Report to Congress

Tobacco Regulation Activities

FY 2022

Submitted Pursuant to Public Law 117-103

Executive Summary

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) 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, enacted in 2009, 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 2022.

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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
FDLI	Food and Drug Law Institute
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
TMA	Tobacco Manufacturers Association
TPSAC	Tobacco Products Scientific Advisory Committee

I. Background

Tobacco use is the single most 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.

In particular, 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/fact_sheets/fast_facts/diseases-and-death.html.

(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 fully 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) 2022 was $713.4M; this amount is over the authorized and appropriated amount of $712.0M in FY 2022 because of late payments of user fees assessed in previous fiscal years. The total tobacco user fees obligated to FDA by Congress in FY 2022 was $774.5M. The carryover balance from FY 2022 to FY 2023 was $221.2M.[3]

FDA's FY 2022 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.

Table 1. CTP's FY 2022 Obligations (in Millions).

	FY 2022 Actual Obligations	
	Acquisitions	**Personnel/ Operating**
Program Area		
Scientific Research and Research Infrastructure	$ 207.6	$ 91.1
Compliance and Enforcement	$ 80.8	$ 60.6
Public Education Campaigns	$ 164.0	$ 7.3
Communications	$ 9.0	$ 7.3

[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 FY24 budget request proposes an additional $100 million 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.

[3] 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.

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. As such, there will always be a carryover balance equal to at least the fourth quarter projected collections, which is currently $178M.

Leadership, Management Oversight, and Administrative	$ 8.1	$ 31.1
Related Overhead Activities	$ 76.5	$ 31.1
Total	**$ 546.0**	**$ 228.5**
	Total Obligations: $774.5	

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) tobacco harm reduction. This research 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.[4] As part of FDA's compliance and enforcement program, the Agency closely monitors tobacco product manufacturers and retailers to ensure compliance, including through tobacco operations (e.g., 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/ctp-compliance-enforcement.

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.

[4] 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#:~:text=Consistent%20with%20the%20requirements%20of,marketing%2C%20labeling%2C%20and%20advertising.

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 additional information about the harms of tobacco product use, please see https://www.fda.gov/tobacco-products/public-health-education/health-effects-tobacco-use. For additional information 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.

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 as a critical public health gatekeeper between tobacco product manufacturers and consumers by performing a scientific review of new tobacco products[5] before they are commercially marketed and sold. 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,[6] or
- that they are substantially equivalent[7] to a valid predicate tobacco product,[8] 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.

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[5] 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.

[6] The finding of whether the marketing of a tobacco product for which an application has been submitted 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.

[7] 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.

[8] 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.

Section 905

Under the SE pathway in section 905, manufacturers must submit SE reports to FDA to seek its 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 (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 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. Any application submitted as a MRTPA is reviewed by TPSAC. Additionally, other applications, such as PMTAs, can be reviewed by TPSAC when FDA is soliciting advice on a particular topic. In FY 2022, no application in any tobacco class was submitted for review by TPSAC.

C. Data on Product Applications

Information about FY 2022 product applications, broken down by application type and product class (including cigars, cigarettes, electronic nicotine delivery systems (ENDS), heated tobacco products (HTPs),[9] other tobacco products,[10] pipe tobacco, roll-your-own tobacco, smokeless tobacco products, and waterpipes/hookahs), is presented in Table 2.

[9] 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.

