



**U.S. FOOD & DRUG
ADMINISTRATION**

Report to Congress

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



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Executive Summary

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) amended the Federal Food, Drug, and Cosmetic Act to authorize the Food and Drug Administration (FDA or Agency) to oversee the manufacture, marketing, distribution, and sale of tobacco products and to protect the public from the harmful effects of tobacco product use. 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, 2020, to December 31, 2021—to implement that Act. During this time frame, FDA had several significant accomplishments related to its implementation of the Act, including the following:

- Issuing two foundational rules to provide additional information on the requirements for the content, format, and review of Premarket Tobacco Product Applications and Substantial Equivalence Reports—namely, the Premarket Tobacco Product Applications and Recordkeeping Requirements rule and the Content and Format of Substantial Equivalence Reports rule;
- Finalizing an enforcement policy for e-cigarettes and other unauthorized deemed products, resulting in the Agency taking action against over 200 online and brick-and-mortar establishments for selling unauthorized flavored, cartridge-based e-cigarette products;
- Preparing for the implementation of the premarket authorization requirement for electronic nicotine delivery systems (ENDS) and other “deemed” new tobacco products;
- Continuing work to transform the marketplace towards one in which deemed new tobacco products available for sale will have undergone careful, science-based review and oversight;
- Processing, reviewing, and acting on 99 percent of the applications for nearly 6.7 million deemed new tobacco products submitted and received by the court-ordered deadline of September 9, 2020;
- Issuing hundreds of warning letters to firms that continued to market deemed tobacco products either (1) without submitting an application to FDA or (2) after receiving a negative decision from the Agency, such as a Marketing Denial Order, a Refuse to Accept letter, or a Refuse to File letter;
- Issuing the first marketing decisions for ENDS product, including the first marketing granted order after determining that the marketing would meet the statutory standard of “appropriate for the protection of the public health”;

- Authorizing the marketing of a heated tobacco product as a modified risk tobacco product, only the second set of products to receive such authorization;
- Enforcing the provisions of a new law increasing the federal minimum age for sale of tobacco products from 18 to 21 years and updating related retailer educational materials;¹ and
- Educating youth, through the “The Real Cost” campaign, about the dangers of youth use of e-cigarettes, reaching almost 90 percent of teens in the United States.

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.

¹ On December 20, 2019, the President signed legislation amending the Federal Food, Drug, and Cosmetic Act, which raised the federal minimum age for sale of tobacco products from 18 to 21 years. This legislation became effective immediately, and it is now illegal for a retailer to sell any tobacco product—including cigarettes, cigars, and e-cigarettes—to anyone under the age of 21. The new federal minimum age of sale applies to all retailers, with no exceptions.

Acronym List

A	AI/AN	American Indian/Alaska Native
	APPH	Appropriate for the Protection of the Public Health
C	CCI	Confidential Commercial Information
	CDC	Centers for Disease Control and Prevention
	CDER	Center for Drug Evaluation and Research
	CMP	Civil Money Penalty
	CTP	Center for Tobacco Products
E	ENDS	Electronic Nicotine Delivery System
	EVALI	E-cigarette, or Vaping, Product Use-Associated Lung Injury
	EX REQ	Request Exemption from Demonstrating Substantial Equivalence
F	FDA	Food and Drug Administration
	FD&C Act	Federal Food, Drug, and Cosmetic Act
	FY	Fiscal Year
M	MDO	Marketing Denial Order
	MGO	Marketing Granted Order
	M RTP	Modified Risk Tobacco Product
	M RTPA	Modified Risk Tobacco Product Application
N	NCI	National Cancer Institute
	NIH	National Institutes of Health
	NSE	Not Substantially Equivalent
	NYTS	National Youth Tobacco Survey
O	OSBA	Office of Small Business Assistance
P	PATH	Population Assessment of Tobacco and Health
	PMTA	Premarket Tobacco Product Application
R	RTA	Refuse to Accept
	RTF	Refuse to File
S	SE	Substantial Equivalence
	SRP	Safety Reporting Portal
T	TCORS	Tobacco Centers of Regulatory Science
	TPSAC	Tobacco Products Scientific Advisory Committee
	TRSP	Tobacco Regulatory Science Program

I. Overview

Tobacco use is the single most preventable cause of disease, disability, and death in the United States. Each year, an estimated 480,000 Americans die prematurely from smoking or from exposure to second-hand smoke.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 tobacco products. This new authority gave FDA comprehensive tools—including a thorough science-based regulation of the manufacturing, marketing, and distribution of tobacco products—to protect the public from the harmful effects of tobacco use.

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

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.*

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.

II. FDA's Progress in Implementing the Tobacco Control Act

FDA's Center for Tobacco Products (CTP) continues to show major progress in fully implementing the Tobacco Control Act. This section of the report provides updates on priorities and major accomplishments, including objective measures of progress, during the reporting period (i.e., from January 1, 2020, to December 31, 2021).

A. CTP's Strategic Priorities

CTP's mission is to protect Americans from tobacco-related death and disease by regulating the manufacture, distribution, and marketing of tobacco products and by educating the public, especially young people, about tobacco products and the dangers that the use of such products poses to themselves and others. In support of this mission, CTP developed key Strategic Priorities.³ CTP's activities over the past 2 years align with these priorities.

- *Product Standards* – Advancing a product standard strategy that yields strong standards to improve public health and that can withstand legal challenge;
- *Comprehensive FDA Nicotine Regulatory Policy* – Establishing an integrated, FDA-wide policy on nicotine-containing products that is public health based;
- *Pre- and Post-Market Controls: Regulations and Product Reviews* – Exploring developing rules and guidance for product review pathways, Tobacco Product Manufacturing Practices, and analytic test method validation;
- *Compliance and Enforcement* – Conducting inspections, investigations, monitoring, and review activities and initiating appropriate enforcement actions that are supported by evidence;
- *Public Education* – Using proven, evidence-based strategies to educate at-risk audiences on the dangers of tobacco use, with a focus on youth e-cigarette prevention; and
- *Investing in Human Capital* – Growing the CTP workforce to support strategic initiatives and investing in that workforce to strengthen retention, diversity and inclusion, and engagement.

³ CTP's Key Strategic Priorities. FDA. <https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/ctps-key-strategic-priorities>.

B. Moving Toward a Fully Regulated Marketplace: Premarket Review and Actions for Deemed New Tobacco Products

1. Background

As defined in the Tobacco Control Act, *new tobacco products*⁴ may not be legally marketed in the United States without a tobacco product marketing order from the FDA. This requirement applies to all FDA-regulated tobacco products, including those affected by the “Deeming Rule,”⁵ which, as of the August 8, 2016, effective date, extended the Agency’s tobacco authority to all tobacco products that meet the statutory definition of a *tobacco product* (except accessories of deemed products).⁶

There are three pathways to market for new tobacco products:

- *Premarket Tobacco Product Application (PMTA)*⁷ – A PMTA may be submitted when an applicant is seeking marketing authorization for any new tobacco product. However, for some products, other pathways may be more suitable.
- *Substantial Equivalence (SE)*⁸ – A new tobacco product may be found “substantially equivalent” to a “predicate” product by demonstrating that the new product has the same characteristics as that predicate product, or if the product has different characteristics, by demonstrating that the new product does not raise different questions of public health than the predicate product.
- *Request Exemption from Demonstrating Substantial Equivalence (EX REQ)*⁹ – A tobacco product that is modified—either (1) by adding or deleting a tobacco additive or (2) by increasing or decreasing the quantity of an existing tobacco additive—may be considered for an exemption from demonstrating substantial equivalence.

⁴ A *new tobacco product* means “any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007” (section 910(a)(1) of the FD&C Act).

⁵ Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act. 81 FR 28973 (May 10, 2016).

⁶ Products deemed under the “Deeming Rule” include e-cigarettes and other electronic nicotine delivery systems (ENDS), cigars, hookah (also called waterpipe tobacco), pipe tobacco, nicotine gels, dissolvables that did not previously fall under FDA’s authority, and future tobacco products.

⁷ Premarket Tobacco Product Applications. FDA. <https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/premarket-tobacco-product-applications>.

⁸ Substantial Equivalence. FDA. <https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/substantial-equivalence>.

⁹ Exemption from Substantial Equivalence. FDA. <https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/exemption-substantial-equivalence>.

To receive a marketing order under the PMTA pathway, an applicant must provide scientific data that demonstrate that permitting the product to be marketed would be “appropriate for the protection of the public health” (APPH). As set forth in section 910(c)(4) of the FD&C Act, the finding as to whether the marketing of a tobacco product for which an application has been submitted is APPH shall be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account:

- The increased or decreased likelihood that existing users of tobacco products will stop using such products; and
- The increased or decreased likelihood that those who do not use tobacco products will start using such products.

Deemed products that meet the definition of a *new tobacco product* must have authorization from FDA to be legally marketed. However, as part of the Deeming Rule, FDA issued a compliance policy for electronic nicotine delivery systems (ENDS) and other deemed products that were on the market as of the date the rule took effect (i.e., August 8, 2016) that in effect provided additional time for manufacturers to obtain marketing authorization. FDA later updated this compliance policy in a guidance document (referred to in this document as the “August 2017 compliance policy guidance”) that extended the compliance period. During the compliance period, FDA stated that it did not intend to initiate enforcement against certain deemed products for failure to have premarket authorization.

At the time FDA issued the August 2017 compliance policy to modify the enforcement discretion policies regarding premarket authorization, nationally representative data suggested that youth use of e-cigarettes had declined.¹⁰ While no level of youth use is acceptable, FDA took this directional data into consideration, along with the potential benefits some of these products might provide to some addicted individual adult smokers seeking to make a complete transition away from combustible cigarettes.

The Agency was engaged in a public health balancing act. Given the then-existing evidence suggesting a decline in youth use, and with the potential for FDA to pursue other bold measures, in part by reducing the addictiveness of combustible cigarettes while temporarily delaying the likely immediate market exit of newly deemed tobacco products that could be potentially less harmful to individual users, FDA determined that the balancing of public health considerations argued in favor of a different comprehensive approach to nicotine and tobacco regulation.

