Report to Congress

Progress and Effectiveness of the Implementation of the Family Smoking Prevention and Tobacco Control Act

2022-2023

Executive Summary

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act or 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. The Tobacco Control Act, enacted in 2009, directed FDA to establish the Center for Tobacco Products (CTP) to implement this law.

This report, which satisfies the requirements of section 106(a) of the Tobacco Control Act, provides an assessment of FDA's efforts—from January 1, 2022, to December 31, 2023—to implement that Act. During this time frame, FDA had several significant accomplishments related to its implementation of the Act, including the following:

- Publishing a strategic plan to further reduce the negative health effects of tobacco product use by defining five goals, 10 outcomes, and several corresponding objectives after assessing the current vision and mission statements and engaging with staff and external stakeholders;
- Authorizing the marketing of 23 e-cigarette products and devices following extensive scientific review and determining, among other things, that the benefits to adults outweighed the risks to youth;
- Issuing over 29,000 warning letters to retail establishments in which violations were found during compliance check inspections;
- Issuing civil monetary penalty complaints against 22 retailers for the sale of unauthorized electronic nicotine delivery system products;
- Collaborating with U.S. Customs and Border Protection to seize approximately 1.4 million units of unauthorized e-cigarette products with a total value of more than $18 million;
- Filing, through the U.S. Department of Justice (DOJ), the first of their kind, permanent injunctions against a total of seven e-cigarette manufacturers;
- Publishing a proposed rule to establish tobacco product manufacturing practice requirements for the manufacture, preproduction, design validation, packing, and storing of finished and bulk tobacco products;
- Publishing two proposed product standard rules – one that would prohibit menthol as a characterizing flavor in cigarettes and the other that would prohibit all characterizing flavors (other than tobacco) in cigars;
- Launching two new ads as part of "The Real Cost" campaign communicating scientific facts about cigarette smoking and;
- Launching the "Next Legends" campaign that aims to educate American Indian/Alaska Native youth about the harms of e-cigarette use by youth.

This report describes the growth, development, and accomplishments of FDA in implementing the Tobacco Control Act, as well as the progress of CTP's programs and initiatives during the reporting period.

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Acronym List

AI/AN	American Indian and Alaska Native
APPH	Appropriate for the Protection of the Public Health
CBP	U.S. Customs and Border Protection
CDC	Centers for Disease Control and Prevention
CMP	Civil Money Penalty
CTP	Center for Tobacco Products
ENDS	Electronic Nicotine Delivery Systems
EX REQ	Exemption from Substantial Equivalence Request
FD&C Act	The Federal Food, Drug, and Cosmetic Act
FDA	Food and Drug Administration
FY	Fiscal year (October 1 to September 30)
LGBTQI+	Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex
MDO	Marketing Denial Order
MGO	Marketing Granted Order
MRGO	Modified Risk Granted Order
MRTP	Modified Risk Tobacco Product
MRTPA	Modified Risk Tobacco Product Application
NCI	National Cancer Institute
NIH	National Institutes of Health
NSE	Not Substantially Equivalent
NYTS	National Youth Tobacco Survey
OMB	Office of Management and Budget
PATH	Population Assessment of Tobacco and Health
PMTA	Premarket Tobacco Product Application
RFI	Request for Information

RTA	Refuse to Accept
RTF	Refuse to File
RUF	Reagan-Udall Foundation
RYO	Roll-your-own
SE	Substantial Equivalence
SRP	Safety Reporting Portal
TCORS	Tobacco Centers of Regulatory Science
Tobacco Control Act	The Family Smoking Prevention and Tobacco Control Act
TPPI	Tobacco Product Perception and Intention
TPSAC	Tobacco Product Scientific Advisory Committee
TRSP	Tobacco Regulatory Science Program

I. Background

A. Overview

Tobacco product 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.[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), granting authority to the Food and Drug Administration (FDA or Agency) to regulate the manufacture, marketing, and distribution of cigarettes, cigarette tobacco, roll-your-own (RYO) tobacco, smokeless tobacco products, and any other tobacco products the Agency "deems" by regulation to be subject to the tobacco authorities. FDA finalized the "deeming rule,"[3] effective August 8, 2016, to cover all products meeting the statutory definition of "tobacco product", including e-cigarettes, and subject all tobacco products to regulatory requirements in Chapter IX of the FD&C Act, such as premarket review. In response to the increased use of non-tobacco nicotine (NTN) in popular tobacco products, Congress passed The Consolidated Appropriations Act of 2022 (P.L. 117–103),[4] clarifying FDA's authority to regulate tobacco products containing nicotine from any source, including synthetic nicotine.

Since the enactment of the Tobacco Control Act, FDA has made important progress in reducing the negative health effects of tobacco product use. The Center for Tobacco Products (CTP) takes a comprehensive approach to regulation, including compliance and enforcement, regulations including product standards, premarket review, public education, and research efforts.

This report satisfies the requirements of section 106(a) of the Tobacco Control Act, which states:

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[1] Smoking & Tobacco Use: Tobacco-Related Mortality. Centers for Disease Control and Prevention. https://www.cdc.gov/tobacco/data_statistics/fact_sheets/health_effects/tobacco_related_mortality/index.htm.

[2] Smoking & Tobacco Use: Health Effects. Centers for Disease Control and Prevention. https://www.cdc.gov/tobacco/basic_information/health_effects/index.htm.

[3] 81 FR 28974 (May 10, 2016), available at https://www.federalregister.gov/documents/2016/05/10/2016-10685/deeming-tobacco-products-to-be-subject-to-the-federal-food-drug-and-cosmetic-act-as-amended-by-the.

[4] Sec. 111, FDA Authority Over Products Containing Nicotine, 136 Stat. 49, 789-790, available online at https://www.congress.gov/117/plaws/publ103/PLAW-117publ103.pdf.

Not later than 3 years after the date of enactment of this Act, and not less than every 2 years thereafter, the Secretary of Health and Human Services shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report concerning—

(1) the progress of the Food and Drug Administration in implementing this division, including major accomplishments, objective measurements of progress, and the identification of any areas that have not been fully implemented;

(2) impediments identified by the Food and Drug Administration to progress in implementing this division and to meeting statutory timeframes;

(3) data on the number of new product applications received under section 910 of the Federal Food, Drug, and Cosmetic Act and modified risk product applications received under section 911 of such Act, and the number of applications acted on under each category; and

(4) data on the number of full-time equivalents engaged in implementing this division.

B. Reagan-Udall Foundation Evaluation

In September 2022, at the request of Commissioner Robert Califf, an independent expert panel facilitated by the Reagan-Udall Foundation (RUF) began an operational evaluation of CTP. The evaluation's goal was to help ensure that CTP has the tools to address today's challenges as it works to prevent tobacco use among youth and to reduce tobacco-attributable death and disease. The panel's report was issued on December 19, 2022, and included 15 recommendations across a number of areas, including the development of the new Center-wide strategic plan.

In January 2023, CTP convened six distinct task forces to address the RUF report recommendations, which were led by relevant center leadership for the topic area of focus. The task forces were comprised of Agency staff with relevant subject matter expertise for each topic area, both across CTP and in other relevant FDA offices.

The task forces covered:

- Cross-Cutting
- Science and Application Review
- Regulation and Guidance
- Compliance and Enforcement

- Public Education Campaigns
- Resources

CTP has made considerable progress in meaningfully addressing the recommendations.[5] Throughout the process, the Center shared routine public updates on the plan's development, issued proposed goal areas and cross-cutting themes, and collected internal and external feedback in a variety of ways including a public listening session held on August 22, 2023. Specific activities stemming from the goals, outcomes, and objectives outlined in the plan are announced as they are implemented, and routine updates will be provided to the public on these activities.

C. Strategic Plan

In February 2023, the Center began partnering with FDA's Office of Planning, Evaluation, and Risk Management on the overall strategic plan development process. This included assessing the current vision and mission statements and engaging with CTP staff and external stakeholders in multiple ways including opening a docket and holding a public listening session to receive feedback on the components of the plan. CTP developed the strategic plan by defining the Center's goals, outcomes, and objectives, publishing it on the FDA website in December 2023.[6] CTP's Strategic Plan builds upon the strong foundation that has been cultivated since the Center's inception in 2009. The plan defines five goals, 10 outcomes, and several corresponding objectives reinforced by the cross-cutting themes of science, health equity, stakeholder engagement, and transparency. Guided by this plan, CTP aims to reduce the negative health effects caused by tobacco use by ensuring a well-regulated marketplace, preventing people from starting to use tobacco products, encouraging people who use tobacco products to quit, and reducing the harm caused by tobacco product use.

As outlined in the plan, the Center is collectively committed to issuing impactful regulations, using robust science to inform application reviews, pursuing timely and impactful compliance and enforcement strategies, educating the public about the risks of tobacco products, and advancing operational excellence. CTP will track and monitor progress and make necessary adjustments to key activities to reflect challenges and maximize opportunities.

[5] https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/actions-address-recommendations-reagan-udall-evaluation-ctp

[6] https://www.fda.gov/media/174911/download?attachment

As part of the development of the strategic plan, CTP also refreshed its vision and mission statements[7] to reflect its charge as a public health regulatory agency and to reinforce the importance of strategies to advance health equity.

In accordance with CTP's strategic plan, the Center's work in the following major programmatic priorities help to reduce the impact of tobacco use in the United States.

[7] https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp#our%20vision

II. Programmatic Priorities

A. Application Review

Ensuring new tobacco products undergo premarket evaluation by FDA is a critical part of the Agency's mission to protect the public health, particularly youth, and to reduce tobacco-related disease and death. "New" tobacco products, which are products that were not on the market as of February 15, 2007, may not be legally marketed in the United States without authorization from FDA. Tobacco products may enter the market if authorized by FDA through one of three pathways: Substantial Equivalence (SE) Report, Premarket Tobacco Product Application (PMTA), or an Exemption from Substantial Equivalence Request (EX REQs).

1. Pre-existing Determinations

A pre-existing tobacco product[8] is any tobacco product (including those products in test markets) that was commercially marketed in the United States as of February 15, 2007. Pre-existing tobacco products are regulated under the FD&C Act and do not require premarket authorization to be legally marketed. FDA has reviewed and made pre-existing tobacco product[9] determinations for over 12,000 voluntary submissions from industry. From January 1, 2022 through December 21, 2023, FDA reviewed and made pre-existing tobacco product determinations for 900 submissions.