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

Table 2. FY 2022 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	27	166	0	0
	Cigarette	184	281	0	0
	ENDS	0	0	955,073	0
	HTP	0	0	8	0
	Other	0	49	947	0
	Pipe	6	2	0	0
	Roll-Your-Own	0	129	0	0
	Smokeless	3	38	3	0
	Waterpipe/Hookah	282	73	0	0
Pending	Cigar	139	2,976	10	0
	Cigarette	408	756	0	3
	ENDS	0	0	338,915	0
	HTP	0	0	13	0
	Other	0	55	1,150	0
	Pipe	6	1,282	12	0
	Roll-Your-Own	0	263	0	0
	Smokeless	7	208	3	7
	Waterpipe/Hookah	535	920	0	0

		Section 905 Exemption Requests	Section 905 SE Reports	Section 910 PMTAs	Section 911 MRTPAs
Accepted	Cigar	77	52	0	0
	Cigarette	369	20	0	0
	ENDS	0	0	56,736	0
	HTP	0	0	0	0
	Other	0	0	40	0
	Pipe	6	1	0	0
	Roll-Your-Own	0	11	0	0
	Smokeless	4	17	0	0
	Waterpipe/Hookah	298	132	0	0
Refused to File	Cigar	N/A*	N/A	0	0
	Cigarette	N/A	N/A	0	0
	ENDS	N/A	N/A	20,339	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	19	49	0	0
	Cigarette	53	71	0	0
	ENDS	0	0	1,820	0
	HTP	0	2	0	0
	Other	0	0	0	0
	Pipe	0	12	0	0
	Roll-Your-Own	0	3	0	0
	Smokeless	0	1	0	0
	Waterpipe/Hookah	1	1	0	0

* The Tobacco Control Act allows for “refuse to file” actions only under PMTA and MRTPA pathways.

		Section 905 Exemption Requests	Section 905 SE Reports	Section 910 PMTAs	Section 911 MRTPAs
Denied	Cigar	0	21	0	0
	Cigarette	0	0	0	0
	ENDS	0	0	30,133	0
	HTP	0	0	0	0
	Other	0	0	0	0
	Pipe	0	15	0	0
	Roll-Your-Own	0	0	0	0
	Smokeless	0	1	0	0
	Waterpipe/Hookah	0	15	0	0
Authorized for Marketing Order	Cigar	31	25	0	0
	Cigarette	40	10	0	3*
	ENDS	0	0	23	0
	HTP	0	0	0	0
	Other	0	0	4	0
	Pipe	0	100	0	0
	Roll-Your-Own	2	7	0	0
	Smokeless	0	1	0	0
	Waterpipe/Hookah	3	1	0	0
Issued Deficiency Letter/ Environmental Information Request Letter	Cigar	8	83	0	0
	Cigarette	0	10	0	0
	ENDS	0	0	0	0
	HTP	0	0	0	0
	Other	0	0	0	0
	Pipe	0	54	0	0
	Roll-Your-Own	0	0	0	0
	Smokeless	0	0	0	0
	Waterpipe/Hookah	15	15	0	0

* Due to reporting limitations at the time, one authorized MRTPA cigarette is listed as an HTP.

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 FY 2022 guidance documents and regulations related to the process for the review of tobacco product applications. Please note that the table does not provide an exhaustive list of guidances and regulations published in FY 2022. Instead, 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 2022 Guidance Documents and Regulations Related to the Process for the Review of Tobacco Product Applications.

Date of Publication	Name of Document	Type of Document
October 5, 2021	Content and Format of Substantial Equivalence Reports; Food and Drug Administration Actions on Substantial Equivalence Reports	Final Rule
October 5, 2021	Premarket Tobacco Product Applications and Recordkeeping Requirements	Final Rule
December 21, 2021	Validation and Verification of Analytical Testing Methods used for Tobacco Products; Draft Guidance for Industry; Availability; Request for Comments	Draft Guidance
August 23, 2022	Tobacco Products: Principles for Designing and Conducting Tobacco Product Perception and Intention Studies; Guidance for Industry; Availability	Final Guidance

September 7, 2022	Meetings with Industry and Investigators on the Research and Development of Tobacco Products (Revised)	Revised Final Guidance

None of the regulation or guidance documents listed in Table 3 were required to be produced by statute or by other legal or regulatory requirements and did not have a deadline set forth by an applicable statute or other requirement.

V. Public Meetings

CTP held three public meetings during FY 2022: two related to the proposed menthol and cigar product standards and one related to the development and testing of warnings for tobacco products. Of note, while not during FY 2022, FDA held a public meeting in June 2021 on its scientific review of applications.