However, only a year after we announced the 2017 comprehensive plan, the National Youth Tobacco Survey (NYTS) in 2018 showed a new and significant increase in youth use of e-cigarettes.

¹⁰ Jamal A, Gentzke A, Hu SS, et al. Tobacco Use Among Middle and High School Students — United States, 2011–2016. *MMWR Morb Mortal Wkly Rep* 2017;66:597–603. https://www.cdc.gov/mmwr/volumes/66/wr/mm6623a1.htm?s_cid=mm6623a1_w. The NYTS defines e-cigarettes as “battery-powered devices that provide nicotine and other additives to the user in the form of an aerosol.”

Meanwhile, the Agency’s 2017 modification to the compliance policy for the premarket review of deemed products was the subject of litigation. In May 2019, the U.S. District Court for the District of Maryland vacated FDA’s August 2017 compliance policy guidance.¹¹

2. *Court-Established Deadline*

In July 2019, the district court issued a further order¹² (with a subsequent extension due to the unique circumstances of the COVID-19 pandemic), which required that applications for deemed new tobacco products that were on the market as of August 8, 2016, be submitted to FDA by September 9, 2020. The court order also provided a 1-year period during which products with timely filed applications might remain on the market pending FDA’s review. In addition, in separate litigation,¹³ the U.S. District Court for the District of Columbia issued a ruling that FDA could not enforce the premarket review requirement against manufacturers of “premium cigars” as defined in that court’s ruling.

3. *Preparation for the Review of Deemed New Tobacco Products*

Prior to the September 9, 2020, deadline, FDA took multiple actions to help ensure that it was prepared to receive, process, and review what was expected to be an unprecedented number of applications for deemed new tobacco products, particularly from manufacturers of e-liquids, e-cigarettes, and other ENDS products. For example, FDA:

- Increased staffing in CTP’s Office of Science, CTP’s largest office, which is composed of 556 employees and accounts for 51 percent of CTP’s staff.
- Encouraged companies to submit their applications as early as possible and to make use of available FDA resources as a guide for their submission to the Agency.
- Published regulatory documents related to the application processes, such as the Refuse to Accept Procedures for Premarket Tobacco Product Submissions rule¹⁴ and the Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems guidance document.¹⁵

¹¹ *Am. Acad. of Pediatrics v. FDA*, 379 F. Supp. 3d 461 (D. Md. 2019).

¹² *Am. Acad. of Pediatrics v. FDA*, 399 F. Supp. 3d 479 (D. Md. 2019).

¹³ On Aug. 19, 2020, the U.S. District Court for the District of Columbia issued a ruling, in part, to prohibit FDA’s enforcement of the Tobacco Control Act’s premarket authorization requirement for premium cigars until after the Agency considers developing a streamlined SE process specifically for premium cigars. *Cigar Ass’n of Am. v. FDA*, 480 F. Supp. 3d 256 (2020). Accordingly, FDA currently is not enforcing the premarket review requirement against manufacturers of premium cigars (as those products were defined by the court).

¹⁴ 21 CFR 1105.10, available in the federal register at <https://www.federalregister.gov/documents/2016/12/29/2016-31370/refuse-to-accept-procedures-for-premarket-tobacco-product-submissions>.

¹⁵ This guidance document is available at <https://www.fda.gov/media/127853/download>.

- Held multiple meetings with manufacturers to hear about their products and scientific seminars to discuss the details and constituents of certain tobacco products (such as ENDS products and e-liquids).
- Engaged in research to fill knowledge gaps about certain tobacco products.
- Improved systems to electronically receive, at any date and/or time, tobacco product application submissions through the CTP Portal or Electronic Submissions Gateway.
- Provided resources, such as webinars and a dedicated public website, to help industry prepare and submit premarket applications. Better quality applications can result in faster FDA processing and review.

4. *PMTA Review Process and Status Update*

FDA received premarket applications for nearly 6.7 million tobacco products by the September 9, 2020, deadline. While the initial processing of PMTAs was challenging due to the size, complexity, and diversity of the submissions, as well as the wide variety of content in each submission, tremendous progress was made between the deadline and December 31, 2021 (the end of the reporting period for this report).

CTP conducts the following three-phase review for PMTAs: (1) acceptance review, (2) filing review, and (3) substantive review. First, the acceptance review entails determining whether the product falls under the jurisdiction of CTP and whether the application meets certain basic requirements, like being in an accessible electronic format and including an environmental assessment. FDA completed the acceptance review for all submissions received by the September 9, 2020, deadline.¹⁶ Of the nearly 6.7 million products that were the subject of timely submitted applications, FDA refused to accept the applications for approximately 220,000 products that did not meet the basic application requirements.

Second, the filing review entails determining whether the application contains all the items required by statute or regulation, like ingredient listings, labels for each product to be marketed, and adequate environmental assessments. As part of this filing review, the Agency refused to file the applications for over 5 million products. By December 2021, FDA had completed the filing review for about 95 percent of the applications submitted via the PMTA pathway by the September 2020 deadline.

Third, 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. This multi-disciplinary approach helps determine if marketing the new product would be appropriate for the protection of the public health and whether it should receive an order allowing the introduction or delivery for

¹⁶ This deadline applied to deemed new tobacco products on the market as of August 8, 2016.

introduction into interstate commerce.

When FDA completes its review, there are one of two actions the Agency typically takes: (1) a Marketing Denial Order (MDO) or (2) a Marketing Granted Order (MGO). On October 12, 2021, FDA issued the first MGOs for a closed ENDS device and accompanying tobacco-flavored e-liquid pods. By December 31, 2021, FDA had issued MDOs for more than 1.2 million flavored ENDS products after determining that the related applications lacked sufficient evidence to demonstrate that the marketing of these products would be appropriate for the protection of the public health.

5. *SE and EX REQ Review Process and Status Update*

Although the vast majority of the premarket applications submitted by the September 9, 2020, deadline were for ENDS products and therefore were submitted to the Agency through the PMTA pathway, FDA also received applications for other deemed products via the SE and EX REQ pathway. The Agency continues to make considerable headway in reviewing all applications received, and it has consistently updated the public about its progress.

By September 2021, FDA had completed, via all three pathways, the acceptance review for all submissions received by the September 2020 deadline. For the SE pathway, FDA accepted applications for more than 5,200 products and issued Refuse to Accept (RTA) letters for applications for roughly 1,900 products. For the EX REQ pathway, FDA accepted applications for more than 240 products and issued RTA letters for applications for about 100 products.

By December 31, 2021, FDA's substantive review has resulted in SE marketing orders for over 120 products and EX REQ orders for over 250 products.

6. *Next Steps for the Premarket Review of Deemed New Tobacco Product Applications*

FDA's review of premarket applications, including applications submitted after the court-ordered deadline, is ongoing. By December 31, 2021, FDA had taken action on 99 percent of the timely submitted premarket applications. The Agency is continuing to devote significant resources to expeditiously resolve the remaining pending applications and is issuing further decisions on a rolling basis.

7. *Review Metrics and Public List of Submissions*

FDA is committed to providing updates and other information about its review of products to the public through posting online perspective pieces, metrics, and a list of non-confidential information about product applications. FDA regularly updates its Tobacco Product Applications: Metrics & Reporting web page with reporting and information on the progress of FDA's intermediate and final actions taken on premarket applications—PMTA, SE Report, and EX REQ—across the application review process.¹⁷ The information posted includes data broken

¹⁷ Tobacco Product Applications: Metrics & Reporting, available at <https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-product-applications-metrics-reporting> (updated on Jan. 18, 2022).

down into various categories, such as product type and review milestones. FDA provides these metrics and data on a regular basis, typically within a month of the closing of the reporting period.

In addition, FDA developed lists of deemed new tobacco products for which a timely premarket application was received. In March 2021, FDA posted a list of products that are the subject of timely applications received through the SE and EX REQ pathways.

On May 20, 2021, FDA posted a list of products for which a premarket application was received via the PMTA pathway by September 9, 2020 and for which the manufacturers of these products indicated that the products were on the U.S. market as of August 8, 2016.¹⁸ Generally, the submission of a premarket application and intent to commercially market a new tobacco product that has never been marketed would be considered confidential commercial information (CCI) that FDA would not disclose. However, the products included in the “Lists of Deemed New Tobacco Products with Timely Applications” are being treated differently because FDA has determined that, based on communications with the applicants, these deemed new tobacco products were currently being marketed; therefore, the submission of their premarket applications could be disclosed. FDA had to ensure that the development and posting of the list was done in accordance with applicable laws; for example, FDA needed to contact each individual applicant to request the dates of initial marketing and current marketing status of each product for which an application was submitted by the deadline.

C. Preventing Youth from Initiating and Using Tobacco Products

Protecting our nation’s youth from the dangers of tobacco products is among FDA’s most important responsibilities, and the Agency continues to take steps to make sure tobacco products are not being marketed or sold to youth.

FDA remains focused on its regulatory oversight of e-cigarettes, other ENDS products (the most commonly used tobacco product by youth), and tobacco products that are specifically marketed towards youth. As noted below, data from the 2021 NYTS showed that more than 2 million middle and high school students reported currently using e-cigarettes in 2021.

FDA’s work to protect youth from tobacco products is wide ranging and includes, among other activities, the premarket review of new tobacco products, compliance and enforcement actions, and public education. These three areas are discussed in turn below.

First, ensuring new tobacco products undergo a premarket evaluation by FDA is a critical part of the Agency’s mission to protect the public health. Although the authorization of a new tobacco product does not mean the product is safe, FDA’s review process under the PMTA pathway ensures that the marketing of the product is APPH taking into account the risks and benefits to the population as a whole, including youth, the increased or decreased likelihood that

¹⁸ See the Deemed New Tobacco Product Applications Lists, available at <https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/deemed-new-tobacco-product-applications-list>.

existing users of tobacco products will stop using such products, and the increased or decreased likelihood that those who do not use tobacco products will start using such products.