2. PMTA Review Process and Status Update

As of December 2023, FDA has received PMTAs for nearly 27 million e-cigarette products. The PMTAs that FDA has received include applications for nearly one million non-tobacco nicotine products. This also includes applications for more than 6.5 million products received by September 9, 2020.[10]

FDA has resolved applications for more than 26 million products. By December 2023, the Agency had authorized 23 e-cigarette products and devices, all of which are

[8] Previously referred to as "grandfathered tobacco products."

[9] Pre-existing tobacco products may serve as a predicate tobacco product in SE Reports (if not exclusively in a test market as of February 15, 2007).

[10] Applications for deemed new tobacco products on the market as of August 8, 2016, were required to be submitted to FDA by September 9, 2020, per a federal court order. *American Academy of Pediatrics, et al. v. FDA*, 399 F. Supp. 3d 479 (D. Md. 2019).

tobacco-flavored. These products were authorized because the applicant submitted data that demonstrated that the marketing of the products met the applicable "appropriate for the protection of the public health" (APPH) standard required by law. As part of FDA's evaluation of these products, the Agency determined that the potential for these products to benefit adults who smoke outweighed the risk to youth. In addition, the Agency has issued marketing denial orders for over a million non-tobacco flavored products because the applicant failed to show that the products met the public health standard.

PMTA review has three phases, and, if a product is authorized, there is a fourth post market phase: (1) acceptance review, (2) filing review, (3) substantive review, and (4) post market reporting. The acceptance review entails determining whether the product falls under the jurisdiction of CTP and whether the application meets certain requirements set forth by the PMTA final rule[11] and Section 910 of the FD&C Act. Filing review determines whether the application contains sufficient information to permit a full substantive review of the application.

The substantive review phase includes an evaluation of the scientific information and data in an application. The scientific review of an application is a collaborative process that may include reviewers from a wide variety of scientific disciplines, including microbiology, chemistry, engineering, behavioral and clinical pharmacology, social science, medicine, toxicology, epidemiology, and environmental science. The review may also include reviewers from disciplines such as bioresearch monitoring, promotion, advertising and labelling, and product compliance. This multi-disciplinary approach helps determine if marketing the new product would be APPH and whether it should receive an order allowing the introduction or delivery for introduction into interstate commerce. When FDA completes substantive review the Agency typically takes one of two actions: (1) a Marketing Granted Order (MGO), or (2) a Marketing Denial Order (MDO).

[11] https://www.federalregister.gov/d/2021-21011

FDA's progress on PMTA Review is summarized below.

Data on PMTA Submissions[12] (As of December 31, 2023)

TYPE	Closure Reason	# Closed
PMTA Submissions	Marketing Granted Order	45
	Marketing Denial Order	1,240,576
	Withdrawals	2,400
	Refuse to Accept	19,562,494
	Refuse to File	5,159,247
	Administratively Closed	80,678
Total (26,606,552 received)		26,045,440 (98%)

Of the 2 percent (n = 561,112) of open applications: 274,260 are pending acceptance; 80,730 completed the acceptance phase; 206,115 completed the filing phase; 7 paused within substantive review phase (issued a deficiency letter where the time for the company to respond has not concluded).

During the period of time covered by this report, FDA also continued to provide information to the public about the PMTA process. In March 2023, FDA revised the guidance, "Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (ENDS)," which assists persons in submitting PMTAs for ENDS under section 910 of the FD&C Act (21 U.S.C. 387j).[13] In October 2023, FDA held a public meeting, "Premarket Applications: Opportunities for Stakeholder Engagement,"[14] to provide information about PMTAs and information to assist applicants with avoiding problems that CTP had observed in reviewing applications over the past three years.

[12] These data include PMTA submissions for all tobacco products, including e-cigarette products and devices.

[13] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/premarket-tobacco-product-applications-electronic-nicotine-delivery-systems-ends

[14] https://www.fda.gov/tobacco-products/ctp-newsroom/premarket-applications-opportunities-stakeholder-engagement-public-meeting-10232023

3. SE and EX REQ Review Process and Status Update

A substantially equivalent tobacco product is one that has been found by FDA to have either the same characteristics as a predicate product, or has different characteristics than the predicate product but the substantial equivalence report demonstrates that the new tobacco product does not raise different questions of public health. A tobacco product that is modified by adding or deleting a tobacco additive, or by increasing or decreasing the quantity of an existing tobacco additive may be considered for an exemption from demonstrating substantial equivalence.

SE and Exemption from EX REQs follow a review process similar to PMTAs, with the main differences being that there is no filing review and no post-market reporting requirements. In 2022 and 2023, FDA accepted applications for more than 10 SE products and issued refuse-to-accept (RTA) letters for 19 products. For the EX REQ-pathway, FDA accepted applications for 1,801 products and issued RTA letters for 240 products. During 2022 and 2023, FDA's substantive review resulted in SE marketing orders for 268 products and 83 marketing denials. FDA issued EX REQ orders for 800 products and 263 marketing denials. By the end of 2023, FDA had issued a cumulative total of 1,895 SE marketing orders, 503 Not Substantially Equivalent (NSE) orders, 1,658 EX REQ orders, and 469 Not Exempt from Substantial Equivalence orders.

Data on SE and EX Submissions (As of December 31, 2023)

TYPE	Closure Reason	# Closed
Regular SE (12,220 received)	SE Order	1,617
	NSE Order	289
	Withdrawal	1,333
	Refuse to Accept	2,354
	Administratively Closed[15]	531
	Regular SE Total	6,124 (50%)
Provisional SE[16] (3,645 received)	SE Order	278
	NSE Order	214
	Withdrawal	1,284
	Refuse to Accept	14
	Administratively Closed	69

[15] CTP issues a letter administratively closing the SE Report if it is not possible to make a determination on an SE Report.

[16] The TCA provides that tobacco products introduced into commercial distribution after February 15, 2007 – but before March 22, 2011 – could remain on the market if they were the subject of an SE Report submitted no later than March 22, 2011.

	Removed from Review[17]	1,387
	Provisional SE Total	3,246 (89%)
Total SE (15,865 received)		9,370 (59.1%)

Of the SEs that have not been closed (n=6,495): 799 are pending acceptance and 3,984 have completed the acceptance phase; 1,712 are in scientific review and 131 are paused within substantive review phase (issued a deficiency letter).

TYPE	Closure Reason	# Closed
EX REQs	Ex Order	1,658
	NEX Order	469
	Withdrawals	135
	Refuse to Accept	1,450
	Administratively Closed	95
Total (5,032 received)		3,807 (76%)

Of the EX REQs that have not been closed (n=1,225): 12 are pending acceptance and 387 have completed the acceptance phase; 817 are in scientific review and 9 are paused within substantive review phase (issued a deficiency letter).

4. MRTP Review Process and Status Update

A modified risk tobacco product application (MRTPA) is an application to market a product for use to reduce harm or the risk of tobacco-related disease or to reduce exposures to harmful substances associated with commercially marketed tobacco products; it is not a pathway to market a new tobacco product. An MRTPA can be submitted by any person for a proposed MRTP seeking an FDA modified risk granted order (MRGO) under section 911 of the FD&C Act and generally must demonstrate that the product will significantly reduce harm and the risk/exposure of tobacco-related disease to individual tobacco users and benefit the health of the population as a whole. The issuance of an order permitting the sale of an MRTP applies to tobacco products that have already received a marketing order through one of the premarket pathways or a pre-existing tobacco product. It is important to note that an MRGO refers to specific products subject to the application, not an entire class of tobacco products.

Similar to PMTAs, the MRTPA review has three review phases, and if authorized, a fourth phase consisting of post market: (1) acceptance review, (2) filing review, (3)

[17] "Removed from Review" means that CTP decided to not review a provisional product due to a low potential for the new tobacco product to raise different questions of public health. These products can be legally marketed unless they receive an NSE order.

substantive review and action, and (4) postmarket surveillance and studies. The acceptance review entails whether the application meets the statutory and regulatory criteria under Chapter IX of the FD&C Act and 21 CFR 1105 to ensure that basic elements are included.[18,19] Filing review determines whether the application contains sufficient information to permit a full substantive review of the application. If filed, FDA will refer each filed application to the Tobacco Product Scientific Advisory Committee (TPSAC) for its recommendations and will make the MRTPA publicly available as it goes into substantive review.[20] The substantive review phase for MRTPAs involves a multi-disciplinary, collaborative review of the application, similar in structure to premarket pathway review teams. Separate from substantive review team evaluations, TPSAC assessments may take the form of specific findings or recommendations related to an application and are mandated for MRTPAs under Section 911(f) of the FD&C Act. During substantive review and prior to an order action, a TPSAC meeting is held with the committee and is generally open to the public. The collective assessments, public commentary, and substantive review findings are used in FDA's determination of whether an MRTPA meets the minimum scientific standards, and the provided evidence sufficiently supports the issuance of an MRGO.

As of December 31, 2023, FDA had received MRTPAs for 83 products. As of December 31, 2023, FDA had taken action on 57.8 percent of the applications which includes refusing to accept applications for 10 products, refusing to file applications for 11 products, and authorizing the marketing of 16 products.

Data on Modified Risk Tobacco Products (MRTPs) (As of December 31, 2023)

TYPE	Closure Reason	# Closed
Modified Risk Tobacco Product Applications (MRTPA)	Modified Risk Granted Order	16
	Modified Risk Denial Order	0
	Withdrawals	11
	Refuse to Accept	10
	Refuse to File	11
	Administratively Closed	0
Total (83 received)		48 (57.8%)

[18] https://www.federalregister.gov/documents/2016/12/29/2016-31370/refuse-to-accept-procedures-for-premarket-tobacco-product-submissions.

[19] There is no MRTPA final rule, however, FDA published a 2012 MRTPA Draft Guidance For Industry: https://www.fda.gov/media/83300/download.

[20] Under Section 911(e), FDA must make the MRTPA publicly available and request comments for the application and on the label, labeling, and advertising (excluding confidential or trade secret information).

Of the MRTPAs that have not been closed (n = 35): 19 are pending acceptance; 8 have completed the acceptance phase; 8 have completed the filing phase and made publicly available.

B. Compliance and Enforcement

FDA closely monitors retailer, manufacturer, importer, and distributor compliance with federal tobacco laws and regulations and may take regulatory or enforcement action when violations occur. The Agency's efforts help ensure that regulated industry and regulated tobacco products are in compliance with the laws designed to protect public health generally and to prevent access to tobacco products by underage persons.

