacco products,[13] pipe tobacco, roll-your-own tobacco, smokeless tobacco products, and waterpipes/hookahs), is presented in Table 2.

[10] 21 U.S.C. 387k(f).

[11] Though referred in 2025, the meeting was not held until 2026.

[12] HTPs are non-combusted products that heat tobacco to a lower temperature than combusted cigarettes to create an aerosol that is inhaled by the user. Different forms of tobacco can be used in HTPs including dry tobacco wrapped in paper that resembles a cigarette. HTPs that are capable of using multiple consumables (e.g., tobacco fillers, e-liquids, and/or gels) are also known as multi-modals. ENDS heat and aerosolize a liquid and cannot be used with non-liquid forms of tobacco. An HTP that only uses an e-liquid would be classified as an ENDS.

[13] This class includes tobacco products that are not defined (e.g., nicotine gels, dissolvable products from extracts, tobacco-derived nicotine discs).

Table 2. FY 2025 Data on Product Applications (by Application Type and Product Class)[14]

Application Status	Product Class	Application Types			
		Section 905 Exemption Requests	Section 905 SE Reports	Section 910 PMTAs	Section 911 MRTPAs
Submitted/ Received	Cigar	32	20	0	0
	Cigarette	144	10	0	0
	ENDS	40	0	24,766	0
	HTP	0	0	12	0
	Other	0	0	1,350	52
	Pipe	0	1	0	0
	Roll-Your-Own	0	34	0	0
	Smokeless	4	4	121	0
	Waterpipe/Hookah	0	47	198	0
Pending	Cigar	85	2,296	10	0
	Cigarette	179	481	0	0
	ENDS	46	0	145,566	0
	HTP	0	0	32	31
	Other	0	61	2,699	96
	Pipe	0	1,092	12	0
	Roll-Your-Own	4	257	0	0
	Smokeless	18	211	271	0
	Waterpipe/Hookah	485	211	138	0

[14] FDA received some submissions that could not be processed for various reasons, including but not limited to lack of required forms, use of an incorrect form, or use of an incorrect format for the application. Given that FDA was unable to fully process these submissions, the submissions were issued Refuse to Accept Letters or withdrawn by the applicant. Since complete information was not available, metrics for these submissions are not provided in the reported tables.

Application Status	Product Class	Application Types			
		Section 905 Exemption Requests	Section 905 SE Reports	Section 910 PMTAs	Section 911 MRTPAs
Accepted	Cigar	29	68	0	0
	Cigarette	156	30	0	0
	ENDS	40	0	15,666	0
	HTP	0	0	7	0
	Other	0	36	1,266	20
	Pipe	0	1	0	0
	Roll-Your-Own	0	56	0	0
	Smokeless	4	55	143	0
	Waterpipe/Hookah	38	23	57	0
Refused to File*	Cigar	N/A	N/A	0	0
	Cigarette	N/A	N/A	0	0
	ENDS	N/A	N/A	37	0
	HTP	N/A	N/A	0	0
	Other	N/A	N/A	0	0
	Pipe	N/A	N/A	0	0
	Roll-Your-Own	N/A	N/A	0	0
	Smokeless	N/A	N/A	0	0
	Waterpipe/Hookah	N/A	N/A	0	0
Withdrawn	Cigar	0	221	0	0
	Cigarette	50	0	0	0
	ENDS	0	0	156	0
	HTP	0	0	0	0
	Other	0	0	0	0
	Pipe	0	101	0	0
	Roll-Your-Own	0	11	0	0
	Smokeless	0	0	11	0
	Waterpipe/Hookah	0	25	0	0

* According to 21 USC 387(j) and (k), “refuse to file” actions are allowed only under PMTA and MRTPA pathways.

