Report to Congress

Tobacco Regulation Activities

FY 2024

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 2024.

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Acronym List

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)
HTP	Heated Tobacco Product
MRTPA	Modified Risk Tobacco Product Application
NTSO	No-Tobacco-Sale Order
ORA	Office of Regulatory Affairs
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.—
>
> Each report submitted under subsection (a) shall contain the following information for the previous fiscal year:

[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] https://www.cdc.gov/tobacco/about/index.html.

(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, no-tobacco sale orders, 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. Historically, FDA has collected 99.8 percent of the $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. FDA's FY 2025 budget request proposed an additional $114M in user fees to support e-cigarette regulatory activities; this request included $14.2M to adjust the currently authorized collections of $712M for inflation, an inflation adjustment for all future collections, and the authority to include manufacturers and importers of all deemed products among the tobacco product classes for which FDA assesses tobacco user fees. 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 2024. FDA's total annual tobacco user fee collections in FY 2024 were $711.9M, of which $690.6M was collected from FY 2024 tobacco invoices and $21.2M was collected from prior cohort tobacco invoices. FDA delayed issuing the fourth quarter of FY 2023 cigar invoices due to a court ruling on this ongoing litigation; this delay accounts for most of the prior cohort collections in FY 2024. The Agency is continuing to evaluate the evolving legal and practical implications of this ruling.

FDA's FY 2024 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 2024 was $697.3M. The carryover balance from FY 2024 to FY 2025 was $279.2M.[4]

[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). On January 24, 2025, the U.S. Court of Appeals for the District of Columbia Circuit affirmed the decision to exempt premium cigars from the Deeming Rule, and remanded to the lower court for "briefing on the appropriate definition of 'premium cigars'". *Cigar Ass'n of Am. v. FDA,* 132 F.4th 535 (D.C. Cir. 2025).

[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 2024 Obligations (in Millions)

FY 2024 Actual Obligations		
	Acquisitions	**Personnel/Operating**
Program Area		
Product Review, Scientific Research, and Research Infrastructure	$ 174.6	$ 110.2
Compliance and Enforcement	$ 76.5	$ 70.3
Public Education Campaigns	$ 85.0	$ 7.7
Communications	$ 7.2	$ 7.7
Leadership, Management Oversight, and Administrative	$ 8.2	$ 33.5
Related Overhead Activities	$ 85.8	$ 30.6
Total	**$ 437.3**	**$ 260.0**
Total Obligations: $697.3		

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 public health." 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. 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 Regulatory Affairs (ORA)[6]. 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 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

[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.

[6] ORA became the Office of Inspections and Investigations (OII) on October 1, 2024.

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[7] 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 products would be appropriate for the protection of the public health (APPH),[8] or

2. The Substantial Equivalence (SE) pathway, under which an applicant must show among other things, that the tobacco products are substantially equivalent[9] to a valid predicate tobacco product,[10] 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 a Modified Risk Tobacco Product Application (MRTPA) and receive an FDA order authorizing the marketing of the product.

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[7] 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.

[8] 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.

[9] 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.

[10] 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 appropriate for the protection of the public health; and (4) an EX REQ is otherwise appropriate.

Section 910

Under the PMTA pathway in section 910, manufacturers must demonstrate to FDA, among other things, that the marketing of the new tobacco product would be appropriate for the protection of the public health. This "appropriate for the protection of public health" 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 or is expected to 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.[11] For example, on June 26, 2024, FDA held a TPSAC meeting to discuss the renewal of a risk modification order submitted by Swedish Match USA, Inc., for General Snus tobacco products. The meeting also included discussion about the conceptualization and measurement of consumer understanding within the broader MRTP program. Additionally, FDA may choose to solicit advice from TPSAC for other applications, such as PMTAs.

C. Data on Product Applications

Information about FY 2024 product applications, broken down by application type and product class (including cigars, cigarettes, electronic nicotine delivery systems (ENDS), heated tobacco products (HTPs),[12] other tobacco products,[13] pipe tobacco, roll-your-own tobacco, smokeless tobacco products, and waterpipes/hookahs), is presented in Table 2.

[11] 21 U.S.C. 387k(f).