1. Retailer Compliance Check Program

FDA estimates that there are more than 360,000 retailers that sell tobacco products in the United States. The Tobacco Control Act specifically directed FDA to contract with states, U.S. territories, and Indian Tribes, to the extent feasible, to conduct tobacco compliance check inspections of retail establishments to determine these establishments' compliance with applicable provisions of the Tobacco Control Act and its implementing regulations. FDA may contract with third-party entities when it is not feasible to contract with the states or territories. The Agency may also conduct inspections using FDA personnel.

FDA has contracts for tobacco retailer compliance check inspections in 56 states and territories. The FDA Tobacco Retail Inspection Contracts webpage contains pertinent information about each jurisdiction where FDA has contracts, including the most recent contract start date in those jurisdictions.[21]

Tobacco compliance check inspections cover the marketing, sale, and distribution of tobacco products at retail locations and include ensuring compliance with age and ID verification requirements. In general, inspections are conducted by officers and employees from the entities under contract. FDA has commissioned and trained more than 700 officials who conduct inspections on the Agency's behalf. From January 1, 2022, through December 31, 2023, over 201,000 inspections of tobacco retailers were conducted.

FDA's enforcement work is a multi-step process that takes time to ensure that its actions are legally supportable. Every action requires an individual investigation through which the Agency collects and reviews evidence to build a case. Compliance

[21] https://www.fda.gov/tobacco-products/retail-sales-tobacco-products/fda-tobacco-retail-inspection-contracts

and enforcement actions build on one another and escalate if firms continue to violate the law. FDA conducts compliance check inspections and issues advisory and enforcement actions such as warning letters, Civil Money Penalties (CMPs), and No-Tobacco-Sale Orders when violations are found. The table below lists CMP amounts as of December 31, 2023.[22]

Number of Regulation Violations	CMP Amount[23]
1	$0, warning letter issued
2 within a 12-month period	$345
3 within a 24-month period	$687
4 within a 24-month period	$2,757
5 within a 36-month period	$6,892
6 within a 48-month period	$13,785

FDA also conducted multiple coordinated nationwide retailer inspection efforts that included investigations of hundreds of retailers and distributors and resulted in warning letters and civil money penalties for the illegal sale of unauthorized tobacco products.

Examples of accomplishments of FDA's tobacco retail inspection program[24] from January 1, 2022, through December 31, 2023, include the following:

- Issued over 29,000 warning letters (over 8,000 pertained to the sales of ENDS products to underage purchasers) to retail establishments in which violations were found during compliance check inspections;
- Initiated over 6,200 CMP administrative actions (over 1,900 pertained to the sales of ENDS products to underage purchasers) to retail establishments in which subsequent violations were found during follow-up compliance check inspections;
- Filed 4 No-Tobacco-Sale-Order complaints to retail establishments in which repeated violations[25] were found during follow-up compliance check inspections;

[22] https://www.fda.gov/tobacco-products/compliance-enforcement-training/advisory-and-enforcement-actions-against-industry-selling-tobacco-products-underage-purchasers

[23] When determining the amount of CMP to seek against a retailer, it is generally FDA's policy to count only one regulation violation from the first inspection that finds one or more violations at an outlet, regardless of the number of violations that were noted and included in a warning letter. For subsequent inspections, CTP's general policy is to count all violations individually. See Orton Motor, Inc. v. HHS, 884 F.3d 1205, 1211–1214 (D.C. Cir. 2018) and https://www.fda.gov/regulatory-information/search-fda-guidance-documents/civil-money-penalties-and-no-tobacco-sale-orders-tobacco-retailers-revised.

[24] https://timp-ccid.fda.gov/

[25] The phrase *repeated violations* is defined as "at least 5 violations of particular requirements over a 36-month period at a particular retail outlet that constitute a repeated violation." Section 103(q)(1)(A) of the Tobacco Control Act.

- On September 14, 2023, FDA issued warning letters to 15 online retailers and 3 manufacturers and/or distributors for selling or distributing unauthorized e-cigarette products. The warning letters cite a range of popular and youth-appealing e-cigarette products, including disposable products, marketed under the brand names Elf Bar, EB Design, Lava, Cali, Bang, and Kangertech;[26] and
- On December 13, 2023, FDA issued warning letters to 11 online retailers selling unauthorized e-cigarette products marketed under the brand names Lost Mary, Funky Republic/Funky Lands, Elf Bar/EB Design, Kangvape, Cali, and Breeze.

2. Oversight of Promotion, Advertising, and Labeling

FDA has conducted routine surveillance of the sales, distribution, marketing, labeling, and advertising activities related to regulated tobacco products. This surveillance has occurred on the Internet, including social media; in publications; and through other compliance and enforcement activities. For example, this surveillance has consisted of monitoring thousands of unique publications and websites each year in which regulated tobacco products might be sold, distributed, or advertised.

FDA also reviews notices required to be submitted by industry 30 days before disseminating tobacco product advertising or labeling online. The notice must include "the extent to which the advertising or labeling may be seen by persons younger than 18 years of age."[27] In addition, FDA has reviewed smokeless tobacco warning plans and smokeless tobacco warning plan supplements in accordance with the Comprehensive Smokeless Tobacco Health Education Act, as amended by section 204 of the Tobacco Control Act.

When violations have been observed through these surveillance and investigation activities, FDA has generally issued a warning letter. These proactive compliance activities have helped protect the public health by preventing the sale and distribution of misbranded and adulterated tobacco products, including those with marketing and advertising materials that violated the FD&C Act.

Examples of FDA accomplishments as a result of monitoring tobacco promotion, advertising, and labeling activities from January 1, 2022, through December 31, 2023, include the following specific actions:

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[26]. https://www.fda.gov/tobacco-products/ctp-newsroom/fda-warns-companies-selling-illegal-e-cigarettes-emerging-popularity-among-youth

[27] 21 CFR 1140.30, eCFR: 21 CFR Part 1140 -- Cigarettes, Smokeless Tobacco, and Covered Tobacco Products

- On August 18, 2022, FDA issued a warning letter for marketing illegal flavored nicotine gummies—the first warning letter for this type of product. These types of gummies are of particular public health concern because of their resemblance to food or candy products and the potential to cause severe nicotine toxicity or even death among young children;[28]
- On November 16, 2022, FDA issued warning letters to five firms for the unauthorized marketing of 15 different e-cigarette products. Each e-cigarette product was packaged to look like toys (i.e. glow sticks, Nintendo Game Boy), food (i.e. popsicles), or cartoon characters (i.e. Simpsons, Family Guy, Minions) and was likely to promote use by youth;[29]
- On August 23, 2023, FDA issued warning letters to 15 online retailers for selling and/or distributing unauthorized e-cigarette products packaged to look like youth-appealing characters, school supplies, toys, and drinks;[30]
- On November 7, 2023, FDA issued a warning letter to Nic Nac Naturals, LLC for the marketing of their unauthorized dissolvable nicotine products, which the company describes as "nicotine mints" and resemble a pack of mints;[31]
- On November 16, 2023, FDA issued warning letters to seven online retailers for selling and/or distributing e-cigarettes. The e-cigarettes are packaged to look like youth-appealing toys and drink containers, including milk cartons, soft drink bottles, and slushies;[32] and
- On December 20, 2023, FDA issued warning letters to three online retailers selling and/or distributing unauthorized e-cigarette products that imitate packaging for bottles of alcohol. These retailers sold Luckee Vape Daniels brands, which are flavored, disposable e-cigarette products that come in a variety of common alcoholic drink flavors that may be appealing to young people.[33]

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[28] https://web.archive.org/web/20221208150310/https://www.fda.gov/news-events/press-announcements/fda-warns-manufacturer-marketing-illegal-flavored-nicotine-gummies

[29] https://www.fda.gov/tobacco-products/ctp-newsroom/unauthorized-e-cigarettes-appeal-youth

[30] https://www.fda.gov/tobacco-products/ctp-newsroom/retailers-warned-stop-selling-illegal-e-cigarettes-resembling-youth-appealing-characters-school

[31]. https://www.fda.gov/tobacco-products/ctp-newsroom/fda-warns-firm-selling-illegal-flavored-nicotine-mints-agency-remains-committed-protecting-youth

[32]. https://www.fda.gov/tobacco-products/ctp-newsroom/fda-warns-retailers-stop-selling-illegal-youth-appealing-e-cigarettes-disguised-everyday-items

[33] https://www.fda.gov/tobacco-products/ctp-newsroom/fda-warns-online-retailers-sale-unauthorized-e-cigarettes-resembling-alcohol-bottles

3. Manufacturer Compliance and Enforcement Activities

As required by section 905(g) of the FD&C Act, FDA conducts inspections of registered establishments engaged in the manufacture, compounding, or processing of a tobacco product. These inspections are designed to determine compliance with tobacco product manufacturer requirements of the FD&C Act, such as domestic establishment registration, tobacco product and ingredient listing, packaging, labeling, and advertising requirements, as well as marketing authorization for new tobacco products or MRTPs.

FDA's tobacco product manufacturer inspections also include inspections of vape shop establishments.[34] During these inspections, FDA seeks to determine the types of activities that are performed at the establishment and the establishment's compliance with applicable requirements under the FD&C Act. FDA also conducts other types of tobacco product manufacturer inspections, including inspections of manufacturing facilities as part of review of a PMTA. To support the inspections and potential actions, the Agency also has laboratories with the capacity to conduct analyses of tobacco product samples. This testing also develops and validates methods and informs the establishment of product standards and baselines.

Examples of FDA accomplishments in this area from January 1, 2022, through December 31, 2023, include the following significant specific actions:

- Conducted more than 1,800 inspections of registered domestic tobacco product manufacturing facilities, over 1,100 of which were vape shops (these include remote regulatory assessments);
- Conducted 14 premarket manufacturing and bioresearch monitoring inspections associated with PMTAs (these include remote regulatory assessments); and
- Issued over 250 warning letters to manufacturers and/or importers for various violations of the FD&C Act, including for failure to pay user fees, failure to have the required FDA marketing authorization in effect for products such as ENDS products and cigarettes, failure to comply with various requirements of section 905 of the FD&C Act (including: failure to register a tobacco product manufacturing establishment, failure to update registration, failure to list tobacco products, and failure to update tobacco product list), and failure to submit ingredient listings.

