Report to Congress

Tobacco Regulation Activities

FY 2023

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 2023.

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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 use is the leading preventable cause of disease, disability, and death in the United States. Each year, an estimated 480,000 Americans die prematurely from smoking or from exposure to second-hand smoke. More than 16 million people in the United States live with a serious illness caused by smoking.[1]

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 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) Total annual user fee collections.
>
> (2) Total amount of fees obligated.

[1] https://www.cdc.gov/tobacco/data_statistics/index.htm

(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; and/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,[2] and these fees are authorized by Congress to remain available until expended. FDA's total annual tobacco user fee collections in fiscal year (FY) 2023 were $687.4M. FDA historically collects 99.8 percent of the authorized and appropriated amount of $712M. Due to the recent premium cigar court ruling,[3] the cigar invoices from the fourth quarter of FY 2023 were delayed, thereby impacting the collection amount. In addition, the funding associated with premium cigars was not received, resulting in a decrease in overall collections. The Agency is continuing to evaluate the evolving legal and practical implications of this ruling.

FDA's FY 2023 tobacco-related obligations (in millions), which are listed by the applicable program area of FDA's Center for Tobacco Products (CTP), are included in Table 1 below. The total tobacco user fees obligated in FY 2023 was $723.3M. The carryover balance from FY 2023 to FY 2024 was $221.8M.[4]

[2] The FD&C Act authorizes FDA to assess and collect tobacco user fees from domestic manufacturers and importers of six classes of products: cigarettes, cigars, snuff, chewing tobacco, pipe tobacco, and roll-your-own tobacco. FDA's FY 2025 budget request proposes an additional $100M in user fees to support e-cigarette regulatory activities; and requests 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 Center's portfolio. Therefore, FDA has had to spend a significant portion of user fees collected from other product classes to regulate e-cigarettes. FDA's FY 2025 budget request also proposes an increase of $14.2M to adjust the currently authorized collections of $712M to inflation.

[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 means premium cigars are not subject to the requirements of Chapter IX of the Federal Food, Drug, and Cosmetic 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). FDA has appealed this decision. For purposes of this ruling, premium cigars are those cigars that: (1) are wrapped in whole tobacco leaf; (2) contain a 100 percent leaf tobacco binder; (3) contain at least 50 percent (of the filler by weight) long filler tobacco; (4) are handmade or hand rolled; (5) have no filter, nontobacco tip, or nontobacco mouthpiece; (6) do not have a characterizing flavor other than tobacco; (7) contain only tobacco, water, and vegetable gum with no other ingredients or additives; and (8) weigh more than 6 pounds per 1,000 units. *See Id.*

[4] The carryover exists due to tobacco industry user fees being collected at the end of each quarter; therefore, most of the fourth quarter collections are not available for obligation until the first quarter of the following fiscal year. This carryover balance can vary from year to year based on when user fee payments are received from industry. Contract obligations are sometimes delayed until the next fiscal year due to protests or difficulty awarding. This delay would be reflected in the carryover balance.

Table 1. CTP's FY 2023 Obligations (in Millions).

	FY 2023 Actual Obligations	
	Acquisitions	**Personnel/ Operating**
Program Area		
Scientific Research and Research Infrastructure	$ 206.8	$ 98.2
Compliance and Enforcement	$ 75.8	$ 58.1
Public Education Campaigns	$ 107.5	$ 7.6
Communications	$ 9.2	$ 7.6
Leadership, Management Oversight, and Administrative	$ 6.8	$ 31.5
Related Overhead Activities	$ 85.1	$ 29.1
Total	**$ 491.2**	**$ 232.1**
	Total Obligations: $723.3	

A. Scientific Research and Research Infrastructure

FDA's scientific research of tobacco products informs its efforts to achieve the goals of (1) tobacco prevention and cessation and (2) reducing the harms of tobacco products . The Scientific Research and Research Infrastructure program area includes the premarket review of new tobacco products and the review of modified risk tobacco product applications. For additional information about FDA's tobacco research efforts, please see https://www.fda.gov/tobacco-products/tobacco-science-research. 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.

B. Compliance and Enforcement

FDA has implemented a 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). 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 public education campaigns work in concert with its regulatory actions to reduce tobacco use and improve public health. For additional information about FDA's tobacco-specific public health education campaigns, please see https://www.fda.gov/tobacco-products/public-health-education/public-health-education-campaigns.

D. Communications

FDA creates campaign-specific websites on which target audiences can seek additional information about the harms of tobacco product use and find connections to resources for quitting. For an example of information that FDA provides about the harms 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. For more information about CTP's leadership, please see https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/ctp-leadership.

[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.

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. New tobacco products are required to demonstrate the following to receive FDA authorization before marketing:

- that permitting the marketing of the tobacco products would be appropriate for the protection of the public health,[7] or
- that they are substantially equivalent[8] to a valid predicate tobacco product,[9] or
- that they are exempt from the requirements of substantial equivalence (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.

A. FDA's Tobacco Review Pathways

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

[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.