The prevention of initiation and assessment of a new product's likely impact on addiction, especially among youth, is important in determining whether permitting the marketing of a new tobacco product would be APPH. Issues related to the manufacturing and marketing of ENDS products, including e-cigarettes from the use of flavors and nicotine salts, to the levels of nicotine in the finished product, and the manner in which the product is marketed and sold are all factors FDA considers as part of the review of PMTAs for these products. FDA also assesses the health risks and benefits associated with changes in tobacco product use behavior (e.g., initiation, switching, dual use, cessation) that are likely to occur with the marketing of the new tobacco products.

As part of the PMTA review process, as set out by FDA's PMTA rule¹⁹, FDA can put in place postmarket requirements aimed at, among other things, monitoring market dynamics such as potential youth uptake. If the Agency determines the continued marketing of a product is no longer APPH, such as if there is a significant increase in youth initiation, FDA may suspend or withdraw a marketing order issued under the PMTA pathway for a variety of reasons.

Second, compliance and enforcement actions play a key role in stopping youth use of, and access to, ENDS products and other tobacco products. For example, from January 2020 through December 2021, FDA:

- Conducted over 81,000 tobacco retail inspections to crack down on the sale of tobacco products, including ENDS products, to underage persons at brick-and-mortar and online retailers;
- Refused admission into the United States over 380 lines of ENDS products, including disposables, worth over \$2.5 million for violations of the FD&C Act; and
- In collaboration with U.S. Customs and Border Protection, seized more than 2 million units of unauthorized e-cigarettes worth over \$1.5 million.

Third, FDA's public education campaigns have been a powerful tool for preventing youth from initiating the use of tobacco products, including flavored ENDS products. For instance, "The Real Cost" cigarette prevention campaign, which launched in 2014, has prevented more than 587,000 teens from initiating cigarette smoking.²⁰

¹⁹ 21 CFR 1114, available in the Federal Register at <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-K/part-1114>.

²⁰ Duke JC, MacMonegle AJ, Nonnemaker JM, et. al. Impact of *The Real Cost* Media Campaign on Youth Smoking Initiation. 2019. *Am. J. Prev. Med.* 2019;57:645-651. DOI: [10.1016/j.amepre.2019.06.011](https://doi.org/10.1016/j.amepre.2019.06.011).

D. Regulations and Guidance Documents

FDA's mission to protect Americans from tobacco-related death and disease is accomplished, in part, by issuing regulations and guidance documents that explain FDA's expectations to the regulated industry and the public. These documents serve to implement the Tobacco Control Act.

1. *January 2020 Enforcement Priorities Guidance Document*

On January 2, 2020, FDA issued a final guidance document entitled *Enforcement Priorities for Electronic Nicotine Delivery System (ENDS) and Other Deemed Products on the Market Without Premarket Authorization*, which was later revised in April 2020.²¹ This document states that CTP would prioritize enforcement against certain unauthorized ENDS products, such as flavored ENDS products that appeal to kids, including fruit and mint flavored products.

On February 6, 2020, FDA began to prioritize enforcement against illegally marketed ENDS products by focusing on the following groups of products that did not have premarket authorization:

- Any flavored, cartridge-based ENDS product (other than a tobacco- or menthol-flavored ENDS product);
- All other ENDS products for which the manufacturer has failed to take (or is failing to take) adequate measures to prevent minors' access; and
- Any ENDS product that is targeted to minors or likely to promote use of ENDS products by minors.

The guidance document also stated that FDA would prioritize enforcement against any ENDS products that were continuing to be sold and for which the manufacturers had not submitted a premarket application by the September 9, 2020, submission deadline (or after a negative action by FDA on a timely submitted application). Examples and data on these enforcement actions are outlined in the Compliance and Enforcement section of this report.

2. *Final Rules Issued*

a. Cigarette Health Warnings Final Rule

The Agency undertook a science-based approach to develop and evaluate new warnings that focus on serious health conditions that are less known by the public to be caused by smoking, such as bladder cancer, diabetes, erectile dysfunction, and conditions that can cause blindness. On March 18, 2020, to promote a greater public understanding of the negative health

²¹ *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised)** (April 2020). FDA. <https://www.fda.gov/media/133880/download>.

consequences of smoking, FDA issued a final rule²² to require new health warnings on cigarette packages and in advertisements. This rule requires the warnings to appear prominently on cigarette packages and in advertisements.

Now finalized, this rule fulfills a requirement in the Tobacco Control Act and will complement additional important work FDA is undertaking to advance the health of America's families.²³ However, the U.S. District Court for the Eastern District of Texas has issued multiple orders postponing the effective date of the final rule.²⁴ See *R.J. Reynolds Tobacco Co. et al. v. United States Food and Drug Administration et al.*, No. 6:20-cv-00176.

b. Final Rules Related to PMTAs and SE Reports

On October 4, 2021, FDA issued two final rules for the premarket review of new tobacco products.²⁵ These foundational rules provide additional information on the requirements for the content, format, and review of PMTAs²⁶ and SE Reports,²⁷ which are two of the most commonly used pathways through which a manufacturer can seek marketing authorization from FDA for a new tobacco product. The finalization of these rules has helped ensure that all submissions contain the basic information needed to determine whether the new tobacco products meet the statutory standard in the FD&C Act.

The PMTA rule is intended to improve the efficiency of the review process, for both FDA and industry, by helping to ensure that PMTAs contain sufficient information for FDA to determine whether an MGO should be issued and by providing clarity to industry as to what information is needed in a PMTA to permit full review. This rule establishes procedures for a more predictable review process and describes postmarket reporting requirements to help ensure FDA can adequately monitor the public health impact of PMTA-authorized products.

The SE final rule provides additional information on the requirements for the content and format of SE reports, allowing for greater predictability and efficiency for all stakeholders by providing

²² Tobacco Products; Required Warnings for Cigarette Packages and Advertisements. 85 FR 15638 (March 18, 2020).

²³ Following the March 2020 publication of this rule, two lawsuits were filed in federal district court challenging the rule: (1) *R.J. Reynolds Tobacco Co. et al. v. United States Food and Drug Administration et al.*, No. 6:20-cv-00176 (U.S. District Court for the Eastern District of Texas, April 3, 2020) and (2) *Philip Morris USA Inc. and Sherman Group Holdings LLC v. United States Food and Drug Administration et al.*, No. 1:20-cv-01181 (U.S. District Court for the District of Columbia, May 6, 2020). These cases are ongoing, and the court in *R.J. Reynolds* has granted multiple extensions of the effective date of the final rule while litigation is pending.

²⁴ At the time of this report, the new effective date of the final rule is July 8, 2023.

²⁵ FDA Finalizes Two Foundational Rules for Companies Seeking to Market New Tobacco Products. FDA. <https://www.fda.gov/news-events/press-announcements/fda-finalizes-two-foundational-rules-companies-seeking-market-new-tobacco-products>.

²⁶ Premarket Tobacco Product Applications and Recordkeeping Requirements. 86 FR 55300 (October 5, 2021) (codified at 21 CFR 1107).

²⁷ Content and Format of Substantial Equivalence Reports; Food and Drug Administration Actions on Substantial Equivalence Reports. 86 FR 55224 (October 5, 2021) (codified at 21 CFR 1107).

applicants with a better understanding of the level of detail that an SE report must contain for FDA to evaluate the comparison of the new tobacco product to a predicate tobacco product.

3. *Selected Regulations in Progress*

a. Tobacco Product Manufacturing Practice

FDA is developing a proposed rule that would set forth requirements for the manufacture, pre-production design validation, packing, and storage of a tobacco product. This regulation would provide the framework that tobacco product manufacturers must follow when manufacturing tobacco products. FDA continues to work on this effort.

b. Product Standards for Menthol Cigarettes and Flavored Cigars

On April 29, 2021, FDA announced²⁸ that it was working toward issuing two proposed product standards in 2022. The first proposes to prohibit menthol as a characterizing flavor in cigarettes, and the second proposes to prohibit all characterizing flavors (other than tobacco) in cigars. The authority to adopt product standards such as these is one of the most powerful tobacco regulatory tools Congress gave the Agency. These forthcoming standards are based on clear science and evidence establishing the addictiveness and harm of menthol cigarettes and flavored cigars and build on a statutory prohibition of all other flavored cigarettes since 2009. When final, these actions will help significantly reduce youth initiation, increase the chances of smoking cessation among current smokers, and address health disparities experienced by communities of color, low-income populations, and lesbian, gay, bisexual, transgender, and queer (LGBTQ+) individuals, all of whom are far more likely to use these tobacco products.

c. Increase in the Federal Minimum Age for the Sale of Tobacco Products

In December 2019, the President signed legislation raising the federal minimum age for sale of tobacco products from 18 to 21 years. Effective immediately, this law (known as “Tobacco 21”) makes it illegal for a retailer to sell any tobacco product—including cigarettes, cigars, and e-cigarettes—to anyone under the age of 21. The new federal minimum age of sale applies, with no exceptions, to all retail establishments and persons. FDA is continuing to work on a final rule to make conforming changes to its regulations to reflect this increased minimum age of sale for tobacco products and to increase the age for checking buyers’ IDs.

A complete list of all tobacco-related regulations and guidance documents can be found in Appendix A.

E. Scientific Efforts to Expand the Knowledge Base for the Regulated Products

²⁸ FDA Commits to Evidence-Based Actions Aimed at Saving Lives and Preventing Future Generations of Smokers. FDA. <https://www.fda.gov/news-events/press-announcements/fda-commits-evidence-based-actions-aimed-saving-lives-and-preventing-future-generations-smokers>.