[34] Operators of vape shops that mix or prepare liquid nicotine or nicotine-containing e-liquids, or create or modify any type of ENDS, in addition to product sales, may be considered manufacturers and must comply with the requirements for manufacturers. https://www.federalregister.gov/documents/2016/05/10/2016-10685/deeming-tobacco-products-to-be-subject-to-the-federal-food-drug-and-cosmetic-act-as-amended-by-the

4. Import Compliance and Enforcement Activities

FDA is actively engaged with other government agencies and organizations to enhance enforcement and compliance activities. FDA works closely with the U.S. Customs and Border Protection (CBP) to prevent illegal tobacco products, including ENDS, from passing through U.S. ports. CBP and FDA, as well as the United States Postal Service at the International Mail Facilities, work collaboratively to screen products at entry for compliance with applicable requirements under the FD&C Act. This includes, checking for unauthorized tobacco products (which are among our highest enforcement priorities) and taking appropriate action, as warranted, such as detention or refusal of admission.

FDA has eight active tobacco import alerts.[35] Import alerts inform FDA's field staff and the public that the Agency has enough evidence to allow for the detention of tobacco products that appear to be in violation of FDA's laws and regulations without physical examination. Many e-cigarette products offered for import are not properly declared. CBP has authority to administratively seize products that are smuggled or clandestinely imported. During the timeframe of this report, these Import Alerts addressed over 40 firms importing e-cigarettes, each of which covers multiple products. FDA regularly updates the Import Alerts, including to account for changes in brand name. FDA has generally been refusing admission to products listed on these Import Alerts.

Examples of FDA accomplishments in this area from January 1, 2022, through December 31, 2023, include the following significant specific actions:

- Reviewed approximately 500,000 lines of imported tobacco products using the Agency's information technology systems and in collaboration with CBP; and
- In December 2023, FDA, in collaboration with CBP, announced the seizure of approximately 1.4 million units of unauthorized e-cigarette products, including brands such as Elf Bar. These actions were part of a three-day joint operation which resulted in the seizure of 41 shipments containing illegal e-cigarettes with a total value of more than $18 million.[36]

5. Notable Compliance and Enforcement Actions Related to a Lack of Premarket Authorizations

A new tobacco product must have FDA authorization before it can be legally marketed, and generally, products without authorization are at risk of enforcement action.

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[35] https://www.fda.gov/industry/import-alerts/search-import-alerts

[36] https://www.fda.gov/news-events/press-announcements/joint-federal-operation-results-seizure-more-18-million-illegal-e-cigarettes

Enforcing against unauthorized ENDS products, including unauthorized products popular with youth, are among FDA's highest enforcement priorities as they relate to tobacco.

As a result of collaboration between FDA's tobacco product manufacturer inspection and internet surveillance programs, from January 1, 2022, through December 31, 2023, the Agency issued more than 360 warning letters to manufacturers, importers and distributors not in compliance with the premarket requirements.[37] FDA also pursued its first-ever injunctions and CMP complaints against tobacco manufacturers to enforce the premarket review requirements for new tobacco products.

In October 2022, DOJ, on behalf of FDA, filed complaints for permanent injunctions against six e-cigarette manufacturers.[38] DOJ filed an additional complaint for injunction in December 2023 for a total of seven complaints for injunctions filed.[39] The injunctions sought to require the defendants to stop manufacturing, selling, and distributing their e-cigarettes and to obtain marketing authorization from FDA before marketing such products, as required by law.

In February 2023, FDA filed its first CMP complaints to enforce premarket review requirements against four e -cigarette manufacturers.[40] The Agency filed CMP complaints against 42 e-cigarette manufacturers in 2023 for violations of the FD&C Act relating to tobacco products, including the failure to obtain the required marketing authorization for new tobacco products.

FDA conducted multiple coordinated nationwide retailer inspection efforts that included investigations of hundreds of retailers and distributors and resulted in FDA issuing over 400 warning letters for the illegal sale of unauthorized tobacco products. These products included Puff, Hyde, and Elf Bar brand disposable e-cigarettes — products that come in flavors known to appeal to youth and which were commonly reported brands used by youth e-cigarette users in 2022.

In September 2023, CTP issued CMP complaints against 22 retailers for the sale of unauthorized ENDS products, mostly Elf Bar/EB Design products. These CMP complaints sought over $19,000 from each retailer. As of December 31, 2023, FDA has

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[37] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters

[38] https://web.archive.org/web/20221209191055/https://www.fda.gov/news-events/press-announcements/fda-doj-seek-permanent-injunctions-against-six-e-cigarette-manufacturers

[39] https://www.fda.gov/tobacco-products/ctp-newsroom/fda-doj-seek-permanent-injunction-against-e-cigarette-manufacturer

[40] https://www.fda.gov/news-events/press-announcements/fda-files-civil-money-penalty-complaints-against-four-e-cigarette-product-manufacturers

filed CMP complaints for the sale of unauthorized ENDS products against 67 brick-and-mortar and online retailers.

6. Potential Tobacco Product Violation Reports

Any stakeholder, including an individual member of the public, may report to FDA — via FDA's Potential Tobacco Product Violation Reports[41] — a potential violation of Agency-enforced tobacco laws. FDA reviews all reports of potential tobacco violations and conducts investigations of complaints. After reviewing a report, FDA may find it appropriate to, among other things:

- Conduct a compliance check inspection of a tobacco retailer and/or online retailer; and/or
- Initiate monitoring and surveillance of the tobacco product website; and/or
- Inspect a tobacco product manufacturing establishment.

From January 1, 2022, through December 31, 2023, FDA received and reviewed over 13,500 potential tobacco product violation reports. Many of these violation reports were for (1) sales to minors at brick-and-mortar and online retailers; (2) potential violations related to deemed tobacco products such as flavored cigars and ENDS products; (3) complaints regarding product quality including potential counterfeits; (4) the sales of cigarettes in packages of less than 20; (5) illegal marketing and advertising, such as describing tobacco products as safer or less harmful without an FDA order; and (6) products lacking the required premarket authorization. FDA investigates numerous potential tobacco product violations reports and takes action on them when appropriate.

7. CTP's Office of Small Business

CTP's Office of Small Business Assistance[42] (OSBA) has provided technical and other nonfinancial assistance to small tobacco product manufacturers and other small businesses to help them comply with the tobacco provisions of the FD&C Act. OSBA has answered questions from the regulated industry, including small tobacco product manufacturers and retailers, consumers of regulated tobacco products, and the public. The office has responded to thousands of calls, emails, and correspondence every year to assist in answering specific questions about requirements of the law and how to comply with the law.

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[41] Report Potential Tobacco Product Violation. FDA. https://www.fda.gov/tobacco-products/compliance-enforcement-training/report-potential-tobacco-product-violation.

[42] https://www.fda.gov/tobacco-products/compliance-enforcement-training/small-business-assistance-tobacco-product-industry.

OSBA received over 4,300 inquiries from January 1, 2022, through December 31, 2023. All inquiries received are tracked to ensure timely and appropriate responses. OSBA responds to the vast majority of inquiries within 30 days. These inquiries have become topics for OSBA's compliance training webinars and other outreach efforts.

8. Compliance Training Assistance

Stakeholder engagement is a priority for FDA and CTP and ongoing interactions with industry stakeholders help identify areas where training materials and/or guidance may be helpful for them. FDA provides educational materials and webinars, training videos, and guidance documents to help industry, including retailers, comply with the law.

CTP regularly hosts webinars[43] designed to provide compliance education and information to retailers and to small business manufacturers to encourage compliance with FDA's tobacco laws and regulations. From January 1, 2022, through December 31, 2023, 18 webinars or updates were developed and posted on FDA's website. CTP has created Spanish-language webinars to help small businesses learn about and comply with federal laws and regulations for manufacturing, distributing, and marketing tobacco products. We also maintain a dedicated CTP en Español Outlook mailbox to handle inquiries, complaints, and reportable safety events from the Hispanic community. These communications are translated and reviewed for appropriate action. FDA continues to update and provide new webinars (totaling more than 100) to assist regulated industry.

FDA has a voluntary retailer education program entitled "This Is Our Watch."[44] This program—through its messages, materials, and communications activities—has aimed to raise retailers' awareness and understanding of FDA's tobacco regulations. It also has sought to encourage voluntary compliance with the law and to highlight the importance of compliance and the critical role of retailers in achieving it. "This is Our Watch" materials, including an age verification digital calendar (designed to sit on retail countertops), were mailed to retailers across the country and are currently available to order at no charge through CTP's Tobacco Education Resource Library—an online digital repository of health education materials. Stakeholders, to include state health departments, military exchange establishments, and national and local retailers, have found the materials helpful in their efforts to educate staff and the public about the law.

[43] https://www.fda.gov/tobacco-products/compliance-enforcement-training/fda-tobacco-compliance-webinars.

C. Regulations and Guidance Documents

FDA's mission to protect Americans from tobacco-related death and disease is accomplished, in part, by issuing regulations pursuant to the Tobacco Control Act and guidance documents that explain FDA's current thinking on policy matters. In December 2023, CTP published and will update annually its policy agenda outlining rules and guidance documents that are in development or planned for development.[45]

1. Proposed Product Standards and Other Regulations in Progress

a. Product Standard for Menthol Cigarettes

On May 4, 2022, FDA published a proposed rule that would prohibit menthol as a characterizing flavor in cigarettes.[46] This product standard is based on clear science and evidence establishing the addictiveness and harm of menthol cigarettes and builds on a statutory prohibition of characterizing flavors in cigarettes (other than tobacco or menthol) in place since 2009.

Prohibiting menthol as a characterizing flavor in cigarettes will reduce the appeal of cigarettes, particularly to youth and young adults, and thereby decrease the likelihood of experimentation, and progression to regular cigarette smoking. In addition to benefiting the population as a whole, populations that disproportionately use these products – such as people who identify as part of a historically marginalized race or ethnicity, people who identify as lesbian, gay, bisexual, transgender, queer, and intersex (LGBTQI+), people with mental health conditions, and people with lower household incomes, among others – will have pronounced benefits. For example, published modeling studies estimate that prohibiting menthol cigarettes will prevent between 92,000 to 238,000 deaths among African Americans over the course of 40 years. The product standard will improve the health and reduce the mortality risk of current menthol cigarette smokers by substantially increasing the likelihood of cessation or switching to less harmful tobacco products. Further, the product standard will improve the health of non-smokers by decreasing secondhand smoke exposure because of a reduction in smoking consumption and prevalence.

[45] https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/center-tobacco-products-regulation-and-guidance-policy-agenda

[46] Tobacco Product Standard for Menthol in Cigarettes (Proposed Rule). 87 FR 26454 (May 4, 2022).