[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 2024 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	49	0	0	0
	Cigarette	140	3	0	0
	ENDS	10	0	3,591	0
	HTP	0	0	8	23
	Other	0	14	421	0
	Pipe	0	14	0	0
	Roll-Your-Own	8	8	0	0
	Smokeless	2	6	24	0
	Waterpipe/Hookah	114	4	0	0
Pending	Cigar	81	2,868	10	0
	Cigarette	783	480	0	0
	ENDS	6	0	473,764	0
	HTP	0	0	20	31
	Other	0	35	2,464	44
	Pipe	6	1,255	12	0
	Roll-Your-Own	4	245	0	0
	Smokeless	17	207	259	8
	Waterpipe/Hookah	500	840	0	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	27	2	0	0
	Cigarette	251	0	0	0
	ENDS	10	0	73,214	0
	HTP	0	0	8	23
	Other	0	0	242	0
	Pipe	0	0	0	0
	Roll-Your-Own	8	4	0	0
	Smokeless	1	4	41	0
	Waterpipe/Hookah	76	8	0	0
Refused to File*	Cigar	N/A	N/A	0	0
	Cigarette	N/A	N/A	0	0
	ENDS	N/A	N/A	6,088	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	6	7	0	0
	Cigarette	0	367	0	0
	ENDS	4	0	33	0
	HTP	0	0	2	1
	Other	0	0	0	0
	Pipe	0	4	0	0
	Roll-Your-Own	0	0	0	0
	Smokeless	0	19	0	0
	Waterpipe/Hookah	0	20	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	0	52	0	0
	Cigarette	33	0	0	0
	ENDS	0	0	62,844	0
	HTP	0	0	0	0
	Other	0	0	0	0
	Pipe	0	23	0	0
	Roll-Your-Own	0	0	0	0
	Smokeless	1	0	0	0
	Waterpipe/Hookah	1	13	0	0
Authorized for Marketing Order	Cigar	0	31	0	0
	Cigarette	53	3	0	0
	ENDS	0	0	11	0
	HTP	5	0	0	0
	Other	0	0	0	0
	Pipe	0	9	0	0
	Roll-Your-Own	4	6	0	0
	Smokeless	0	10	0	0
	Waterpipe/Hookah	0	22	0	0
Issued Deficiency Letter/ Environmental Information Request Letter	Cigar	0	169	0	0
	Cigarette	28	0	0	0
	ENDS	0	0	15	0
	HTP	0	0	0	0
	Other	0	0	0	0
	Pipe	0	0	0	0
	Roll-Your-Own	0	9	0	0
	Smokeless	0	0	0	8
	Waterpipe/Hookah	0	82	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 2024, FDA did not publish any guidance documents or regulations related to the process for the review of tobacco product applications. However, in FY 2024, FDA did publish other regulations and guidance that will help the Agency increase its efficiency and improve public health.

FDA proposed a rule[15] that would require importers of any ENDS to include the Submission Tracking Number for the product(s) in the Automated Commercial Environment, which is the imports system operated by the Customs and Border Protection. The proposed rule, if finalized, would result in a more effective and efficient import admissibility review process by lowering instances of manual review by FDA of entries containing ENDS products, which will protect the public health by conserving Agency resources and more quickly identifying ENDS products that do not have marketing authorization and that may be associated with a greater public health risk.

The Agency also published a final rule[16] increasing the minimum age for certain restrictions on tobacco sales. In December 2019, Congress passed legislation that immediately raised the federal minimum age of sale of tobacco products in the United States from 18 to 21 years of age. This final rule is in line with that legislation. The final rule changes the age for which photo identification is needed for purchase from 27 to 30 years of age. In addition, the final rule restricts the sale of tobacco products through vending machines to facilities where individuals under the age of 21, rather than 18, are present or permitted to enter at any time. The rule's requirements are expected to help decrease underage tobacco sales.

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/documents/2024/08/16/2024-18343/submission-of-food-and-drug-administration-import-data-in-the-automated-commercial-environment-for.

[16] https://www.federalregister.gov/documents/2024/08/30/2024-19481/prohibition-of-sale-of-tobacco-products-to-persons-younger-than-21-years-of-age.

V. Public Meetings

CTP held two public meetings during FY 2024: (1) a public meeting on October 23 and 24, 2023, about the application review process to improve public understanding of the review process and (2) a TPSAC meeting to discuss the renewal of a risk modification order submitted by Swedish Match USA, Inc., for General Snus and to discuss the conceptualization and measurement of consumer understanding within the broader MRTP program. These meetings are part of FDA's continued engagements with external stakeholders to better communicate on scientific issues and practices to support efficiency, effectiveness, and transparency.