1. *Expand the Science Base for Regulatory Actions*

A strong science base is a key underpinning of the tobacco regulatory framework and FDA's ability to develop product standards, review product applications, support compliance and enforcement actions, and develop science-based public education campaigns. Within FDA, CTP is tasked with using the science that is currently available and with carrying out new research to drive tobacco regulatory action based on the best available science. In fiscal years (FYs) 2020 and 2021, FDA invested more than \$454 million in scientific research with a focus on reducing youth initiation of tobacco use, reducing tobacco product harms, and encouraging those who already use tobacco products to quit or switch to tobacco products that are potentially less harmful.

2. *Tobacco Science and Research*

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 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 that include, when appropriate to the research question, vulnerable populations, including (but not limited to) youth and young adults, individuals from lower socioeconomic backgrounds (e.g., those with lower household incomes or lower educational attainment), racial or ethnic minorities, sexual and/or gender minorities, rural populations, individuals who are pregnant or trying to become pregnant, active-duty military or veterans, individuals who are or have been incarcerated, and individuals with mental health conditions or 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, dissolvables, hookah (waterpipe), pipe tobacco, roll-your-own tobacco, and bidis, as well as low-nicotine cigarettes. CTP, in addition to conducting independent research to support regulatory science, collaborated 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, the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC). Since FY 2010, CTP has funded 650 research projects, resulting in more than 3,000 peer-reviewed publications. In particular, during FY 2020 and FY 2021, CTP funded approximately 250 active research projects each fiscal year, which resulted in more than 1,000 peer-reviewed publications over those 2 fiscal years.

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.

A key component of the TRSP grant program was the establishment of the Tobacco Centers of Regulatory Science (TCORS).²⁹ The TCORS are composed of scientists with a broad range of expertise (e.g., in epidemiology, economics, toxicology, addiction, and marketing) at research institutions across the country. 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, nine research centers are funded for

²⁹ Tobacco Centers of Regulatory Science (TCORS). FDA. <https://www.fda.gov/tobacco-products/research/tobacco-centers-regulatory-science-tcors>.

FY 2018 to FY 2022 as part of the TCORS 2.0 program.³⁰ NIH and FDA intend to reissue the TCORS grant program in FY 2023.

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 a contract 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 appropriate inclusion of biomarkers to assess tobacco exposure and potential harm. The PATH Study is an ongoing, nationally 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; and biomarkers associated with tobacco use.

Since the PATH Study data collection started in FY 2013, the results of five data collection waves and one special collection have been made available to the public. Data from two additional collections are forthcoming. In particular, during 2020 and 2021, there were seven data releases from three waves of data collection, with more than 2,100 data downloads of public-use data files. Over the same time frame, PATH Study data contributed to more than 250 peer-reviewed publications. Study methods were adapted during this period to allow data collections to continue yielding nationally representative data for adults and youth 13 years of age and older on tobacco use, including the use of electronic nicotine products during the COVID-19 pandemic. Studies examine youth 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.

3. *The Annual NYTS*

To provide critical data on youth use and perceptions of tobacco products, FDA collaborates with the CDC's Office of Smoking and Health 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. 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.

In September 2020, published data from the 2020 NYTS, collected prior to the COVID-19 pandemic, showed a decline in current e-cigarette use among high and middle school students—i.e., 19.6 percent of high school students, down from 27.5% the previous year, and 4.7 percent of middle school students, down from 10.5% the previous year were current e-cigarette users. Despite the decline in current use, in 2020, approximately 3.6 million U.S. youths reported

³⁰ Tobacco Centers of Regulatory Science (TCORS). FDA. <https://www.fda.gov/tobacco-products/research/tobacco-centers-regulatory-science-tcors>.

current e-cigarette use, more than 8 out of 10 youth users reported current use of flavored e-cigarettes, and disposable e-cigarette use increased significantly from 2019.³¹

In September 2021, FDA and the CDC released ENDS product use data from the 2021 NYTS. Though methodological changes made in 2021 during the COVID-19 pandemic prevented year-to-year comparisons of 2021 data to previous years, the 2021 study showed that e-cigarette use remained an ongoing concern. The study found that more than 2 million U.S. middle and high school students reported currently using e-cigarettes in 2021, with more than 8 in 10 of those youth using flavored e-cigarettes. Overall, the most commonly used flavor types were fruit; candy, desserts, or other sweets; mint; and menthol.

4. *Tobacco Products Scientific Advisory Committee*

The 12-member Tobacco Products Scientific Advisory Committee (TPSAC)³² is tasked with providing appropriate advice, information, and recommendations to the Secretary of Health and Human Services 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 modified risk tobacco product applications (MRTPAs) filed and reviewed by FDA.

On February 14, 2020, the Committee met in open session to discuss MRTPAs submitted for certain cigarette tobacco products.³³ The format for this meeting was discussion only with no voting and no recommendations.

5. *Safety Reporting Portal*

Since January 2014, consumers, healthcare professionals, and other members of the public have been able to use the Safety Reporting Portal (SRP),³⁴ an online standardized reporting system, to submit voluntary reports about tobacco-related health or product problems. Since June 2016, manufacturers and researchers similarly have been able to use the SRP. In October 2020, FDA announced that several updates were made to the SRP questionnaires to better capture information about affected individuals, pre-existing health conditions, and product-specific details. FDA reviews all tobacco-related SRP reports to identify and monitor known and emerging safety issues.

³¹ Wang TW, Neff LJ, Park-Lee E, Ren C, Cullen KA, King BA. E-cigarette Use Among Middle and High School Students—United States, 2020. *MMWR Morb Mortal Wkly Rep* 2020;69:1310-1312. DOI: <http://dx.doi.org/10.15585/mmwr.mm6937e1>.

³² Tobacco Products Scientific Committee. FDA. <https://www.fda.gov/advisory-committees/committees-and-meeting-materials/tobacco-products-scientific-advisory-committee>.

³³ February 14, 2020: Tobacco Products Scientific Advisory Committee Meeting. FDA. <https://www.fda.gov/advisory-committees/advisory-committee-calendar/february-14-2020-tobacco-products-scientific-advisory-committee-meeting-02142020-02142020>.

³⁴ Safety Reporting Portal for Tobacco Products. FDA. <https://www.fda.gov/tobacco-products/tobacco-science-research/safety-reporting-portal-tobacco-products>.

Between January 1, 2020, and December 31, 2021, 251 new tobacco-related reports were submitted to the SRP, with the majority of those reports related to ENDS products. Safety issues that were monitored or identified during this time period included ENDS product-associated overheating/fire/explosion, seizure, severe respiratory illness, potential electromagnetic interference, and medical oxygen-associated events. Reporting to SRP has informed industry application reviews, public education efforts, and research priorities. For example:

- For public awareness, CTP posted redacted reports³⁵ of and a special announcement³⁶ on a relationship between ENDS product use and seizures.
- For public awareness and increased safety, CTP updated its *Tips to Help Avoid Vape Battery or Fire Explosions*.³⁷
- CTP collaborated with FDA’s Center for Drug Evaluation and Research (CDER) on CDER’s effort to expand medical oxygen labeling to include a warning against proximate ENDS product use.
- CTP scientists participated in FDA’s collaboration with the CDC on the E-cigarette, or Vaping, Product Use-Associated Lung Injury (EVALI) investigation.³⁸

F. Compliance and Enforcement

1. Compliance and Enforcement Actions Related to a Lack of Premarket Authorization

Applications for the premarket review of deemed new tobacco products on the market as of August 8, 2016, were required to be submitted to FDA by September 9, 2020.³⁹ Certain deemed new tobacco products, including new ENDS products for which no application is pending (including, for example, those with an MDO and those for which no application was submitted), remain among FDA’s highest enforcement priorities. In a collaborative effort among FDA’s

³⁵ Tobacco Product Problem Reports. FDA. <https://www.fda.gov/tobacco-products/tobacco-science-research/tobacco-product-problem-reports>.

³⁶ Some E-cigarette Users Are Having Seizures, Most Reports Involving Youth and Young Adults. FDA. <https://www.fda.gov/tobacco-products/ctp-newsroom/some-e-cigarette-users-are-having-seizures-most-reports-involving-youth-and-young-adults>

³⁷ Tips to Help Avoid Vape Battery or Fire Explosions. FDA. <https://www.fda.gov/tobacco-products/products-ingredients-components/tips-help-avoid-vape-battery-or-fire-explosions>.

³⁸ Lung Injuries Associated with Use of Vaping Products. FDA. <https://www.fda.gov/news-events/public-health-focus/lung-injuries-associated-use-vaping-products>.

³⁹ Per a court ruling issued Aug. 19, 2020, FDA will not enforce the premarket review requirement for “premium cigars,” as defined in that ruling, until after it considers developing a streamlined SE process specifically for these products. (See <https://www.fda.gov/tobacco-products/ctp-newsroom/ctp-statement-premarket-authorization-requirements-premium-cigars>). Additionally, some deemed tobacco products that are considered *Pre-Existing* because they were commercially marketed in the United States as of Feb. 15, 2007, therefore do not require premarket applications (unless the products were since modified). 21 CFR 1107.3.

tobacco product manufacturer inspection and internet surveillance programs, the Agency issued warning letters to firms not in compliance with the premarket requirements.⁴⁰ From September 9, 2020, through December 31, 2021, FDA issued more than 200 warning letters to manufacturing firms selling and/or distributing unauthorized ENDS products that did not submit premarket applications by the September 9, 2020, deadline. Collectively, these companies have listed⁴¹ a total of over 17 million tobacco products with FDA. In addition, from the time FDA began issuing deemed tobacco marketing orders, including negative orders, through December 31, 2021, CTP issued more than 75 warning letters to companies for continuing to unlawfully market ENDS products that were the subject of a negative decision, such as an MDO, an RTA letter, or a Refuse to File (RTF) letter.

2. *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 webpage⁴² contains pertinent information about each jurisdiction where FDA has contracts, including the most recent contract start date in those jurisdictions.

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 states and territories under contract. FDA has commissioned and trained more than 700 officials who conduct inspections on the Agency's behalf.

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, 2021.⁴³

⁴⁰ Warning Letters. FDA. <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters>.