Initially, FDA provided a 60-day comment period for the rule, but the Agency later extended the comment period to a total of 90 days.[47] FDA received approximately 175,000 comments on this proposed rule. There were other opportunities for the public to engage with FDA and provide comments. These opportunities included the June 2022 listening sessions[48] and the June 2022 Tribal consultation.[49] In accordance with the Administrative Procedure Act, FDA considers and responds to substantive comments submitted to the docket on the proposed rule in the final rule.

b. Product Standard for Flavored Cigars

On May 4, 2022, FDA published a proposed rule that would prohibit all characterizing flavors (other than tobacco) in cigars.[50] This product standard is based on clear science and evidence establishing the addictiveness and harm of flavored cigars and builds on a statutory prohibition of characterizing flavors in cigarettes (other than tobacco or menthol) in place since 2009.

This product standard will reduce the appeal of cigars, particularly to youth and young adults, and thereby decrease the likelihood of experimentation, development of nicotine dependence, progression to regular use, and the resulting tobacco-related disease and death. The product standard also will improve public health by increasing the likelihood of cessation among existing cigar smokers. As with the menthol in cigarettes product standard, this product standard is expected to substantially decrease tobacco-related health disparities and to advance health equity across population groups.

Initially, FDA provided a 60-day comment period for the rule, but the Agency later extended the comment period to a total of 90 days.[51] FDA received approximately 71,000 comments on this proposed rule. There were other opportunities for the public to engage with FDA and provide comments. These opportunities included the June 2022 listening sessions and the June 2022 Tribal consultation. In accordance with the

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[47] Establishment of Tobacco Product Standards for Menthol in Cigarettes and Characterizing Flavors in Cigars; Extension of Comment Period. 87 FR 36786 (June 21, 2022).

[48] Proposed Regulations to Establish Tobacco Product Standards for Menthol in Cigarettes and Characterizing Flavors in Cigars: Listening Sessions; Public Meeting; Request for Comments. 87 FR 26311 (May 4, 2022) (Notification of public meeting).

[49] https://www.fda.gov/media/158519/download?attachment.

Recording of FDA Tribal Consultation available here: https://www.youtube.com/watch?v=CY-q-wPr6ok.

[50] Tobacco Product Standard for Characterizing Flavors in Cigars (Proposed Rule). 87 FR 26396 (May 4, 2022).

[51] Establishment of Tobacco Product Standards for Menthol in Cigarettes and Characterizing Flavors in Cigars; Extension of Comment Period. 87 FR 36786 (June 21, 2022).

Administrative Procedure Act, FDA considers and responds to substantive comments submitted to the docket on the proposed rule in the final rule.

c. Requirements for Tobacco Product Manufacturing Practice

On March 10, 2023, FDA published a proposed rule to establish tobacco product manufacturing practice requirements for manufacturers of finished and bulk tobacco products.[52] When final, this rule would set forth the requirements with which finished and bulk tobacco product manufacturers must comply in the manufacture, preproduction design validation, packing, and storage of finished and bulk tobacco products, to assure that the public health is protected and that tobacco products are in compliance with chapter IX of the FD&C Act.

FDA held a public oral hearing on April 12, 2023, to elicit additional comments from stakeholders including industry, the scientific community, advocacy groups, and the public.[53] FDA also held a meeting of TPSAC on May 18, 2023, to seek recommendations from FDA's outside panel of experts on the requirements laid out in the proposed rule.[54]

FDA extended the proposed rule's comment period by an additional 30 days and closed the comment period on October 6, 2023.[55] The Agency will comprehensively review and analyze the comments, scientific data, expert opinions, and facts that have been submitted.

d. Product Standard to Regulate Nicotine Yield by Establishing a Maximum Nicotine Content in Cigarettes and Certain Other Combusted Tobacco Products

On June 21, 2022, FDA announced that it was working toward issuing a proposed product standard that would regulate nicotine yield by establishing a maximum nicotine level in cigarettes and certain other combusted tobacco products.[56] Because the

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[52] Requirements for Tobacco Product Manufacturing Practice (Proposed Rule). 88 FR 15174 (March 10, 2023).

[53] Proposed Requirements for Tobacco Product Manufacturing Practice; Public Hearing; Request for Comments. 88 FR 14962 (March 10, 2023).

[54] https://www.fda.gov/advisory-committees/advisory-committee-calendar/may-18-2023-tobacco-products-scientific-advisory-committee-meeting-05182023.

[55] Proposed Requirements for Tobacco Product Manufacturing Practice; Extension of Comment Period. 88 FR 59481 (August 29, 2023).

[56] https://www.fda.gov/news-events/press-announcements/fda-announces-plans-proposed-rule-reduce-addictiveness-cigarettes-and-other-combusted-tobacco.

majority of tobacco-related harms result from addiction that repeatedly exposes people to toxins from cigarettes and other combusted products, FDA is proposing this action to reduce the addictiveness of cigarettes and certain other combusted tobacco products, thus giving people who are addicted to these products the ability to quit smoking more easily. This product standard would also help to prevent people who experiment with cigarettes and other combusted products (mainly youth) from progressing to regular use of combusted tobacco products when they otherwise wouldn't choose to do. The authority to adopt product standards is one of the most powerful tobacco regulatory tools Congress gave the Agency. This proposed product standard, if finalized, is anticipated to benefit the population as a whole, while also advancing health equity by addressing disparities associated with cigarette smoking, dependence, and cessation.

2. Final Guidances

On August 23, 2022, FDA issued a final guidance document entitled *Tobacco Products: Principles for Designing and Conducting Tobacco Product Perception and Intention Studies.*[57] This document provides information intended to help applicants design and conduct tobacco product perception and intention (TPPI) studies that may be submitted as part of an MRTPA, PMTA, or an SE Report.

TPPI studies can be used to assess, among other things, individuals' perceptions of tobacco products, understanding of tobacco product information (e.g., labeling, modified risk information), and intentions to use tobacco products. The results of these studies may in some circumstances help predict tobacco use behavior. The results can in some circumstances help an applicant demonstrate that its new tobacco product meets the applicable premarket authorization standard and can help an applicant demonstrate that its proposed MRTP satisfies the standard in section 911(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 301 et seq.).

3. Updates to Tobacco-Related Guidance Documents

FDA continues to ensure the public receives accurate and timely information regarding the Agency's current thinking on tobacco regulatory issues. To that end, FDA has revised several guidance documents to ensure clarity, address points of confusion, or to reflect policy changes and statutory amendments. The following final guidance documents have been revised during the two years (2022-2023) covered by this report.

[57] https://www.fda.gov/media/143322/download.

- Meetings with Industry and Investigators on the Research and Development of Tobacco Products (Originally issued June 2020, third revision September 7, 2022.)[58]
- Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance With an Order (Originally issued August 2015, revised March 17, 2023.)[59]
- Small Entity Compliance Guide: Further Amendments to General Regulations of the Food and Drug Administration to Incorporate Tobacco Products (Originally issued March 2012, revised March 17, 2023.)[60]
- *Listing of Ingredients in Tobacco Products* (Sixth revision March 17, 2023.[61])
- *Prohibition of Distributing Free Samples of Tobacco Products* (Originally issued October 2017, revised March 17, 2023.)[62]
- *Interpretation of and Compliance Policy for Certain Label Requirement; Applicability of Certain Federal Food, Drug, and Cosmetic Act Requirements to Vape Shops* (Originally issued March 2019, revised March 17, 2023.)[63]
- *Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (ENDS)* (Originally issued June 2019, revised March 17, 2023.)[64]
- *FDA Deems Certain Tobacco Products Subject to FDA Authority, Sales and Distribution Restrictions, and Health Warning Requirements for Packages and Advertisements* (Originally issued May 2016, seventh revision March 17, 2023.)[65]
- *Health Document Submission Requirements for Tobacco Products* (Originally issued April 2010, fifth revision March 31, 2023.)[66]
- *Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments* (Originally issued November 2009, eighth revision March 31, 2023.)[67]
- *Civil Money Penalties and No-Tobacco-Sale Orders For Tobacco Retailers* (Originally issued March 2011, seventh revision August 31, 2023.)[68]

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[58] https://www.fda.gov/media/83420/download.

[59]. https://www.fda.gov/media/93328/download.

[60] https://www.fda.gov/media/83261/download.

[61] https://www.fda.gov/media/101162/download.

[62] https://www.fda.gov/media/118928/download.

[63] https://www.fda.gov/media/102420/download.

[64] https://www.fda.gov/media/127853/download.

[65] https://www.fda.gov/media/143049/download.

[66] https://www.fda.gov/media/78616/download.

[67] https://www.fda.gov/media/78165/download.

[68] https://www.fda.gov/media/80888/download.

- *Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007* (Originally issued September 2014, revised October 17, 2023.)[69]
- *Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions* (Originally issued December 2016, third revision October 17, 2023.)[70]

D. Health Education

CTP engages in multiple educational efforts, including educating youth about the risks of tobacco products, educating people who use tobacco products about the benefits of cessation, and educating adults who smoke about the relative risks of tobacco products.

Public education campaigns are a proven, evidence-based component of comprehensive tobacco control efforts.[71] FDA has implemented multiple public education campaigns and other efforts designed to prevent youth use. From 2014 – 2016, FDA's first youth tobacco product prevention campaign, "The Real Cost," prevented more than 580,000 youth from starting to smoke cigarettes, saving the nation more than $53 billion by reducing smoking-related costs.[72] Preventing youth from initiating tobacco keeps the next generation of adults from smoking-related illness and death, ensuring a healthier future and advancing health equity for all Americans.

Since FDA launched "The Real Cost" campaign in 2014, the introduction of e-cigarettes and the rates of youth e-cigarette use over time have dramatically changed the tobacco product landscape. In response to e-cigarettes being the most commonly used tobacco product by youth, and to reflect current budget levels, FDA has prioritized youth e-cigarette prevention. The Agency will also continue to conduct foundational research and education outreach on other tobacco products that pose particular risk to specific populations and have shown recent increases in youth use, such as little cigars and cigarillos.

Below is a chart of FDA's current tobacco public education campaigns, followed by details on each of the listed campaigns.

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[69] https://www.fda.gov/media/173091/download.

[70] https://www.fda.gov/media/173089/download.

[71] https://www.cdc.gov/tobacco/stateandcommunity/guides/pdfs/2014/comprehensive.pdf

[72] Jennifer C. Duke, Anna J. MacMonegle, James M. Nonnemaker, et. al. "Impact of The Real Cost Media Campaign on Youth Smoking Initiation," *American Journal of Preventive Medicine*, Volume 57, Issue 5, 2019, Pages 645-651, https://doi.org/10.1016/j.amepre.2019.06.011.