Additionally, CTP staff regularly present at public health and industry conferences to provide information on the review process and answer questions. CTP staff have presented at meetings such as the Global Tobacco and Nicotine Forum, Tobacco Science Research Conference, Cooperation Centre for Scientific Research Relative to Tobacco Congress, Food and Drug Law Institute Annual Conference, and the Tobacco Merchants Association Annual Meeting. The 28 meetings and conferences in which CTP staff presented on product review during FY 2024 are listed in Table 4.

CTP's Office of Stakeholder Relations also hosted multiple meetings in FY 2024, including with the Cigar Rights of America and the Tennessee Advisory Commission on Intergovernmental Relations.

In FY 2024, CTP leadership publicly presented updates on the Agency's tobacco work, including its review of product applications and transparency about the process, during stakeholder conferences.

Table 4. CTP's Presentations on the Review of Tobacco Product Applications at Conferences/Meetings During FY 2024

Conference/Meeting Name	Date
Fall 2023 Tobacco Regulatory Science Meeting	10/16/2023
American Academy of Pediatrics National Conference	10/20/2023
Parents Against Vaping E-Cigarettes Clear the Vapor Conference	10/24/2023
National Association of Attorneys General – Annual Tobacco Issues Seminar	10/24/2023
Food and Drug Law Institute: Tobacco and Nicotine Products Regulation and Policy Conference	10/26/2023
National Association of Tobacco Outlets Year End Summit	11/16/2023
Centers for Disease Control and Prevention Office on Smoking and Health National Partner Exchange Webinar	12/11/2023

Conference/Meeting Name	Date
Substance Abuse and Mental Health Services Administration's (SAMHSA) 20th Prevention Day	1/29/2024
E-Vapor and Tobacco Law Symposium	1/29/2024
National Association of State Alcohol and Drug Agency Directors National Prevention Network Webinar	2/14/2024
Convenience Distribution Association 2024 Marketplace Event	2/27/2024
Society for Research on Nicotine and Tobacco Annual Meeting	3/30/2024
American Association for Cancer Research Annual Meeting	4/8/2024
National Association of Attorneys General Meeting	4/10/2024
National Council of Mental Wellbeing 2024	4/15/2024
Tobacco Merchant Association Annual Meeting	4/22/2024
The Behavioral Science & Policy Association Annual Conference	5/2/2024
Delaware Tobacco Prevention Conference	5/8/2024
The E-Cigarette Summit	5/14/2024
Annual Meeting of the Global Tobacco Regulators Forum	5/15/2024
Food and Drug Law Institute Annual Conference	5/15/2024
National Association of Tobacco Outlets and the Energy Marketers of America Meeting	5/15/2024
American Thoracic Society International Conference	5/19-20/2024
SAMHSA Center for Substance Abuse and Treatment Youth and Family Substance Use Conference	7/23/2024
Tobacco Science Research Conference	9/8/2024
North American Quitline Consortium Webinar	9/11/2024
Convenience Store Products Forum	9/13/2024
Global Tobacco and Nicotine Conference	9/24-26/2024

VI. Pre-Submission Meetings

Tobacco manufacturers, importers, researchers, and/or investigators may seek meetings[17] 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 2024, CTP received eight pre-submission meeting requests for premarket applications, including PMTAs. There was an average of approximately 29 days between FDA's receipt of the meeting request and FDA's granting or denial of the request. FDA granted four meeting requests and denied four meeting requests. The denials were for providing incomplete information to determine the utility of the meeting (e.g., a lack of questions for FDA response), proposing questions that were addressed by publicly available information,[18] and proposing meeting scope and questions that duplicated efforts by staff (e.g., would be addressed during review).

[17] 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.

[18] In these cases, FDA pointed the requestor to the publicly available information.

VII. Full-Time Equivalent Employees

CTP ended FY 2024 with 1,195 employees onboard. In addition, approximately 241 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 2024, OII, ORA at the time, had about 19 full-time equivalent inspectors dedicated to CTP's tobacco manufacturing inspections.

Table 5. CTP's FY 2024 Onboard Staff

Office	Onboard Staff (as of 9/30/24)
Office of the Center Director	32
Office of Regulations	26
Office of Management	108
Office of Compliance and Enforcement	305
Office of Science	648
Office of Health Communication and Education	76
CTP-Wide	**1195**

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 2024, FDA conducted inspections and/or investigations of more than 930 brick-and-mortar tobacco product manufacturers, with approximately 590 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 civil money penalty (CMP) complaints,
    - Issuing no-tobacco-sale order (NTSO) complaints, 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 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.