⁴¹ Section 905 to the FD&C Act (21 U.S.C. 387e) requires the owners and operators of domestic manufacturing establishments engaged in manufacturing tobacco products to register with FDA and submit product listings.

⁴² FDA Tobacco Retail Inspection Contracts. FDA. <https://www.fda.gov/tobacco-products/retail-sales-tobacco-products/fda-tobacco-retail-inspection-contracts>.

⁴³ CTP Compliance & Enforcement. FDA. <https://www.fda.gov/tobacco-products/compliance-enforcement-training/ctp-compliance-enforcement>.

Number of Regulation Violations	CMP Amount⁴⁴
1	\$0, warning letter issued
2 within a 12-month period	\$301
3 within a 24-month period	\$601
4 within a 24-month period	\$2,409
5 within a 36-month period	\$6,022
6 within a 48-month period	\$12,045

Due to public health safety concerns related to the coronavirus pandemic, FDA temporarily suspended its inspections from March through September 2020. During that time frame, FDA issued partial Stop-Work-Orders to retail inspection contractors and instituted systems to determine where and when it may be relatively safe to resume inspections. In the fall of 2020, retailer inspections resumed on a limited basis, increasing throughout the year. Although inspections have now resumed, they have not yet returned to the pre-pandemic level of activity due to continued concerns related to the pandemic. From January 1, 2020, through December 31, 2021, over 81,000 inspections of tobacco retailers were conducted.

With the passage of the Tobacco 21 law in December 2019, FDA began implementing and enforcing its provisions by incorporating the law into FDA’s tobacco retail inspection program. All contracts, IT systems, template documents, guidance documents, webpages, retailer education and compliance training related to the new federal minimum age for sale were updated to reflect the changes to the law. These updates included enhancing FDA’s public searchable database of tobacco retail compliance check inspection results⁴⁵ to address program changes related to Tobacco 21. FDA also used this opportunity to enhance data and search features and add information on the flavor of certain tobacco products.

Additional accomplishments of FDA’s tobacco retail inspection program from January 1, 2020, through December 31, 2021, include the following:

- Issued over 8,700 warning letters (over 3,100 pertained to the sales of ENDS products to underage purchasers) to retail establishments in which violations were found during compliance check inspections);
- Initiated over 1,100 CMP administrative actions (over 200 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; and

⁴⁴ 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).

⁴⁵ Compliance Check Inspections of Tobacco Product Retailers. FDA. https://www.accessdata.fda.gov/scripts/oc/inspections/oc_insp_searching.cfm.

- Filed over 25 No-Tobacco-Sale-Order complaints to retail establishments in which repeated violations⁴⁶ were found during follow-up compliance check inspections.

3. *Retailer Education*

In the fall of 2017, FDA launched a voluntary retailer education program entitled “This Is Our Watch.” 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 Library⁴⁷—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. Consequently, in 2021, over 20,000 additional digital calendars were provided to tobacco retail establishments.

In 2021, FDA embarked upon a research effort to update the retailers’ education materials to reflect the Tobacco 21 law. The overarching goal of the research was to gain feedback from retailers about their awareness, preferences, and experiences related to “This is Our Watch” materials. FDA plans to update these education materials and provide them, free of charge, to retailers in the future.

4. *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; at promotional events; and through other compliance and enforcement activities. For example, this surveillance has consisted of monitoring thousands of unique publications and websites in which regulated tobacco products might be sold, distributed, or advertised. This has allowed FDA to identify and evaluate over 100,000 advertisements of regulated tobacco products in the U.S. market to determine compliance with advertising and promotion requirements.

FDA also reviews notices required to be submitted by industry 30 days before advertising online, regarding the use of online media for advertising and the promotion of tobacco products. The notice must include “the extent to which the advertising or labeling may be seen by persons younger than 18 years of age.”⁴⁸ In addition, FDA has reviewed smokeless tobacco warning plans and smokeless tobacco warning plan supplements in accordance with

⁴⁶ 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.

⁴⁷ Tobacco Education Resource Library. FDA. <https://digitalmedia.hhs.gov/tobacco/>.

⁴⁸ 21 CFR 1140.30, available in the federal register at: <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-K/part-1140>.

the Comprehensive Smokeless Tobacco Health Education Act, as amended by section 204 of the Tobacco Control Act.

Further, FDA has sent letters to companies requesting information about their specific products or activities that may be in violation of promotion, advertising, and labeling requirements. When violations have been observed through these surveillance and investigation activities, FDA has generally issued a warning letter. These proactive compliance and enforcement 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. Accomplishments of FDA in this area from January 1, 2020, through December 31, 2021, include the following:

- Issued 10 warning letters, some of which were issued for violations found on more than one website, to companies for selling or distributing modified risk tobacco products (MRTPs), including products with “low,” “light,” or “mild” claims without a marketing authorization order from FDA; and
- Issued more than 270 additional warning letters, such as the following, for other violations of the law related to tobacco product sales, advertising, and labeling online, in print, and at promotional events:
 - In July 2021, issued a warning letter to a company that was manufacturing and operating a website selling ENDS products, including e-cigarettes and e-liquids, advising them that marketing these new tobacco products, which lacked premarket authorization, was illegal and that therefore these products could not be sold or distributed in the United States. The company had more than 15 million products listed with FDA.
 - In September 2020, issued warning letters to three companies for marketing tobacco products without the required premarket authorization. These companies were illegally marketing unauthorized menthol-flavored e-liquids that contained labeling and/or advertising featuring cartoon images, such as vampires and kings, that are commonly marketed and/or appeal to youth.
 - In July 2020, issued warning letters to 10 companies for marketing tobacco products without the required premarket authorization. Three of the firms were illegally marketing disposable e-cigarettes, two of which were cited for an additional violation for marketing their products as MRTPs without an FDA order in effect that permitted such marketing. The remaining seven firms were issued warning letters for selling or distributing unauthorized ENDS products targeted to youth or likely to promote use by youth; these seven firms were cited for marketing unauthorized e-liquids that imitated packaging for food products that often are marketed and appeal to youth (such as Cinnamon Toast Crunch cereal, Twinkies, Cherry Coke, and popcorn) or featured cartoon characters.

- In April 2020, issued warning letters to 10 online retailers and manufacturers that sold, manufactured, and/or imported unauthorized ENDS products targeted to youth or likely to promote use by youth (such as a backpack and a sweatshirt that were designed with stealth pockets to hold and conceal an e-cigarette, ENDS products that resembled smartwatches, or devices that appeared as children’s toys, such as a portable video game system or fidget spinner). Warning letters were also issued to companies marketing e-liquids that imitated packaging for food products that often are marketed and appeal to youth (such as candy) or featured cartoon characters like SpongeBob SquarePants.
- In January 2020, issued a warning letter to a company that sold dissolvable tobacco products, including Peppermint Ice Nicotine Toothpicks. The three specific violations cited in the warning letter were for selling a tobacco product to a minor through the company’s website; selling unauthorized MRTPs, and failing to include the required nicotine warning statements on the products’ packaging and advertising.

5. *Manufacturer Compliance and Enforcement Activities*

As required by section 905(g) of the FD&C Act, FDA conducts inspections of registered tobacco product establishments that manufacture regulated tobacco products. 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, as well as marketing authorization for new tobacco products or MRTPs.

FDA’s tobacco product manufacturer inspections also include inspections of vape shop establishments, many of which manufacture and/or sell flavored ENDS products. 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 cited in a PMTA.

The Agency’s laboratories have the capacity to evaluate tobacco products by conducting analyses of tobacco samples to develop and validate methods, establish product standards and baselines, and identify ingredients to support FDA’s enforcement actions.

Additionally, as of December 31, 2021, FDA has eight active tobacco import alerts. 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. Import alerts are currently in place for flavored cigarettes or their components or parts; regulated tobacco products whose labeling or advertising uses the descriptors “light,” “mild,” or “low”; smokeless tobacco products without the required warning label; certain tobacco products that cannot be legally sold or distributed due to a finding that they are not substantially equivalent (NSE); regulated tobacco products for non-payment of user fees;

certain regulated tobacco products lacking specified labeling requirements; and two import alerts pertaining to new tobacco products without required marketing authorization.

Accomplishments of FDA’s tobacco enforcement and manufacturing program from January 1, 2020, through December 31, 2021, include the following:

- Conducted more than 1,425 inspections of registered tobacco product manufacturing facilities, over 1,000 of which were vape shops;
- Conducted 19 premarket manufacturing and bioresearch monitoring inspections associated with PMTAs;
- Reviewed and made Pre-Existing (previously “grandfathered”) tobacco product determinations for over 6,800 voluntary submissions from industry using a newly streamlined process. A *Pre-Existing tobacco product* is a tobacco product that was commercially marketed in the United States as of February 15, 2007, and therefore does not require premarket authorization to be legally marketed. 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);
- Reviewed over 540,000 lines of imported tobacco products using the Agency’s information technology systems and in collaboration with U.S. Customs and Border Protection; and
- Issued over 140 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, and failure to list tobacco products), and failure to submit ingredient listings.

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 Reports⁴⁹—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, among other things:

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

⁴⁹ Report Potential Tobacco Product Violation. FDA. <https://www.fda.gov/tobacco-products/compliance-enforcement-training/report-potential-tobacco-product-violation>.

From January 1, 2020, through December 31, 2021, FDA received over 12,900 potential tobacco product violation reports, which was a steep increase from a total of 8,800 during the years 2009 through 2019. 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.

7. *CTP's Office of Small Business Assistance*

CTP's Office of Small Business Assistance⁵⁰ (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.

OSBA received over 5,600 inquiries from January 1, 2020, through December 31, 2021. All inquiries received are tracked to ensure timely and appropriate responses. These inquiries have become topics for OSBA's compliance training webinars and other outreach efforts.