Campaigns	Launch Date	Description
"The Real Cost" Cigarette Campaign	February 2014-Present	Educates at-risk youth aged 12–17 about the harmful effects of cigarette use.
"The Real Cost" E-Cigarette (ENDS) Campaign	September 2018-Present	Educates at-risk youth aged 12–17 about the harmful effects of e-cigarette use.
"Next Legends" American Indian/Alaska Native E-Cigarette (ENDS) Campaign	June 2022-Present	Educates at-risk American Indian/Alaska Native (AI/AN) youth aged 12–17 about the harmful effects of e-cigarette use.

1. "The Real Cost" – Cigarette Smoking Prevention

In February 2014, FDA launched its first national youth cigarette smoking prevention campaign, "The Real Cost,"[73] which was designed and proven to prevent youth from initiating smoking and to reduce the number of youth who moved from experimenting with tobacco products to regular use.

Since its launch, the campaign has shown positive results for reach and engagement, and over the past eight years, the campaign has reached up to 85 percent of teenagers nationwide and has generated over 23 billion ad views from the paid media. Across social media platforms, FDA has engaged teen audiences with more than 21 million likes, over one million shares, and over 4,450,000 comments. The campaign provided a significant return on investment, realizing a cost savings of $180 for every dollar of the nearly $250 million invested in the first two years of the effort. [74]

FDA continues to provide national paid media messages through digital media platforms such as YouTube, while exploring opportunities to deliver critical prevention messaging to specific audiences that are at higher risk of smoking. In January 2023, "The Real Cost" launched two new ads communicating scientific facts about cigarette smoking.

[73] https://www.fda.gov/tobacco-products/public-health-education-campaigns/real-cost-campaign

[74] Anna J. MacMonegle, James Nonnemaker, Jennifer C. Duke, Matthew C. Farrelly, Xiaoquan Zhao, Janine C. Delahanty, Alexandria A. Smith, Pamela Rao, Jane A. Allen, Cost-Effectiveness Analysis of The Real Cost Campaign's Effect on Smoking Prevention, American Journal of Preventive Medicine, Volume 55, Issue 3, 2018, Pages 319-325, ISSN 0749-3797, https://doi.org/10.1016/j.amepre.2018.05.006.

One ad, “Auctioneer,” focuses on the negative mental health effects of cigarette smoking and withdrawal, a new messaging area for the campaign. The other ad, “Said Every Smoker Ever,” introduces youth to the fact that three out of four teens who smoke will continue into adulthood and focuses on the negative consequences of cigarette use.

2. “The Real Cost” – E-cigarette Prevention

Due to the rates of e-cigarette use among youth and the strong evidence of the effectiveness of paid media campaigns to address tobacco product use, FDA adapted and expanded “The Real Cost” campaign to address e-cigarette use among youth. In September 2018, FDA launched “The Real Cost” e-cigarette campaign[75] with the goal of preventing youth e-cigarette use nationwide. The campaign was designed to prevent the nearly 10.7 million youth aged 12 to 17 who are open to using e-cigarettes from trying them and to reduce the number of youth who move from experimenting with e-cigarettes to regular use. The campaign has utilized many different forms and media such as television, online video channels, streaming channels, social media, and online radio. FDA continues to refine and evolve its tactics to ensure the campaign most effectively reaches the youth audience.

Between January 1, 2022, and December 31, 2023, FDA developed and implemented over 100 new video advertisements to appeal and adapt to the changing preferences and trends of the youth audience. To ensure maximum reach and engagement, the campaign implemented a media strategy at the beginning of each year by leveraging various digital platforms, social media channels, and other targeted advertising to amplify the reach and visibility of the videos.

Since launching in 2018, the campaign has reached up to 90 percent of all teenagers nationwide and has generated over 26 billion ad views. In addition, the campaign has engaged teen audiences resulting in more than 10.5 million likes, over 604,000 shares, and over 138,000 comments on social media.[76] The latest outcome evaluation results assessing the impact of “The Real Cost” youth e-cigarette prevention campaign indicate that exposure to the campaign increased population-level risk perceptions about the harms of e-cigarettes among youth.[77] Additionally, a recent randomized clinical trial

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[75] https://www.fda.gov/tobacco-products/real-cost-campaign/real-cost-e-cigarette-prevention-campaign

[76] Percent audience reach is calculated using the industry-standard formula of dividing the number of unique individuals exposed to an ad(s) by the total size of the target audience, then multiplying by 100. This provides the percentage of the target audience that has seen the ad(s). Engagement metrics, such as “likes,” “shares,” and “comments,” are counted and summed across platforms and indicate audience interest in, engagement with, and amplification of campaign content.

[77] MacMonegle, Anna J., et al. "Peer Reviewed: Effects of a National Campaign on Youth Beliefs and Perceptions About Electronic Cigarettes and Smoking." *Preventing Chronic Disease* 19

assessing the impact of “The Real Cost” found the campaign led to more negative perceptions towards e-cigarettes and lower susceptibility to use e-cigarettes in the future among youth.[78] In 2023, baseline data were collected from a new evaluation cohort of teens to assess the effectiveness of “The Real Cost” e-cigarette prevention messages in market over time. To date, results based on multiple years of outcome evaluation data find that the campaign effectively reaches youth at risk for e-cigarette use and increases their beliefs about the harms of vaping.

FDA also continues to partner with the National Cancer Institute (NCI) at the National Institutes of Health (NIH), NCI’s Smokefree.gov initiative to provide youth with resources for quitting e-cigarettes. Since launching the resources in 2019, the vaping cessation webpages have received more than 5 million views. “The Real Cost” connects youth to these resources on social media and various digital platforms.

3. “Next Legends” – American Indian/Alaska Native E-cigarette Prevention

FDA is also engaging in tailored education efforts focused on populations at higher risk of tobacco use. For example, in June 2022, FDA launched “Next Legends” – an e-cigarette prevention campaign that aims to educate American Indian and Alaska Native (AI/AN) youth, ages 12-17, about the harms of e-cigarette use by youth.[79] Native youth have historically been more susceptible to tobacco product use than their non-Native peers, and demonstrated disproportionately high experimentation with, and current use of, e-cigarettes.

The campaign uses unique branding and tailored messaging that is specifically designed to engage, appeal to, and educate AI/AN youth on the harmful effects of vaping and was built on extensive qualitative research that was conducted in partnership with Tribal leaders and AI/AN communities.

“Next Legends” is primarily a digital-based effort designed to reach Native teens on the platforms they commonly use, such as YouTube, Twitch, and Instagram. In addition to the campaign’s digital video and social media presence, select local events well-attended by Native youth are used to extend the message to AI/AN communities.

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[78] Noar, Seth M., et al. "Impact of vaping prevention advertisements on US adolescents: A randomized clinical trial." *JAMA Network Open* 5.10 (2022): e2236370-e2236370.

[79] https://www.fda.gov/tobacco-products/public-health-education-campaigns/next-legends-campaign

4. Vaping Prevention and Education Resource Center – English and Spanish

In September 2022, FDA launched the Vaping Prevention and Education Resource Center[80] containing lesson plans, activity sheets, videos, a student magazine, teacher blogs, informational fact sheets, and more. The Resource Center site and its contents were informed by FDA qualitative and quantitative research with educators to understand what resources teachers need related to youth e-cigarette prevention. The subsequent finding indicated a need for a "one stop" shop for educators to access the latest information and materials related to youth use of e-cigarettes. The resource center is routinely updated, and in early 2024 a Spanish version of the site[81] was established, allowing for all materials to be available to Spanish-speaking educators and students.

E. Regulatory Science

1. Expand Science Base for Regulatory Actions

A robust science base of data and evidence-driven approaches inform all CTP decision-making. A strong regulatory science base underpins the Center's entire framework: FDA's ability to develop product standards and other regulations and guidance documents, review product applications, support compliance and enforcement actions, and develop science-based public education campaigns. Within FDA, CTP is tasked with carrying out new research to drive tobacco regulatory action based on the best available science. In FY 2022 and 2023, FDA invested more than $325 million in scientific research with a focus on reducing youth initiation of tobacco products, reducing tobacco product harms, and encouraging those who already use tobacco products to quit or switch to tobacco products that are potentially less harmful.

CTP has identified priority areas for further research in each of the following domains:

- Product Composition and Design – Understanding the chemical constituents in tobacco products and the methods for measuring these constituents across products with diverse characteristics;
- Toxicity – Understanding how tobacco products and changes to tobacco product characteristics affect these products' potential to cause morbidity and mortality in users and nonusers through secondary exposure by studying, for example, animal (in vivo) and cell culture (in vitro) models and novel alternative toxicology

[80] https://digitalmedia.hhs.gov/tobacco/educator_hub

[81] https://digitalmedia.hhs.gov/tobacco/educator_hub?locale=es

approaches that test the toxicity of tobacco smoke (other than cigarette), aerosols, or specific constituents in tobacco and the tobacco product;
- Addiction – Understanding the effect of tobacco product characteristics on addiction and abuse liability across populations;
- Health Effects – Understanding the short- and long-term health effects of tobacco products (excluding conventional cigarettes) with a priority on longitudinal data. Areas of particular interest include cardiovascular, cancer, neurological (e.g., seizures), oral, reproductive, and respiratory health effects (including inflammation and lung disorders (e.g., asthma, COPD));
- Behavior – Understanding the knowledge, attitudes, perceptions, and behaviors related to tobacco product use and the impact of tobacco product characteristics on behaviors across populations;
- Communications – Understanding how to effectively communicate to the public, through media campaigns and digital media, about nicotine and the health effects of tobacco products;
- Marketing Influences – Understanding the impact of marketing on an individual's (1) susceptibility to and initiation of tobacco products (both classes of products and products within classes) and (2) transition between experimentation, initiation, regular use, product switching, dual use, and cessation-related behaviors among different populations. Topics may include marketing, advertising, digital media, and promotions; and
- Impact Analysis – Understanding the potential and actual impacts of FDA's regulatory actions.

FDA encourages research studies to include all populations appropriate to answering the research question, including populations disproportionately impacted by tobacco use, including youth and young adults, people from lower socioeconomic backgrounds (e.g., those with lower household incomes or lower educational attainment), certain racial or ethnic populations, people identifying as LGBTQI+, people living in rural areas, people who are pregnant or trying to become pregnant, active-duty military or veterans, people who are or have been incarcerated, people with mental health conditions, and people with substance use disorders.