Application Status	Product Class	Application Types			
		Section 905 Exemption Requests	Section 905 SE Reports	Section 910 PMTAs	Section 911 MRTPAs
Denied	Cigar	15	18	0	0
	Cigarette	652	1	0	0
	ENDS	0	0	187,071	0
	HTP	0	0	0	0
	Other	0	0	0	0
	Pipe	6	26	0	0
	Roll-Your-Own	0	2	0	0
	Smokeless	0	0	0	0
	Waterpipe/Hookah	0	13	0	0
Authorized for Marketing Order	Cigar	10	76	0	0
	Cigarette	45	2	0	0
	ENDS	0	0	5	0
	HTP	0	0	0	0
	Other	0	0	20	0
	Pipe	0	12	0	0
	Roll-Your-Own	0	1	0	0
	Smokeless	3	0	0	8
	Waterpipe/Hookah	15	38	0	0
Issued Deficiency Letter/ Environmental Information Request Letter	Cigar	0	367	0	0
	Cigarette	0	0	0	0
	ENDS	0	0	0	0
	HTP	0	0	0	5
	Other	0	0	0	0
	Pipe	0	119	0	0
	Roll-Your-Own	0	0	0	0
	Smokeless	1	2	0	0
	Waterpipe/Hookah	0	50	0	0

IV. Guidance Documents and Regulations Related to the Process for the Review of Tobacco Product Applications

FDA develops regulations to implement the FD&C Act and other laws under which FDA operates. FDA issues guidance documents to help the public understand FDA's current thinking regarding the implementation of tobacco-related regulations and laws.

In FY 2025, FDA published a guidance document related to the review process for tobacco product applications. Specifically, the Agency issued "Validation and Verification of Analytical Testing Methods Used for Tobacco Products,"[15] a final guidance providing information and recommendations to aid tobacco product application submissions. The guidance makes recommendations on how tobacco product manufacturers can provide FDA with validated and verified data for the analytical procedures and test methods used in application submissions to the agency – including PMTAs, SE reports, and MRTPAs. To legally market a new tobacco product or a modified risk tobacco product in the United States, a company must first submit an application to – and receive authorization from – the FDA. These applications often have data and information supporting the analytical methods used for the testing of tobacco products, and this guidance is intended to help manufacturers and laboratories assemble and present scientifically valid information.

In FY 2025, FDA did not publish any regulations related to the review of tobacco product applications.

For a full list of current rules and regulations, please see https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/rules-and-regulations. For a full list of guidance documents, please see https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/guidance.

[15] https://www.federalregister.gov/d/2024-31541.

V. Public Meetings

CTP did not hold any public meetings in FY 2025. However, CTP staff presented at conferences attended by a variety of stakeholders to provide information on the application review process and answer questions.

In FY 2025, CTP leadership publicly presented updates on the Agency's tobacco work, including its review of product applications and transparency about the process and updates on compliance and enforcement activities related to unauthorized tobacco products, during stakeholder conferences. The 10 meetings and conferences in which CTP presented on product review during FY 2025 are listed in Table 4.

CTP's Stakeholder Relations Office also hosted multiple meetings in FY 2025.

Table 4. CTP's Presentations on the Review of Tobacco Product Applications at Conferences/Meetings During FY 2025

Conference/Meeting Name	Date
American Nonsmokers' Rights Foundation Clearing the Air Institute	10/17/2024
2024 Food and Drug Law Institute Tobacco and Nicotine Products Regulation and Policy Conference	10/24/2024
Medical University of South Carolina 2024 Susan Rosenblatt Lecture	10/28/2024
American Public Health Association 2024 Annual Meeting & Expo	10/29/2024
Centers for Disease Control and Prevention Office on Smoking and Health National Tobacco Control Program Webinar	11/14/2024
Big Cities Health Coalition Tobacco Policy Working Group	03/19/2025
Smokefree SC: Tobacco Partners Roundtable	03/28/2025
National Association of Attorneys General Tobacco Policy and Responsible Retailing Conference	04/22/2025
2025 Food and Drug Law Institute Annual Conference	05/16/2025
Federation of Tax Administrators Tobacco Tax Annual Conference	08/13/2025

VI. Pre-Submission Meetings

Tobacco manufacturers, importers, researchers, and/or investigators may seek meetings[16] with CTP staff ahead of their application submission. In general, FDA intends to respond, in writing, to written meeting requests within 21 calendar days of receipt of the request. FDA may determine that a face-to-face meeting or teleconference is unnecessary and instead provide written responses to the questions raised in the request. When the requestor does not provide enough information for FDA to determine the utility of the meeting, the requestor is trying to circumvent the review process, or the requestor is asking questions whose answers have already been made publicly available, a formal denial is provided to the requestor.

During FY 2025, CTP received 12 pre-submission meeting requests for tobacco product applications, including PMTAs and MRTPAs. There was an average of approximately 18 days between FDA's receipt of the meeting request and FDA's granting or denial of the request. FDA granted 11 meeting requests and denied one meeting request. The denial was due to the requestor providing incomplete information to determine the utility of the meeting.