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 2024, FDA inspected over 117,000 brick-and-mortar tobacco retailers, issuing more than 12,600 warning letters and approximately 4,400 CMP actions for violations of the retail underage access restrictions under section 906(d). FDA also issued 12 NTSOs. Results from compliance check inspections of tobacco retailers are available in the Tobacco Compliance Check Outcomes database[19] on FDA's website. In FY 2024, FDA also issued approximately 145 warning letters and over 115 complaints for CMPs

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

against brick-and-mortar tobacco retailers for violations involving the sale of unauthorized tobacco products, seeking a penalty of more than $20,000 against each retailer.

Further, in FY 2024, FDA issued over 60 warning letters to online retailers as a result of online surveillance activities and over 25 CMP complaints related to online retailers selling unauthorized tobacco products. These CMP complaints sought over $20,000 from each online retailer. These actions are also available in the Tobacco Compliance Check Outcomes database.

Additionally, in FY 2024, as noted in the previous section, FDA inspected more than 840 brick-and-mortar tobacco product manufacturers and conducted online surveillance of over 800 manufacturer-owned websites, issuing more than 85 warning letters resulting from these activities. FDA also filed CMP complaints against 44 manufacturers for manufacturing and selling tobacco products without marketing authorizations. Moreover, the U.S. Department of Justice, on behalf of FDA, filed complaints for permanent injunctions in federal district courts against two e-cigarette manufacturers.

FDA also collaborated with its federal partners on five[20] tobacco product seizure operations in FY 2024, involving over $75M in Chinese e-cigarette products headed for the U.S. distribution chain, many of which were the subject of warning letters issued by the Agency.

In FY 2024, FDA's Office of Criminal Investigations conducted criminal investigations into illegal activities involving FDA-regulated tobacco products, which resulted in successful criminal prosecutions and convictions.

[20] Operations are often not announced in the FY in which they occur; therefore, there are three announcements for the five seizure operations, available at (1) https://www.fda.gov/tobacco-products/ctp-newsroom/fda-doj-seize-over-700000-worth-unauthorized-e-cigarettes, (2) https://www.fda.gov/tobacco-products/ctp-newsroom/fda-cbp-seize-more-1m-worth-unauthorized-e-cigarettes, and (3) https://www.fda.gov/news-events/press-announcements/76-million-illegal-e-cigarettes-seized-joint-federal-operation.

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. FDA's efforts have contributed to reducing adult cigarette smoking rates in the United States. Specifically, adult cigarette smoking rates have declined from 20.6 percent in 2009[21] when CTP was founded, to 11.0 percent in 2023.[22]

Youth use of tobacco products has also decreased. Over the past 5 years, the United States has seen a nearly 70-percent decline[23] in the number of middle and high school students using e-cigarettes, including 500,000 fewer students in 2024 compared to 2023 alone. Current (past 30-day) use of any tobacco product among middle and high school students decreased from 2.80 million in 2023[24] to approximately 2.25 million in 2024.[25] FDA's significant accomplishments in FY 2024 contributed to that decline, and its tobacco regulatory actions have had a positive impact on public health in the United States.

[21] https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5935a3.htm?s_cid=mm5935a3_w.

[22] https://odphp.health.gov/healthypeople/objectives-and-data/browse-objectives/tobacco-use/reduce-current-cigarette-smoking-adults-tu-02.

[23] https://www.fda.gov/tobacco-products/ctp-newsroom/year-review-fdas-progress-tobacco-product-regulation-2024; https://www.fda.gov/tobacco-products/youth-and-tobacco/results-annual-national-youth-tobacco-survey, https://www.cdc.gov/mmwr/volumes/73/wr/mm7335a3.htm?s_cid=mm7335a3_w and https://www.cdc.gov/mmwr/volumes/68/ss/ss6812a1.htm?s_cid=ss6812a1_w. In 2019, e-cigarettes were the most commonly cited tobacco product currently used by 27.5% of high school students and 10.5% of middle school students, with 5.3 million students currently using e-cigarettes. In 2024, 7.8% of high school students and 3.5% of middle school students reported current e-cigarette use (an estimated 1.63 million students).

[24] https://www.cdc.gov/mmwr/volumes/72/wr/mm7244a1.htm.

[25] https://www.fda.gov/tobacco-products/youth-and-tobacco/results-annual-national-youth-tobacco-survey.

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