FDA's tobacco regulatory science research covers a wide range of tobacco products, including cigarettes, e-cigarettes, cigars (large cigars, little cigars, cigarillos), heated tobacco, smokeless tobacco, snus, oral nicotine pouches, hookah (waterpipe), pipe tobacco, low-nicotine content cigarettes, and non-tobacco nicotine products. CTP, in addition to conducting independent research to support regulatory science, collaborates with other FDA Centers and Offices—including the National Center for Toxicological Research, the Center for Food Safety and Nutrition, and Office of the Chief Scientist—as well as other governmental agencies, including, but not limited to, NIH and CDC. Since FY 2010, CTP has funded 745 research projects, resulting in more than 4,100 peer-reviewed publications. During the reporting period of 2022 and 2023, CTP funded

an average of 217 active research projects, which resulted in more than 850 peer-reviewed publications.[82]

A cornerstone of FDA's tobacco regulatory science research program is the Tobacco Regulatory Science Program (TRSP), which is a unique collaboration between FDA and NIH. TRSP was jointly established to support the expansion of the regulatory science base related to tobacco products. TRSP has stimulated investigator-initiated research and released targeted funding opportunity announcements to address CTP's research priorities. For example, in 2022 and 2023, TRSP funded research evaluating the impact of flavored e-cigarettes on smoking behavior, the real-world impact of a low-nicotine product standard, and the potential impact of the removal of menthol from cigarettes among current menthol smokers.

FDA will continue to leverage extramural research and partnerships to inform evidence-based efforts to educate stakeholders and adults who use tobacco products about the relative risk of these products. For example, in August 2023 NIH published a Notice of Funding Opportunity reflecting the partnership between NIH and FDA to foster tobacco regulatory research to better understand the impact that messaging about the continuum of risk for tobacco products may have on various segments of the U.S. population. Findings from the collective efforts will inform potential future education efforts about relative risk, including tailored strategies for populations that experience tobacco-related health disparities.

A key component of the TRSP grant program was the establishment of the Tobacco Centers of Regulatory Science (TCORS)[83]. The TCORS are composed of scientists with a broad range of expertise (e.g., epidemiology, economics, toxicology, addiction, marketing) at research institutions across the United States. The TCORS have the ability and capacity to respond to FDA's research priorities as issues involving tobacco products and public health arise. Funds for this research were awarded beginning in FY 2013. Currently, seven research centers are funded for FY 2023 to 2027 as part of the third round of the TCORS program.

Another key component of FDA's tobacco regulatory science research program is the Population Assessment of Tobacco and Health (PATH) Study. FDA funds the PATH Study via contracts administered by NIH's National Institute on Drug Abuse, with both FDA and NIH collaborating on the scientific aspects of the study, such as the development of study measures and the appropriate inclusion of biomarkers to assess tobacco exposure and potential harm. The PATH Study is an ongoing, nationally

[82] The CTP publication database is available to the public through the TRS Publication Database https://trsknowledge.com/trs-publication-database

[83] https://prevention.nih.gov/tobacco-regulatory-research/funded-research/funded-research-tobacco-centers-regulatory-science

representative, longitudinal cohort study of approximately 46,000 users of tobacco products and non-users at risk for tobacco use, ages 12 and older. Research topics include evaluating patterns of tobacco use over time, such as switching products and using multiple products; perceptions, knowledge, and attitudes about tobacco use; health outcomes and biomarkers associated with tobacco use.

Since the PATH Study data collection started in FY 2013, the results of six data collection waves and three special collections have been made available to the public. Data from two additional collections are forthcoming. In particular, from January 1, 2022, through December 31, 2023, there were seven data releases from four waves of data and one special collection, with more than 1,700 data downloads of public-use data files. In 2022, the PATH Study released over 170 files with hundreds of online data tables and figures on youth and adult use of tobacco products, flavored tobacco use, and initiation and discontinuance of cigarette use. To help ensure research results are generalizable across all relevant populations and to inform health equity research, the PATH Study included analyses by age, sex, race and ethnicity, and educational attainment. Also, PATH Study data contributed to more than 250 peer-reviewed publications from 2022 through 2023. Studies examine youth and adult use of cigarettes, e-cigarettes, and other tobacco products; tobacco use initiation, cessation, and relapse; tobacco product attributes such as flavors and device type; perceptions of the harmfulness of tobacco products; and health disparities as a result of tobacco use.

2. The Annual National Youth Tobacco Survey (NYTS)

To provide critical data on youth use and perceptions of tobacco products, FDA collaborates with CDC to conduct the annual NYTS. The NYTS is a large survey of a nationally representative sample of middle and high school students that focuses exclusively on tobacco products. NYTS survey data allow FDA and CDC to monitor youth awareness of, susceptibility to, experimentation with, and use of a wide range of tobacco products.

Full NYTS data sets were published in 2022 and 2023, including youth rates of use of all tobacco products. E-cigarettes are the most commonly used tobacco product among youth. In October 2022, FDA and the CDC released e-cigarette product use data from the 2022 NYTS. Though methodological changes made in 2022 due to the COVID-19 pandemic prevented year-to-year comparisons of 2022 data to previous years, the 2022 study showed that e-cigarette use remained an ongoing concern. The study found that 2.55 million U.S. middle and high school students reported currently using e-cigarettes in 2022. Most reported using flavored products (84.9%), and disposable products (55.3%). Among students who reported using flavored e-cigarettes, approximately 7 of 10 used fruit flavors (69.1%), followed by candy, desserts, or other sweets (38.3%); mint (29.4%); and menthol (26.6%).

The 2022 NYTS conducted an oversample of AI/AN and Asian students. A recently published report using the 2022 NYTS data presented new tobacco use estimates for Asian, AI/AN, Native Hawaiian or Pacific Islander, and multiracial population groups, allowing measurement of disparities in tobacco product use affecting these groups.[84]

In November 2023, published data from the 2023 NYTS showed that a decline occurred in current e-cigarette use among high school students (14.1 percent in 2022 to 10.0 percent in 2023) while no statistically significant change occurred in e-cigarette use among middle school students (3.3 percent in 2022 to 4.6 percent in 2023). Despite the decline among high school students, in 2023, over 2 million U.S. youths reported current e-cigarette use; among those students, approximately 9 of 10 reported current use of flavored products, close to 40 percent of high school students reported frequent use (on ≥ 20 out of the 30 days), and 20.7 percent of middle school students reported frequent use.

3. Tobacco Products Scientific Advisory Committee

The 12-member TPSAC[85] is tasked with providing appropriate advice, information, and recommendations to the Secretary of HHS and the FDA Commissioner. TPSAC's activities include providing scientific advice on general issues (e.g., scientific issues pertaining to dependence and addiction), as well as providing recommendations regarding MRTPAs, filed with and reviewed by FDA. On May 18, 2023, the committee met in open session to discuss the proposed rule, *Requirements for Tobacco Product Manufacturing Practice*.[86]

4. Safety Reporting Portal

Since January 2014, consumers, health care professionals, and other members of the public have been able to use the Safety Reporting Portal (SRP), an online standardized reporting system, to submit voluntary reports about tobacco-related health or product problems. Since June 2016, manufacturers and researchers have also been able to use the SRP. FDA reviews all tobacco-related SRP reports to identify and monitor known and emerging safety issues.

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[84] https://www.cdc.gov/mmwr/volumes/71/wr/mm7145a1.htm

[85] Tobacco Products Scientific Committee. https://www.fda.gov/advisory-committees/committees-and-meeting-materials/tobacco-products-scientific-advisory-committee

[86] 88 FR 15,174, proposing regulations at 21 CFR part 1120.

- Between January 1, 2022, and December 31, 2023, 243 reports were submitted to the tobacco-specific questionnaires in SRP with the majority of these reports related to ENDS products. Safety issues that were monitored during this time period include ENDS-associated overheating/fire/explosion, seizure, and severe respiratory illness. Reporting to SRP has informed industry application reviews, public education efforts, and research priorities.

F. Public Outreach and Stakeholder Engagement

1. Engagement with State and Federal Partners, Public Health, Industry, Academia, and Other Interested Groups

FDA's listening sessions and meetings with stakeholders have provided outside parties with the opportunity to inform the Agency and provide information that may be useful for FDA's work. Engagements with industry provide an opportunity to gather information on shifts in the tobacco product market, marketing techniques, novel products, and other topics that help us better understand the products that FDA regulates. Topics covered during these engagements have included youth tobacco prevention strategies and technologies, synthetic nicotine, novel products, and perspectives on a tobacco product regulatory framework. During 2022 and 2023, FDA held 77 listening sessions and meetings with a broad array of stakeholders.

FDA has participated in many tobacco and public health conferences and meetings to present information to attendees and conduct outreach activities. During 2022 and 2023 alone, FDA participated in 44 conferences. At these tobacco-related conferences, FDA frequently hosted an exhibit booth. These exhibits provide an opportunity to educate diverse audiences about CTP's mission and strategic priorities and to engage with stakeholders who have a direct impact on public health infrastructure and communities. These exhibits also provide a platform for building awareness about FDA's regulatory authority, educating U.S. retailers about the legal age for tobacco sales, expanding the stakeholder network, garnering interest and involvement in the rulemaking process, supporting communication objectives, and disseminating FDA's messages and public education materials. Since beginning this outreach in 2013, FDA has exhibited at 238 conferences, with more than 4 million attendees combined.

2. Tribal Consultation and Engagement

The Agency maintains contact with Tribal governments and communities, including Tribal government leaders, Tribal health leaders, public health professionals, and other relevant federal agencies by various methods including, among other methods,

consulting with Tribes through meetings and "Dear Tribal Leader" letters[87] and communicating through presentations, webinars, and email updates.

FDA sent Dear Tribal Leader letters to the leaders of the Federally Recognized Tribes throughout the United States to inform them of opportunities for consultation on three proposed rules the agency had published. In April 2023, FDA held a consultation on the proposed rule *Requirements for Tobacco Product Manufacturing Practice* (TPMP proposed rule),[88] which would apply to manufacturers (foreign and domestic) of finished and bulk tobacco products and set forth requirements for the manufacture, preproduction design validation, packing, and storage of finished and bulk tobacco products. In June 2022, FDA held a consultation on two proposed rules *Tobacco Product Standard for Menthol in Cigarettes* (Menthol proposed rule)[89] and *Tobacco Product Standard for Characterizing Flavors in Cigars* (Cigar Flavors proposed rule).[90]

FDA issued a Dear Tribal Leader Letter in November 2022, describing an important federal law that went into effect clarifying FDA's authority to regulate commercial tobacco products containing non-tobacco nicotine.[91]

FDA participated in 10 HHS annual regional Tribal consultations held between May and August 2022.