Section 905

Under the SE pathway in section 905, manufacturers must submit SE reports to FDA to seek authorization to legally market a new tobacco product. 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 may either be 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 exemption from SE request (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 exemption is otherwise appropriate.

Section 910

Under the Pre-Market Tobacco Application (PMTA) pathway in section 910, manufacturers must demonstrate to FDA 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.[10] Additionally, FDA may choose to solicit advice from TPSAC for other applications, such as PMTAs. In FY 2023, TPSAC did not provide advice on any tobacco product applications that were submitted to FDA for review.

C. Data on Product Applications

Information about FY 2023 product applications, broken down by application type and product class (including cigars, cigarettes, electronic nicotine delivery systems (ENDS), heated tobacco products (HTPs),[11] other tobacco products,[12] 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] 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.

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

Table 2. FY 2023 Data for Product Applications (by Application Type and Product Class).

Application Status	Product Class	Application Types			
		Section 905 Exemption Requests	Section 905 SE Reports	Section 910 PMTAs	Section 911 MRTPAs
Submitted/ Received	Cigar	16	7	0	0
	Cigarette	875	46	0	0
	ENDS	0	0	14,415	0
	HTP	5	0	0	7
	Other	0	0	72	0
	Pipe	0	0	0	0
	Roll-Your-Own	17	27	0	0
	Smokeless	13	38	73	8
	Waterpipe/Hookah	153	55	0	0
Pending	Cigar	54	2,971	10	0
	Cigarette	606	787	0	0
	ENDS	0	0	559,652	0
	HTP	5	0	14	11
	Other	0	13	1,968	0
	Pipe	6	1,277	12	0
	Roll-Your-Own	0	284	0	0
	Smokeless	16	232	238	8
	Waterpipe/Hookah	387	938	0	0
Accepted	Cigar	15	0	0	0
	Cigarette	892	0	0	0
	ENDS	0	0	72,006	0
	HTP	5	0	10	7
	Other	0	0	536	0
	Pipe	0	0	0	0
	Roll-Your-Own	17	0	0	0
	Smokeless	13	0	13	8
	Waterpipe/Hookah	142	132	0	0

		Section 905 Exemption Requests	Section 905 SE Reports	Section 910 PMTAs	Section 911 MRTPAs
Refused to File*	Cigar	0	0	0	0
	Cigarette	0	0	0	0
	ENDS	0	0	50,448	0
	HTP	0	0	0	0
	Other	0	0	0	0
	Pipe	0	0	0	0
	Roll-Your-Own	0	0	0	0
	Smokeless	0	0	0	0
	Waterpipe/Hookah	0	0	0	0
Withdrawn	Cigar	0	0	0	0
	Cigarette	0	32	0	0
	ENDS	0	0	12	0
	HTP	0	0	0	0
	Other	0	36	0	0
	Pipe	0	0	0	0
	Roll-Your-Own	0	4	0	0
	Smokeless	1	11	0	6
	Waterpipe/Hookah	0	0	0	0
Denied	Cigar	38	21	0	0
	Cigarette	56	14	0	0
	ENDS	0	0	5,896	0
	HTP	0	0	0	0
	Other	0	0	0	0
	Pipe	0	0	0	0
	Roll-Your-Own	0	0	0	0
	Smokeless	1	0	0	0
	Waterpipe/Hookah	263	0	0	0

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

		Section 905 Exemption Requests	Section 905 SE Reports	Section 910 PMTAs	Section 911 MRTPAs
Authorized for Marketing Order	Cigar	41	21	0	0
	Cigarette	637	16	0	0
	ENDS	0	0	0	0
	HTP	0	0	3	0
	Other	0	0	0	0
	Pipe	0	5	0	0
	Roll-Your-Own	17	6	0	0
	Smokeless	2	12	0	1
	Waterpipe/Hookah	21	37	0	0
Issued Deficiency Letter/ Environmental Information Request Letter	Cigar	0	190	0	0
	Cigarette	638	0	0	0
	ENDS	0	0	70	0
	HTP	0	0	0	0
	Other	0	0	0	0
	Pipe	0	63	0	0
	Roll-Your-Own	17	24	0	0
	Smokeless	2	8	0	0
	Waterpipe/Hookah	115	46	0	0

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

FDA develops regulations based on 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.

Per this report mandate, Table 3 lists the two FY 2023 guidance documents and regulations related to the process for 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.

Table 3. FY 2023 Guidance Documents and Regulations Related to the Process for the Review of Tobacco Product Applications.

Date of Publication	Name of Document	Type of Document
March 17, 2023	Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (Revised)	Guidance (Final)
March 20, 2023	Definition of the Term "Tobacco Product" in Regulations Issued Under the Federal Food, Drug, and Cosmetic Act	Technical Amendment (Final)

The final guidance document and technical amendment listed in Table 3 were both issued in response to the Consolidated Appropriations Act of 2022 (Public Law 117-103) which did not require any publication deadlines.