8. *Compliance Training and Assistance*

CTP regularly hosts webinars⁵¹ 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, 2020, through December 31, 2021, 10 webinars were developed and posted on FDA's website. By December 31, 2021, those ten webinars had been viewed over 17,000 times. FDA continues to update and provide new webinars (totaling more than 80) to assist regulated industry, such as its 2021 webinars "Tobacco 21: Update for Retailers" and "Overview of Warning Letters for Online Retailers."

⁵⁰ Small Business Assistance for Tobacco Product Industry. FDA. <https://www.fda.gov/tobacco-products/compliance-enforcement-training/small-business-assistance-tobacco-product-industry>.

⁵¹ FDA Tobacco Compliance Webinars. FDA. <https://www.fda.gov/tobacco-products/compliance-enforcement-training/fda-tobacco-compliance-webinars>.

G. Public Education

1. Public Education Campaigns

Under the Tobacco Control Act, FDA has the authority to educate the public about the dangers of using tobacco products and has implemented multiple public education campaigns and other efforts designed to reduce tobacco initiation, disrupt progression to sustained use, and encourage cessation by focusing on key populations vulnerable to using tobacco in all its forms.

Since FDA launched its first tobacco-related campaign, the tobacco landscape has changed dramatically with the introduction of e-cigarettes and the escalating rates of youth e-cigarette use over time. In response to the shifting patterns of use, and to reflect current budget levels, FDA aligned its public education efforts to address the tobacco products most used by youth. FDA has prioritized youth vaping prevention as its main public education goal and has sunset four of its original public education efforts. The Agency will continue to provide free prevention and cessation resources to stakeholders and conduct foundational research on other tobacco products that pose particular risk to vulnerable populations and have shown recent increases in youth use, such as little cigars and cigarillos.

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

Campaigns	Launch Date	Description
“The Real Cost” E-Cigarette (ENDS) Campaign	September 2018-Present	Educates at-risk youth aged 12 to 17 about the harmful effects of e-cigarette use.
“The Real Cost” Cigarette Campaign	February 2014-Present	Educates at-risk youth aged 12 to 17 about the harmful effects of cigarette use.
“The Real Cost” Smokeless Campaign	April 2016-December 2020	Educated at-risk rural, male youth aged 12 to 17 about the harmful effects of smokeless tobacco use.
“Fresh Empire” Campaign	May 2015-June 2020	Educated at-risk African American, Hispanic, and Asian American/Pacific Islander youth aged 12 to 17 about the harmful effects of cigarette use.
“This Free Life” Campaign	May 2016-February 2020	Educated LGBTQ+ young adults aged 18 to 24 about the harmful effects of cigarette use.

“Every Try Counts” Campaign	January 2018-April 2020	Encouraged adult cigarette smokers who had attempted to quit smoking but were unsuccessful to quit through messages of support that underscored the health benefits of quitting.
“Next Legends” American Indian/Alaska Native ENDS Campaign	2022	Expanding e-cigarette prevention messaging to reach American Indian/Alaska Native (AI/AN) youth audiences.

a. “The Real Cost” – E-Cigarette (ENDS) Prevention

In September 2018, FDA launched “The Real Cost” e-cigarette (ENDS) campaign to prevent youth e-cigarette use across the nation. The campaign was designed to reach the nearly 10.7 million youth aged 12 to 17 who had ever used e-cigarettes or were open to trying them, and the campaign highlights information about the potential risks of e-cigarette 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.

In 2020, FDA launched a video series called “My Vaping Mistake” as part of the campaign.⁵² The series features teens’ true stories of the physical and emotional effects of e-cigarette addiction. The videos were released on youth-focused channels and amplified on social media.

Since the launch, the campaign has shown positive results for effective reach and engagement. This campaign has reached up to 85 percent of all teenagers nationwide and has generated over 16 billion views, from teen exposure to paid media messages and high online engagement. Across social media platforms, FDA has engaged teen audiences with more than 4.2 million likes, over 368,000 shares, and over 94,000 comments. Additionally, on the campaign’s social media channels, approximately 10 percent of the total comments from teens are asking for help and resources to quit vaping. In an ongoing collaboration with the National Cancer Institute (NCI), FDA and NCI developed vaping cessation content for teens to be added on the Teen.SmokeFree.gov website. Information and behavioral techniques help teens deal with cravings, triggers, and mood management (for stress, anxiety and depression); manage nicotine withdrawal; navigate peer pressure; prepare to quit; and make it through their quit day. Since the web content launched in July 2019, there have been over 2 million page views with visitors spending an average of 4 minutes per page.

As part of “The Real Cost” campaign, NCI and FDA co-developed two vaping cessation interactive resources for teens on the Teen.SmokeFree.gov website. The first resource is a quit plan builder which assists teens in developing a detailed and personalized plan for quitting

⁵² FDA In Brief: FDA expands youth e-cigarette prevention campaign to include stories from teenagers addicted to nicotine. FDA. <https://web.archive.org/web/20201220044036/https://www.fda.gov/news-events/fda-brief/fda-brief-fda-expands-youth-e-cigarette-prevention-campaign-include-stories-teenagers-addicted>.

vaping. The second resource helps teens assess their level of nicotine dependence and offers behavioral strategies and resources for quitting targeted to their level of quit readiness.

b. “The Real Cost” – Cigarette Smoking Prevention

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

Since its launch, the campaign has shown positive results for reach and engagement. Over the past 8 years, the campaign has reached up to 85 percent of teenagers nationwide and has generated over 22 billion teen views from the paid media. Across social media platforms, FDA has engaged teen audiences with more than 43 million likes, over one million shares, and over 407,000 comments.

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. FDA launched new advertising for the campaign in December 2020, tested new messages in the fall of 2021, and plans to launch new advertising in the future.

c. “The Real Cost” – Smokeless Tobacco Prevention

Launched in April 2016, “The Real Cost” smokeless tobacco prevention campaign educated at-risk male youth aged 12 to 17 about the harmful effects of smokeless tobacco use. The messaging platform for this campaign was “smokeless doesn’t mean harmless.”

In December 2020, “The Real Cost” smokeless tobacco prevention campaign was sunset. To evaluate the impact of the campaign, FDA implemented a 3-year randomized controlled longitudinal study.

Outcome evaluation results demonstrate significant success. The campaign influenced beliefs and attitudes among older boys in the 15 treatment media markets, increasing their understanding of the harms of smokeless tobacco use. In addition, study results show that those who had increased exposure to the campaign had increased agreement with selected campaign-targeted attitudes and beliefs associated with negative attitudes toward smokeless tobacco. The campaign reached more than 90 percent of the intended audience, and there were over 14 million social media engagements with the campaign’s social media channels.

d. “Fresh Empire” – Cigarette Smoking Prevention Targeting African American, Hispanic, and Asian American/Pacific Island Youth

Launched in May 2015, the “Fresh Empire” campaign educated at-risk African American, Hispanic, and Asian American/Pacific Islander youth aged 12-17 about the harmful effects of cigarette use. The campaign used broadcast TV, radio, digital advertising, and social media to reach the audience with messaging on addiction caused by cigarette smoking.

The campaign had a modest effect on changing tobacco-related attitudes and beliefs among the campaign audience. Overall, the campaign was able to reach 95 percent of the intended audience, and there were over 424 million social media engagements with the campaign’s social media channels.

e. “This Free Life” – Cigarette Smoking Prevention Targeting LGBTQ+ Young Adults

Launched in May 2016, the “This Free Life” campaign educated LGBTQ+ young adults aged 18-24 about the harmful effects of cigarette use. LGBTQ+ young adults are nearly twice as likely to use tobacco as other young adults, ultimately resulting in the loss of tens of thousands of LGBTQ+ lives to tobacco use each year. “This Free Life” was designed to reach occasional or “social” smokers through print and digital advertising and through social media to help prevent tobacco-related death and disease in the LGBTQ+ community.

Overall, “This Free Life” reached 95 percent of the targeted audience through primarily digital means. The campaign also reached LGBTQ+ sub-groups by using innovative approaches with influencers and tailored messaging. The campaign’s messaging resonated with the audience and received over 172 million likes, comments, and shares on the campaign’s social channels.

f. “Every Try Counts” – Adult Smoking Cessation

Launched in January 2018, FDA’s first adult cessation campaign, “Every Try Counts,” encouraged adult cigarette smokers who had attempted to quit smoking but were unsuccessful to try to quit again. The campaign leveraged a novel, strategic approach that utilized positive, non-graphic messaging and reframed past quit attempts not as failures but as important steps towards future success.

The campaign was initially implemented in point-of-sale retail locations in which cigarettes were sold. As the first multi-city point-of-sale tobacco cessation campaign, “Every Try Counts” delivered messages where smokers often encountered tobacco advertising and triggers for smoking relapse. Additionally, each advertisement included a call to action to drive smokers to the campaign website, co-developed by NCI and FDA, which featured quitting tips, “practice the quit” text message programs, and online cessation counseling. In February 2020, “Every Try Counts” expanded to a national digital campaign to reach a broader audience, and messaging reached over 45 million adult smokers.

Overall, “Every Try Counts” served over 769 million digital impressions and drove more than 1.6 million unique visitors to EveryTryCounts.gov, prompting over 15,000 sign-ups for text message programs designed to help smokers quit.

g. “Next Legends” American Indian/Alaska Native Campaign

In 2022, FDA will be expanding e-cigarette prevention messaging to reach AI/AN youth audiences, a population that has historically had higher tobacco usage rates. FDA has conducted research with AI/AN youth to understand tobacco beliefs and perceptions and is determining the best messaging approaches to reach this at-risk audience.

2. *Partnership with Scholastic*

Since 2018, FDA has collaborated with Scholastic, the global children’s publishing, education, and media company, to develop youth e-cigarette prevention resources for middle and high school educators.⁵³ Resources are available in English and Spanish and include lesson plans, activity sheets, and videos to help teachers start educational conversations about the harms of youth e-cigarette use. These free educational materials, as well as a teacher resource guide and youth addiction and cessation materials, have been distributed each year to more than 1.3 million educators and have reached an estimated 5.7 million students.