[16] For more information on these meetings, see the revised guidance document for industry and investigators *Meetings with Industry and Investigators on the Research and Development of Tobacco Products*, available at https://www.fda.gov/media/83420/download.

VII. Full-Time Equivalent Employees

CTP ended FY 2025 with 1,090 employees onboard. In addition, approximately 221 full-time equivalents within FDA, but outside of CTP, also support tobacco product regulation. These employees are located primarily in OII, FDA's Office of the Commissioner, FDA's Office of Operations, and the National Center for Toxicological Research.

CTP's Office of Compliance and Enforcement also utilizes a dedicated cadre of staff from OII to perform inspections and other regulatory work. In FY 2025, OII had about 19 full-time equivalent inspectors dedicated to CTP's tobacco manufacturing inspections.

Table 5. CTP's FY 2025 Onboard Staff[17]

Office	Onboard Staff (as of 9/30/25)
Office of the Center Director	28
Office of Regulations	24
Office of Management	97[18]
Office of Compliance and Enforcement	291[19]
Office of Science	586[20]
Office of Health Communication and Education	64
CTP-Wide	**1090[21]**

[17] CTP Onboard Staff includes 97 staff on paid administrative leave pending reduction in force action.
[18] This number includes 71 staff then on paid administrative leave pending reduction in force action.
[19] This number includes 26 staff then on paid administrative leave pending reduction in force action.
[20] This number includes two staff then on paid administrative leave subject to notices of reassignment.
[21] In FY 2026, reduction in force notices were rescinded and all staff returned to work.

VIII. Inspections and Investigations

Section 905 of the FD&C Act requires owners and operators of establishments in any U.S. state or territory (and Washington, D.C.) engaged in the manufacture, preparation, compounding, or processing of a tobacco product to register their establishments with FDA.

FDA regularly inspects registered establishments that manufacture or process tobacco products to determine compliance with existing laws and regulations. During these inspections, FDA collects evidence to determine compliance with the provisions of the law including registration, product listing, ingredient submission, packaging, labeling, and advertising requirements, and with marketing authorization for new or modified risk tobacco products.

Because vape shops may operate as retailers, manufacturers, or both, any vape shop that conducts manufacturing activities must register with FDA and is therefore subject to inspections. During these inspections, FDA determines the types of activities that are performed at the establishment and the establishment's compliance with applicable requirements under the FD&C Act.

In FY 2025, FDA conducted inspections and/or investigations of more than 1,100 brick-and-mortar tobacco product manufacturers, with approximately 800 of those being vape shops. FDA also conducted online surveillance of over 800 manufacturer-owned websites to determine compliance with the law.

IX. Compliance and Enforcement Actions

FDA closely monitors retailer, manufacturer, importer, and distributor compliance with federal tobacco laws and regulations and takes compliance and/or enforcement action when violations occur.

FDA takes a three-pronged approach to help industry comply with the law, which includes:

1. Developing and providing compliance training and education,

2. Monitoring regulated industry's compliance with the law through surveillance, inspections, and investigations, and

3. Taking action when supported by evidence, including:

    - Issuing warning letters,
    - Issuing CMP complaints,
    - Issuing NTSO complaints to retailers, and
    - Performing seizures, pursuing injunctions, and seeking criminal prosecutions.

Warning letters are an important compliance tool for the FDA. They can be issued to regulated firms, including retailers, distributors, and manufacturers, and are the result of evidence found through various means, including brick-and-mortar inspections and/or online surveillance of sales, distribution, marketing, labeling, and/or advertising activities. Warning letters provide notice and a summary of the violations of the law and explain the consequences for failing to come into compliance with the requirements of the law. Many establishments take action to comply with federal tobacco laws and regulations after receiving a warning letter. Generally, if subsequent violations are identified, the firm may be subject to enforcement action, such as, CMP, seizure, injunction, and criminal prosecution.

If FDA finds subsequent violations at a retail establishment after the issuance of a warning letter, it generally seeks a complaint for a CMP. If FDA finds a retail establishment committed five or more repeated violations in a 36-month period, it may seek a NTSO for that retail establishment.