V. Public Meetings

CTP held three public meetings during FY 2023: (1) a TPSAC meeting that discussed tobacco product manufacturing processes, (2) an oral hearing that gathered additional comments from the public on proposed new requirements for tobacco product manufacturing practices, and (3) a listening session that helped inform the development of CTP's 5-year strategic plan.

FDA personnel often speak at conferences and public health or industry meetings. In FY 2023, CTP leadership presented updates on the Agency's tobacco work, including its review of product applications, at least 14 times.

Table 4. CTP's Presentations on the Review of Tobacco Product Applications at Conferences/Meetings During FY 2023.

Conferences/Meeting	Date
Centre for Scientific Research Relative to Tobacco Symposium	10/21/2022
ENDS U.S. Conference	10/26/2022
Society for Research on Nicotine and Tobacco (SRNT) Annual Meeting	3/1/2023
Food and Drug Law Institute Symposium	3/30/2023
American Association for Cancer Research Annual Meeting	4/17/2023
Tobacco Merchants Association	4/19/2023
E-Cigarette Summit	5/16/2023
Food and Drug Law Institute Annual Conference	5/18/2023
MaineHealth Center for Tobacco Independence Annual Tobacco Treatment and Prevention Conference	6/7/2023
World Health Organization (WHO) Global Consultation on Novel and Emerging Nicotine and Tobacco Products	6/21/2023
Next Generation Nicotine Delivery Conference	6/28/2023
2nd Global Tobacco Control Policy Forum	9/20/2023
Global Tobacco and Nicotine Forum	9/21/2023
Tobacco Science Research Conference	9/25/2023

VI. Pre-Submission Meetings

Tobacco manufacturers, importers, researchers, and/or investigators may seek meetings[13] 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. FDA may also determine that a written response is unnecessary or inappropriate for reasons such as the following: the requestor did 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.

During FY 2023, CTP received nine pre-submission meeting requests for premarket applications, including PMTAs. There was an average of approximately 16 days between FDA's receipt of the meeting request and FDA's grant or denial of the request. FDA granted five meeting requests and denied four meeting requests.

[13] 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 2023 with 1,101 employees onboard. In addition, approximately 214 full-time equivalents within FDA, but outside of CTP, also support tobacco product regulation. These employees are located primarily in ORA, 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 ORA to perform inspections and other regulatory work. In FY 2023, ORA had about 15 full-time equivalent inspectors dedicated to CTP's tobacco manufacturing inspections.

Table 5. CTP's FY 2023 Onboard Staff.

Office	Onboard Staff (as of 9/30/23)
Office of the Center Director	28
Office of Regulations	29
Office of Management	111
Office of Compliance and Enforcement	286
Office of Science	570
Office of Health Communication and Education	77
CTP-Wide	**1,101**

VIII. Inspections and Investigations

Section 905 of the FD&C Act requires owners and operators of establishments in any U.S. state or territory (or 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 2023, FDA conducted inspections and/or investigations of more than 800 brick-and-mortar tobacco product manufacturers, with approximately 500 of those being vape shops. FDA also conducted online surveillance of over 800 manufacturer-owned websites to determine compliance.

IX. Compliance and Enforcement Actions

FDA closely monitors retailer, manufacturer, importer, and distributor compliance with federal tobacco laws and regulations and may take action when violations occur.

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

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 2023, FDA inspected over 108,000 brick-and-mortar tobacco retailers, issuing more than 14,200 warning letters and 3,800 CMP actions for violations of the retail underage access restrictions under section 906(d). FDA, for the first time, also issued complaints for CMPs against 22 tobacco retailers for violations involving the sale of unauthorized tobacco products, seeking a $19,192 penalty amount against each retailer. FDA issued seven NTSOs in FY 2023. Results from compliance check

inspections of tobacco retailers are available in a searchable retailer inspection database[14] on FDA's website.

Further, in FY 2023, FDA issued over 70 warning letters to online retailers as a result of online surveillance activities and three CMP complaints related to online retailers selling unauthorized tobacco products. These CMP complaints sought $19,192 from each online retailer.

Additionally, in FY 2023, as noted in the previous section, FDA inspected more than 800 brick-and-mortar tobacco product manufacturers and conducted online surveillance of over 800 manufacturer-owned websites, issuing more than 160 warning letters. FDA also filed CMP complaints against 32 manufacturers for manufacturing and selling e-liquids without marketing authorizations. Moreover, the U.S. Department of Justice, on behalf of FDA, filed complaints for permanent injunctions in federal district courts against six e-cigarette manufacturers.

In FY 2023, FDA's Office of Criminal Investigations conducted criminal investigations into illegal activities involving FDA-regulated tobacco products and which resulted in successful criminal prosecutions and convictions.

[14] This database is available at https://www.accessdata.fda.gov/scripts/oce/inspections/oce_insp_searching.cfm.

X. Conclusion

Given the substantial impact tobacco use has on the country's health, FDA's regulation of tobacco products remains vital for protecting the public from the harmful effects of tobacco use.

FDA had many significant accomplishments in FY 2023 that demonstrate the positive impact of its tobacco regulatory actions on public health.

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

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