In January 2021, FDA and Scholastic developed new content for the 2020-2021 school year, including a student magazine, an e-cigarette prevention poster contest, and a content refresh of previous materials. The e-cigarette prevention poster contest surpassed expectations by receiving nearly 7,000 entries from middle and high school students. The winners included four middle school and four high school students from across the United States.

Also in 2021, FDA undertook qualitative and quantitative research—a needs assessment, middle and high school teacher focus groups, and teacher surveys—to offer research-informed recommendations for developing new educational materials and to assess educators’ use of and satisfaction with previous educational outreach materials. FDA is now analyzing the results of the research to inform the next phase of education outreach.

H. Public Outreach and Stakeholder Engagement

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

FDA’s listening session program has provided outside parties with an opportunity to educate the Agency and provide information that may be useful for FDA’s work. Topics covered during these sessions have included youth tobacco prevention strategies and technologies, synthetic nicotine, and perspectives on a tobacco product regulatory framework. In 2020, FDA began offering virtual listening sessions. During 2020 and 2021, FDA held 18 listening sessions with a broad array of stakeholders.

FDA has participated in many tobacco industry and public health conferences and meetings to present information to attendees and conduct outreach activities. During 2020 and 2021 alone, FDA participated in 32 conferences. At these tobacco-related conferences, FDA frequently hosts an exhibit booth, both in-person and virtually. These exhibits have provided an opportunity to educate diverse audiences about FDA’s tobacco mission and strategic priorities and to engage with stakeholders who have a direct impact on public health infrastructure and communities. These exhibits have also provided 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.

⁵³ The Real Cost of Vaping. Scholastic. <https://www.scholastic.com/youthvapingrisks/index.html>.

Since beginning this outreach in 2013, CTP has exhibited at 140 conferences, with approximately 1.8 million attendees combined.

2. *Engagement Focused on Health Equity*

The Agency’s diversity and inclusion efforts have included (1) participation in high-level presentations related to FDA’s health education campaigns and (2) outreach efforts to underserved audiences and to high school and college students. These consistent efforts have conveyed FDA's commitment to stay engaged with all communities interested in FDA's regulation of tobacco products.

A novel approach to building awareness and extending FDA’s messaging was achieved through collaboration with a variety of stakeholder outlets. The outreach efforts introduced CTP to diverse audiences and organizations, such as the National Council for Mental Wellbeing; the National Alliance for Hispanic Health; the Asian Pacific Partners for Empowerment, Advocacy, and Leadership; the National Association of School Nurses; and the Center for Black Health and Equity (representing 300,000 college students and 47 historically Black colleges and universities).

3. *Tribal Consultation and Engagement*

For both FYs 2020 and 2021, FDA published a Request for Proposal to contract with AI/AN tribes to conduct compliance check inspections of tobacco product retailers on their tribal lands to help ensure retailer compliance with federal tobacco laws and regulations. FDA sent a Dear Tribal Leader letter in 2020 and 2021 to the leaders of the Federally Recognized Tribes throughout the United States to inform them of the tobacco retail inspection contract opportunity.⁵⁴

FDA developed a printable flyer for tribal retailers on the increase in the federal minimum age for sale of tobacco products to 21. This flyer contains useful information on the applicable law and provides links to additional resources and FDA contact information. This new resource was distributed via a Dear Tribal Leader letter sent in December 2021.⁵⁵

FDA participated in nine Department of Health and Human Services annual regional tribal consultation sessions held virtually between May and August 2021. FDA presented information on “The Real Cost” campaign and tobacco retail inspection contracts available to tribal jurisdictions to help enforce Tobacco Control Act regulations within those jurisdictions.

4. *International Engagement*

To advance its regulatory mission to reduce tobacco use and tobacco’s harms in the United States, FDA has continued to engage with various international stakeholders, including foreign

⁵⁴ FDA. Dear Tribal Leader Letters. <https://www.fda.gov/federal-state-local-tribal-and-territorial-officials/tribal-affairs/dear-tribal-leader-letters>.

⁵⁵ Id.

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 tobacco control implementation challenges, 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 2020 through 2021, 17 bilateral and multilateral meetings were conducted, and FDA responded to inquiries from over 15 countries.

I. User Fee Collections

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 has not been indexed to inflation.

It is important to note that because ENDS products were a relatively new product category when the FD&C Act was amended to include tobacco in 2009, the budgets established by Congress under section 919 could not have considered the resources required for the regulation of ENDS products, which are currently the most used tobacco product category by youth. Manufacturers and importers of regulated tobacco products outside of the six product classes listed above, including ENDS products, do not pay tobacco user fees for their regulatory oversight. FDA has had to use a significant portion of the \$712 million in user fees it collects annually from the existing six product classes to properly regulate deemed products, especially ENDS products. An amendment to section 919 of the FD&C Act would help promote a fair distribution of tobacco user fee assessments to all regulated tobacco products. This amendment would (1) authorize the Agency to assess user fees on, and collect such fees from, each manufacturer and importer 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 future collections to inflation. As a result of this amendment, FDA's tobacco program would not need to continue to spread its flat budget of \$712 million across all regulated products.

In 2020 and 2021, CTP collected 99.9%⁵⁶ of the user fees assessed. Of the six classes that are assessed fees, cigarettes account for 85%, cigars account for 12.4%, snuff accounts for 1.4%, pipe tobacco accounts for 0.8%, chewing tobacco accounts for 0.07%, and roll your own tobacco accounts for 0.05%.

III. Impediments to Implementing the Tobacco Control Act and Meeting Statutory Time Frames

A. Impact of the COVID-19 Pandemic on Compliance and Enforcement Activities

In March 2020, FDA temporarily suspended tobacco manufacturer and retailer inspections due to health and safety concerns related to the COVID-19 pandemic. Also, FDA issued related partial Stop-Work-Orders to the contractors engaged in compliance and enforcement inspection activities, including the tobacco retail compliance check inspections and vape shop inspections, ultimately through the end of that fiscal year. The Agency utilized remote regulatory assessments for some manufacturer inspections related to premarket applications. In the fall of 2020, in-person tobacco manufacturer and retailer inspections resumed on a limited basis based on FDA's COVID Risk Assessment map.

In 2021, to further guide its compliance and enforcement work, FDA activated the Base-Case Scenario: Gradual Transition to Standard Operations detailed in the Agency's Resiliency Roadmap. Inspections increased throughout 2021 and FDA will continue taking appropriate actions that are guided by health and safety considerations and outlined by the Agency's priorities.

Despite the challenges presented by the COVID-19 pandemic, FDA completed over 400 manufacturing inspections, investigations and remote regulatory assessments; over 1,000 vape shop inspections; and over 81,000 retailer inspections from January 1, 2020, through December 31, 2021.

As noted earlier in this report, FDA also conducted compliance and enforcement activities such as monitoring the online marketing and sale of regulated tobacco products and issuing import alerts for unauthorized tobacco products, which were uninterrupted by COVID-19 safety protocols.

⁵⁶ Section 919 of the FD&C Act specifies that CTP shall not invoice and collect more than the appropriated ceiling collection amount of \$712 million each fiscal year; thus, the truncated percentage of 99.9% is the approach taken by the Agency to ensure that CTP adheres to the language in section 919 of the Act. This measure acts as a safeguard to the potential possibility of invoicing more than the appropriated amount of \$712 million in any given fiscal year.

B. Status of Impediments Reported in 2020

As reported in 2020, previous impediments included delays in hiring staff and the inability to collect user fees for all tobacco products. CTP had a variety of challenges that delayed the hiring of staff including competition for talent across the FDA Centers and recruiting/retaining scientists with specialized experience in tobacco product review. Also, as a result of deeming additional products, including ENDS, FDA's inventory of registered tobacco product manufacturers and products listed increased exponentially. However, FDA does not have the authority to collect user fees in support of its regulatory oversight of new tobacco and nicotine-related products as appropriate.

In the last 2 years, FDA has focused on growing its workforce to support its strategic initiatives, and FDA has continued to invest in its workforce by continually assessing workloads, strengthening retention, and anticipating future staffing needs. FDA has significantly increased staffing resources for tobacco in FY 2020 and FY 2021, growing CTP by over 300 additional staff in these 2 years. FDA was able to accomplish this significant hiring through the use of a direct hire authority for CTP-specific positions. FDA is also committed to diversity, equity, inclusion, and accessibility to cultivate an engaged workforce that reflects the country it serves.

The lack of increased user fees remains a challenge as CTP's workload and operational costs increase. Starting in FY 2019, FDA's tobacco user fees have been capped at \$712 million, and the Agency has had to continue spreading a flat budget of \$712 million across all regulated tobacco products, including covering increasing operational costs. ENDS products were a relatively new product category in 2009. The budgets established by Congress under section 919 of the Tobacco Control Act could not have considered the resources required for the regulation of ENDS products.

To fund these increased efforts, the President's budget, since FY 2020, has included a request for \$100 million in new user fees. In the FY 2020, FY 2021, and FY 2022 budget cycles, FDA requested, but did not receive, an additional \$100 million and authority to include manufacturers and importers of all deemed products (i.e., to include those not already subject to user fees, like ENDS products) among the tobacco product classes for which FDA assesses user fees. Additionally, FDA requested an inflation adjustment for all tobacco user fees to ensure that the resources can keep up with the Agency's public health mandate and with the evolving marketplace of tobacco products. FDA is submitting this request again for FY 2023.

Currently, section 919 of the Tobacco Control Act does not provide a means for FDA to assess and collect user fees for ENDS products—which include e-cigarettes—and certain other deemed products. These products have represented a significant share of FDA's tobacco regulatory and enforcement activities. Any modifications to the current list of tobacco products that are subject to user fee assessments would need to be done through legislation.

Out of necessity, FDA has redirected existing funding resources to regulate ENDS products. While FDA is making a considerable investment in the comprehensive regulation of e-cigarettes, manufacturers and importers of ENDS products do not pay any users fees to FDA.