In FY 2025, FDA inspected approximately 119,000 brick-and-mortar tobacco retailers, issuing approximately 11,600 warning letters and 3,400 CMP actions for violations of the retail underage access restrictions under section 906(d). FDA also issued 29 NTSOs. Results from compliance check inspections of tobacco retailers are available in

the Tobacco Compliance Check Outcomes database[22] on FDA's website. In FY 2025, FDA also issued approximately 120 warning letters and 20 complaints for CMPs against brick-and-mortar tobacco retailers for violations involving the sale of unauthorized tobacco products, seeking a penalty of more than $21,000 against each retailer.

Further, in FY 2025, FDA issued over 75 warning letters to online retailers as a result of online surveillance activities and over 40 CMP complaints related to online retailers selling unauthorized tobacco products. These CMP complaints sought over $21,000 from each online retailer. These actions are also available in the Tobacco Compliance Check Outcomes database.

Additionally, in FY 2025, as noted in the previous section, FDA inspected more than 1,100 brick-and-mortar tobacco product manufacturers and conducted online surveillance of over 800 manufacturer-owned websites, issuing more than 125 warning letters resulting from these activities. FDA also filed CMP complaints against 14 manufacturers for manufacturing and selling tobacco products without marketing authorizations.

Moreover, as the result of a national enforcement effort at the end of FY 2025, the U.S. Department of Justice (DOJ), on behalf of FDA, filed complaints for permanent injunctions in federal district courts against 12 e-cigarette manufacturers, distributors and retailers. FDA and DOJ also collaborated on a robust, multi-agency enforcement effort that included the Bureau of Alcohol, Tobacco, Firearms and Explosives and the U.S. Marshals Service to conduct 13 seizure operations at distributor and retailer locations. FDA also collaborated with U.S Customs and Border Protection to conduct two high-volume, high-value seizure operations involving illegally imported unauthorized ENDS at points of entry into the U.S. These two operations alone resulted in the seizure of over 6.5 million units of unauthorized ENDS products valued at well over $100 million.[23] Almost all of the products seized and destroyed originated in China.

FDA has taken additional actions to address the increasing volume of unauthorized tobacco products entering the country. Two Import Alerts that address unauthorized tobacco products, were updated to streamline Agency processes for denying the importation of unauthorized tobacco products. This has resulted in a significant increase in the effectiveness of this enforcement tool and increased operational efficiency, leading to an exponential increase in refusals. FDA refused over 9,000 tobacco products in FY 2025 compared to 1,600 in FY 2024 and 100 in FY 2023.

FDA also issued the first tobacco-related informational letters to importers and import brokers. These letters were sent to over 60 firms found to be misdeclaring or otherwise surreptitiously attempting to import tobacco products. Outcomes of this effort include

[22] This database is available at https://timp-ccid.fda.gov/.

[23] FDA and CBP Seize Nearly $34 Million Worth of Illegal E-Cigarettes During Joint Operation | FDA
HHS, CBP Seize $86.5 Million Worth of Illegal E-Cigarettes in Largest-Ever Operation | FDA

some recipients taking corrective actions, or leaving the illicit tobacco business altogether, in addition to better-informed import screening and targeting.

In FY 2025, FDA's Office of Criminal Investigations conducted criminal investigations into illegal activities involving FDA-regulated tobacco products, which resulted in arrests.

X. Conclusion

Given the substantial impact tobacco product use has on the country's health, FDA's regulation of tobacco products remains vital for protecting the public health. Throughout FY 2025, FDA made significant progress in reducing this burden.

As a result of new product authorizations issued in FY 2025, CTP significantly increased the percentage of e-cigarette products on the U.S. market that are authorized by FDA. In addition, in FY 2025, CTP reduced the backlog of pending PMTAs by 50%, processing applications for over 300,000 products. Among the MGOs FDA issued in 2025, the Agency issued its first ever authorizations for nicotine pouch products.

The agency has taken innovative actions – from educating retailers about which products they can legally to sell[24] to conducting the largest-ever seizure of illegal tobacco products.[25] Such accomplishments in FY 2025 have had a positive impact on public health in the United States.

[24] https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-marty-makary-md-mph-encouraging-retailers-stop-selling-illegal-vapes

[25] https://www.fda.gov/news-events/press-announcements/hhs-cbp-seize-865-million-worth-illegal-e-cigarettes-largest-ever-operation

This report was prepared by FDA's Center for Tobacco Products. For information on obtaining additional copies, please contact:

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