In March 2023, FDA issued a Request for Information (RFI) to notify AI/AN Tribes that FDA was planning to obtain the services of federally recognized AI/AN Tribal governments to assist FDA in conducting commercial tobacco retail inspections within their jurisdictions, with the goal of protecting the public health, including reducing commercial tobacco use by youth. FDA noted that some AI/AN Tribes use traditional

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[87] https://www.fda.gov/federal-state-local-tribal-and-territorial-officials/tribal-affairs/dear-tribal-leader-letters

[88] See 88 FR 15174 (https://www.federalregister.gov/documents/2023/03/10/2023-04591/requirements-for-tobacco-product-manufacturing-practice) ; March 10, 2023 - Invitation to Consultation on the proposed rules for Requirement for Tobacco Product Manufacturing Practice (TPMP). https://www.fda.gov/media/166157/download?attachment

[89] https://www.federalregister.gov/documents/2022/05/04/2022-08994/tobacco-product-standard-for-menthol-in-cigarettes ; May 13, 2022 - Invitation to Consultation on the proposed rules for Tobacco Product Standards for Menthol in Cigarettes and Tobacco Product Standard for Characterizing Flavors in Cigars https://www.fda.gov/media/158519/download?attachment

[90] https://www.federalregister.gov/documents/2022/05/04/2022-08993/tobacco-product-standard-for-characterizing-flavors-in-cigars ; December 7, 2023 - Center for Tobacco Products releases the "FDA Commercial Tobacco Retail Compliance Check Inspection Program" webinar as a resource for federally recognized AI/AN Tribes. https://www.fda.gov/media/174574/download?attachment

[91] November 8, 2022 - Letter to Tribes regarding FDA's authority to regulate non-tobacco nicotine products. https://www.fda.gov/media/163164/download?attachment

(ceremonial) tobacco. The Agency does not regulate the use of traditional (ceremonial) tobacco and understands and respects the use of traditional tobacco by some AI/AN Tribes. The RFI provided high level information on the Tribal Commercial Tobacco Retail Inspection opportunity and solicited business and capability information from interested Tribes.

FDA developed a related webinar entitled "FDA Commercial Tobacco Retail Compliance Check Inspection Program,"[92] which describes a contracting opportunity for federally recognized AI/AN Tribes, highlights key elements of the Retail Compliance Check Inspection Program, and explains how AI/AN Tribes that are interested in partnering with FDA can find out more information about the program and contract opportunity. This new resource is available on FDA's website and was announced via a Dear Tribal Leader letter sent in December 2023.

3. International Engagement

To advance its regulatory mission to protect the public health of the U.S. population from tobacco-related disease and death, FDA has continued to engage with various international stakeholders, including foreign regulatory counterparts, ministries of health, embassies, foreign public health organizations, and multilateral organizations. Through this engagement, FDA has contributed to global collaboration among tobacco regulators regarding public health initiatives. Additionally, FDA has continued to gather valuable information on the regulatory experiences of other governments, particularly as they pertain to novel and emerging tobacco products. Because tobacco control regulators around the world study similar novel products and tobacco-related science and face similar regulatory issues, FDA has sought to learn from international counterparts.

In addition, FDA has continued to engage both bilaterally and multilaterally with these international stakeholders in several ways. For example, FDA has established confidentiality commitments with trusted government partners that might include the sharing of non-public information. From 2022 through 2023, 25 bilateral and multilateral meetings were conducted, and FDA responded to inquiries from over 10 countries.

[92] https://www.youtube.com/watch?v=EGxARZFSWYU

III. Resources

A. User Fees

Section 919 of 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: cigars, pipe tobacco, cigarettes, snuff, chewing tobacco, and roll-your-own tobacco. Section 919 also authorizes the total amount of tobacco user fees FDA must assess and collect each year. For the first 10 years of the FDA tobacco program, the total amount of user fee collections increased each year; however, beginning in FY 2019, the authorized amount of $712 million has been fixed for each subsequent fiscal year and not indexed to inflation.

In 2022 and 2023, CTP collected 99.8 percent and 98.9 percent respectively of the user fees assessed. Of the six classes that are assessed fees, cigarettes account for 85 percent, cigars account for 12.4 percent, snuff accounts for 1.4 percent, pipe tobacco accounts for 0.8 percent, chewing tobacco accounts for 0.07%, and roll your own tobacco accounts for 0.05 percent. In 2023, the U.S. District Court for the District of Columbia issued an order vacating FDA's Deeming Rule "as it applies to premium cigars."[93] Because of this decision, FDA notified cigar companies if they submit a dispute that includes good faith documentation establishing the portion of their assessment that is attributable to premium cigars, they may choose to withhold that portion of the assessment. This resulted in a portion of user fee funding associated with premium cigars not being received, thus causing a decrease in overall collections in FY 2023. The Agency is continuing to evaluate the evolving legal and practical circumstances of this ruling; however, there is potential that continued reduced collections could have significant impact on FDA tobacco priorities.

B. Staffing

Building a scientific knowledge base on tobacco products is critical to effective tobacco product regulation, and staffing is a central component to building this knowledge. Since CTP's inception, staffing has grown to over 1,100 employees dedicated to protecting the public health, including but not limited to consumer safety officers, policy analysts, regulatory health project managers, biologists, engineers, social scientists, pharmacologists, chemists, epidemiologists, physicians, toxicologists, management officers, communications specialists, and other professionals needed to design and

[93] *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.

implement a comprehensive program of tobacco product regulation.

CTP is composed of the following six offices:

- Office of the Center Director
- Office of Compliance and Enforcement
- Office of Health Communication and Education
- Office of Science
- Office of Regulations
- Office of Management

Tobacco program funding supported employees at CTP and other FDA employees assigned to tobacco product regulation, including employees in the Office of the Commissioner, Office of Operations, the Office of Regulatory Affairs, and the National Center for Toxicological Research. The following table displays full-time equivalent program levels from FY 2009– 2023.

Fiscal Year	Program Level Full-Time Equivalents
2009 Actual	0[94]
2010 Actual	113
2011 Actual	256
2012 Actual	426
2013 Actual	569
2014 Actual	650
2015 Actual	788
2016 Actual	844
2017 Actual	949
2018 Actual	971
2019 Actual	984
2020 Actual	1,087
2021 Actual	1,254
2022 Actual	1,303
2023 Actual	1,288

[94] From the time CTP was established on June 22, 2009, until the end of that fiscal year, 22 FDA personnel were temporarily detailed to CTP.

IV. Challenges and Opportunities

A. Resources

Manufacturers and importers of regulated tobacco products outside of the six product classes listed above do not pay tobacco user fees for their regulatory oversight. This includes e-cigarettes, despite being the most popularly used tobacco product among youth and requiring the expenditure of disproportionate regulatory resources. As a result, FDA has redirected existing funding resources to regulate e-cigarettes.

The Agency's budget, since FY 2020, has included a request for additional user fees. FDA is seeking to (1) authorize the Agency to assess user fees on, and collect such fees from, manufacturers and importers of all products subject to Chapter 9 of the FD&C Act; (2) increase the current limitation on total tobacco user fee collections by $100 million; and (3) index all collections to inflation.

B. Litigation

As of December 2023, more than 60 petitions challenging e-cigarette marketing decisions had been brought against FDA. Many cases are ongoing, and FDA is prepared for additional legal challenges as marketing decisions continue to be issued. Defending these lawsuits, including ongoing work to ensure that any marketing decisions are scientifically and legally defensible, is critical.

Since 2021, a majority of circuit courts have issued decisions regarding FDA's MDOs, and the Agency has prevailed in most cases. FDA has received favorable opinions in the Second, Third, Fourth, Seventh, Ninth, Tenth, and D.C. Circuits, all upholding decisions on flavored ENDS products. The Third Circuit issued the first decision[95] upholding a marketing denial order for a menthol ENDS product. A number of cases have reached settlements, and still others have been dismissed by the courts for various reasons. Cases continue to be adjudicated, and just in 2023, the Second, Third, Fifth, Ninth, Tenth, and D.C. Circuits have each issued decisions. FDA was successful in all but one of those instances.

While the decisions have largely reaffirmed the premarket review process, FDA carefully reviews each, regardless of the outcome, and considers whether the court's analysis warrants adjusting its review approach to ensure that it continues to issue

[95] Logic Technology Development LLC v. FDA, 84 F.4th 537 (3rd Cir. 2023).

orders that are appropriate. For example, the Fourth Circuit's[96] affirmation of FDA's approach nevertheless prompted reexamination of the role that marketing plans play in the overall PMTA review process. Providing a thorough legal analysis and making any subsequent adjustments to the review process often take significant time and must be implemented with care.

C. Areas of the Tobacco Control Act That Have Not Been Fully Implemented

FDA continues to work to implement all areas of the Tobacco Control Act, including regulations. The Agency is committed to protecting Americans from tobacco-related disease and death.

FDA continues to develop, draft, and issue regulations and guidance documents for industry to implement the Tobacco Control Act. One rule currently under development is entitled "Establishment Registration and Product Listing for Tobacco Products." This rule would prescribe the format, content, and procedures for domestic and foreign establishment registration and tobacco product listing requirements set forth under section 905 of the Tobacco Control Act. The rule would also define who would be required to register and list, when they would be required to register and list, and how they would be required to register and list their tobacco products.

FDA has yet to issue three rules contained in the Tobacco Control Act related to non-face-to-face sales; requirements for the testing and reporting of tobacco product constituents, ingredients, and additives; and requirements for recordkeeping for tracking and tracing illegal products.

When promulgating regulations, the Agency relies on its experiences to date in addition to research from outside FDA to complement Agency-conducted and -funded research that informs the Agency's rulemaking. The rulemaking process also generally is governed by the Administrative Procedure Act and other requirements found in Executive Orders. Although the rulemaking process can take several years to complete, FDA remains committed to issuing rules to implement the Tobacco Control Act.

[96] *Avail Vapor v. FDA*, 55 F.4th 409 (4th Cir. 2022).

V. Conclusion

Given the significant and harmful impact tobacco product use and exposure have on America's health, FDA's regulation of tobacco products remains a vital step in protecting the public health. From 2022-2023, FDA's accomplishments in tobacco regulation were substantial. Future resource building for FDA's tobacco program is critical to continue and to build on this important work.

This report was prepared by FDA's Center for Tobacco Products.
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This report is available on FDA's home page at https://www.fda.gov/.