FDA personnel often speak at conferences and public health or industry meetings. In FY 2022, CTP leadership presented updates on the Agency's tobacco work, including its review of product applications, at least 12 times. Additionally, personnel from CTP's Office of Science presented specifically on application review at least twice in FY 2022.

Table 4. CTP's Presentations on the Review of Tobacco Product Applications at Conferences/Meetings During FY 2022.

Conferences/Meeting	Date
National Institutes of Health Tobacco Regulatory Science Meeting	10/19/21
Food and Drug Law Institute (FDLI) Tobacco and Nicotine Products Regulation and Policy Conference*	10/27/21
Tobacco Manufacturers Association (TMA) Digital Conference	11/16/21
National Association of Tobacco Outlets	12/2/21
Centers for Disease Control and Prevention Monthly National Tobacco Control Program Webinar	12/9/21
Society for Research on Nicotine and Tobacco Conference	3/15/22
TMA Annual Meeting and Conference	3/29/22
E-Cigarette Summit	5/17/22
American Thoracic Society International Conference	5/18/22
ENDS Europe Conference**	5/24/22
FDLI Annual Conference	6/15/22
National Conference on Tobacco or Health	6/30/22
Global Tobacco and Nicotine Forum Annual Conference	9/28/22

* CTP personnel presented updates on the Agency's work, as well as the presentation "Pre-Market Tobacco Applications: Recent Decisions and Surveying the Post-Deadline Landscape."

** CTP personnel gave a "Standards and FDA Scientific Review" presentation.

VI. Pre-Submission Meetings

Tobacco manufacturers, importers, researchers, and/or investigators may seek meetings[11] 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 2022, CTP received 14 pre-submission meeting requests for PMTAs. FDA responded in writing to nine of these requests and denied five requests. There was a median of 20.5 days between FDA's receipt of the meeting request and FDA's granting or denial of the request.

[11] For more information on these meetings, see the guidance 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 2022 with 1,063 positions onboard. Approximately 228 full-time equivalents 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 2022, ORA had 14.5 full-time equivalent inspectors dedicated to CTP's tobacco manufacturing inspections.

Table 5. CTP's FY 2022 Onboarded Staff.

Office	Onboarded Staff (as of 9/25/22)
Office of the Center Director	32
Office of Regulations	27
Office of Management	107
Office of Compliance and Enforcement	271
Office of Science	544
Office of Health Communication and Education	82
CTP-Wide	**1063**

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 determines 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 2022, FDA conducted inspections and/or investigations of more than 1,130 brick-and-mortar tobacco product manufacturers, with approximately 790 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, including by:

- Developing and providing compliance training and education,
- Monitoring regulated industry's compliance with the law through surveillance, inspections, and investigations, and
- 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 especially 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 brick-and-mortar inspections and/or online surveillance of sales, distribution, marketing, labeling, and/or advertising activities. Warning letters provide a notice and summary of the violations of the law and explain how the regulated firms can come into compliance before FDA initiates enforcement actions. A majority of 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 CMP in amounts adjusted for inflation in accordance with the schedule published in the Tobacco Control Act and implementing regulations. 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 2022, FDA inspected over 93,000 brick-and-mortar tobacco retailers, issuing more than 16,600 warning letters and 1,280 CMP actions. Additionally, in FY 2022, as noted in the previous section, FDA inspected more than 1,130 brick-and-mortar tobacco product manufacturers and conducted online surveillance of over 800 manufacturer-owned websites, issuing more than 325 warning letters.

FDA did not issue any NTSOs in FY 2022.

Results from compliance check inspections of tobacco retailers are available in a searchable retailer inspection database[12] on FDA's website.

[12] 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 a vital step in protecting the public from the harmful effects of tobacco use.

FDA had many significant accomplishments in FY 2022 that demonstrate the positive impact of 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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