Adding all deemed products to section 919 would promote a fair distribution of tobacco user fee assessments to all regulated tobacco products. This additional funding would support actions FDA is taking to combat youth use of tobacco products, including e-cigarettes, through compliance and enforcement efforts for all tobacco products, public education campaigns, and science and research programs.

C. An Emerging Issue: Synthetic Nicotine

FDA has been concerned about increasing reports of ENDS products that purportedly exclusively contained synthetic nicotine (nicotine not made or derived from tobacco) and the efforts of companies marketing such products to take advantage of what they perceive to be a loophole in the law to evade FDA's regulation. For example, FDA was aware of ENDS manufacturers who, upon receiving marketing denial orders from the Agency, stated that they were switching to synthetic nicotine to avoid FDA's regulation.

In addition, the 2021 NYTS⁵⁷ showed that the most commonly used e-cigarette by youth was Puff Bar, one of the products that claimed to contain only synthetic nicotine.

On March 15, 2022, the President signed a spending bill that included a provision amending the definition of a *tobacco product* to be, essentially, "any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption." The law became effective on April 14, 2022, 30 days after enactment.

D. 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 finalizing regulations. As noted earlier, FDA issued two foundational rules in 2021 that provide additional information on the requirements for the content, format, and review of PMTAs and SE Reports, which are two of the pathways through which a manufacturer can seek marketing authorization for a new tobacco product from FDA.

On March 18, 2020, FDA issued a final rule establishing new cigarette health warnings for cigarette packages and advertisements. The final rule implements a provision of the Tobacco Control Act that requires FDA to issue regulations requiring color graphics depicting the negative health consequences of smoking to accompany new textual warning label statements. On April 3, 2020, the final rule was challenged in the U.S. District Court for the Eastern District of Texas.⁵⁸ Starting on May 8, 2020, the court has issued a series of postponements delaying the effective date of the final rule. Pursuant to the court order, any obligation to comply with a deadline tied to the effective date is similarly postponed, and those obligations and deadlines are now tied to the postponed effective date.

⁵⁸ *R.J. Reynolds Tobacco Co. et al. v. United States Food and Drug Administration et al.*, No. 6:20-cv-00176 (E.D. Tex., April 3, 2020).

FDA continues to develop, draft, and issue regulations and guidance documents for industry to implement the Tobacco Control Act. In addition to foundational rules, 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.⁵⁹

When promulgating regulations, the Agency relies on its experience learned 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.

IV. The Number of New Product Applications, MRTPAs, and Applications Acted on Under Each Category

A. SE to Certain Commercially Marketed Products

By December 31, 2021, FDA had received a total of 15,070 SE Reports.⁶⁰ Of these, 3,645 were provisional SE Reports.⁶¹ The remaining 11,425 were regular SE Reports for products.

Cumulatively, by December 31, 2021:

- Of the 15,070 SE Reports received, 59 percent had been closed⁶² (n=8,835)
- Of the 3,645 provisional SE Reports received, 87 percent had been closed (n=3,184)

⁵⁹ FDA is continuing to work on issuing a list of harmful and potentially harmful constituents in each tobacco product by brand and by quantity in each brand and sub-brand in a format that is understandable and not misleading to a lay person.

⁶⁰ This data is produced on an ongoing basis and is subject to change due to updates, corrections, or other reasons. Some metrics can also change as FDA is processing an extremely large number of applications that move through many steps during the review process.

⁶¹ *Provisional* tobacco products refer to those statutorily regulated tobacco products that were first introduced or delivered for introduction into interstate commerce for commercial distribution in the United States after February 15, 2007, and prior to March 22, 2011, and for which an SE report was submitted no later than March 22, 2011. Absent these circumstances, a manufacturer seeking to bring products to market via the SE pathway would submit a regular SE Report.

⁶² *Closed* means CTP has taken a final action on an application. Final actions for the SE pathway include RTAs, positive marketing orders, negative marketing orders, withdrawals, Removed from Reviews, or administrative closures. Following an administrative review, FDA will RTA a tobacco product submission or application if it has not met a minimum threshold for acceptability for FDA's review.

- 282 SE orders
 - 204 NSE orders
 - 1,220 withdrawals
 - 14 RTAs
 - 1,395 Removed from Reviews
 - 69 administrative closures
- Of the 11,425 regular SE Reports received, 49 percent had been closed (n=5,651)
 - 1,410 SE orders
 - 216 NSE orders
 - 1,199 withdrawals
 - 2,335 RTAs
 - 491 administrative closures

B. EX REQs

Cumulatively, by December 31, 2021, FDA had received a total of 3,342 EX REQs. Of the 3,342 EX REQs received, 67 percent had been closed⁶³ (n=2,251).

- 872 EX orders
- 106 Not Exempt orders
- 61 withdrawals
- 1,210 RTAs
- 2 administrative closures

C. PMTAs

Cumulatively, by December 31, 2021, FDA had received a total of 8,085,439 PMTAs. Of the 8,085,439 PMTAs received, 96 percent had been closed⁶⁴ (n=7,795,145). Of those 7,795,145, there were:

- 22 MGOs
- 1,234,715 MDOs
- 1,389,608 RTAs

⁶³ *Closed* means CTP has taken a final action on an application. Final actions for the EX pathway include RTAs, positive marketing orders, negative marketing orders, withdrawals, or administrative closures. Following an administrative review, FDA will RTA a tobacco product submission or application if it has not met a minimum threshold for acceptability for FDA's review.

⁶⁴ *Closed* means CTP has taken a final action on an application. Final actions for a PMTA include RTAs, RTFs, positive marketing orders, negative marketing orders, withdrawals, or administrative closures. Under the PMTA rule, FDA can also cancel an application if FDA finds that it was mistakenly accepted or the application was submitted in error. Following an administrative review, FDA will RTA a tobacco product submission or application if it has not met a minimum threshold for acceptability for FDA's review.

- 5,090,047 RTFs
- 564 withdrawals
- 80,189 administrative closures

D. MRTPAs

According to section 911 of the FD&C Act, FDA may authorize a tobacco product to be sold or distributed for use to reduce harm, the risk of tobacco-related disease, or exposures to harmful substances associated with commercially marketed tobacco products.

Cumulatively, by December 31, 2021, FDA had received a total of 51 MRTPAs. Of the 51 MRTPAs received, 78 percent had been closed⁶⁵ (n=40). Of those 40, there were:

- 14 Modified Risk Granted Orders
- 10 RTAs
- 11 RTFs
- 5 withdrawals

FDA authorized the marketing of the first heated tobacco product as an MRTP on July 7, 2020. This action marked the second set of products ever to be authorized as MRTPs and the first tobacco products to receive “exposure modification” orders, which permit the marketing of a product (1) as containing a reduced level of, or presenting a reduced exposure to, a substance or (2) as being free of a substance when the issuance of the order is expected to benefit the health of the population.

On December 23, 2021, FDA authorized the marketing of very low nicotine combusted, filtered cigarettes as MRTPs, which help reduce exposure to, and consumption of, nicotine for smokers who use them. These are the first combusted cigarettes to be authorized as MRTPs and the second tobacco products overall to receive “exposure modification” orders.

V. The Number of Full-Time Equivalents Engaged in Implementing the Tobacco Control Act

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 regulatory counsels, consumer safety officers, policy analysts, regulatory project managers, social scientists, pharmacologists, chemists, epidemiologists, management officers,

⁶⁵ *Closed* means CTP has taken a final action on an application. Final actions for an MRTPA include RTAs, RTFs, modified risk granted orders, denials of a modified risk order, withdrawals, or administrative closures. Following an administrative review, FDA will refuse to accept a tobacco product submission or application if it has not met a minimum threshold for acceptability for FDA’s review. See 21 CFR 1105. If a preliminary scientific review finds that the application did not contain all the items under section 911(d) of the FD&C Act, FDA will issue an RTF letter.

communications specialists, and other professionals needed to design and 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 has covered employees at CTP and other FDA employees assigned to tobacco product regulation, including employees in the Office of Commissioner, Office of Operations, and the Office of Regulatory Affairs. The following table displays full-time equivalent program levels from FY 2009 through FY 2021.

Fiscal Year	Program Level Full-Time Equivalents
2009 Actual	0 ⁶⁶
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

VI. Conclusion

Given the substantial impact tobacco use and exposure has on America’s health, FDA’s regulation of tobacco products remains a vital step in protecting the public from the harmful effects of tobacco use.

⁶⁶ 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.

In the past 2 years since the last report, FDA has made significant strides in reviewing new tobacco products and in establishing and implementing a framework for tobacco product regulation that is based on an expanding repository of available science.

Appendix A: Current Regulations, Guidance Documents, and Other Regulatory Documents Issued by FDA Related to the Tobacco Control Act (Organized by Type)

Type ^{67, 68, 69}	Title	Date ⁷⁰
Final Rule	Premarket Tobacco Applications and Recordkeeping Requirements	10/05/2021
Final Rule	Content and Format of Substantial Equivalence Reports; Food and Drug Administration Actions on Substantial Equivalence Reports	10/05/2021
Final Rule	Required Warnings for Cigarette Packages and Advertisements	03/18/2020
Final Rule	Clarification of When Products Made or Derived from Tobacco are Regulated as Drugs, Devices, or Combination Products	01/09/2017
Final Rule	Refuse to Accept Procedures for Premarket Tobacco Product Submissions	12/29/2016
Final Rule	Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act	05/10/2016
Final Rule	Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Cigars and Pipe Tobacco	05/10/2016
Final Rule	National Environmental Policy Act; Environmental Assessments for Tobacco Products; Categorical Exclusions	09/24/2015
Final Rule	Tobacco Products, User Fees, Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products	07/10/2014

⁶⁷ Rules and Regulations. FDA. <https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/rules-and-regulations>.

⁶⁸ Guidance. FDA. <https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/guidance>.

⁶⁹ Appendix A does not include guidance documents that have been withdrawn or superseded by a more current version or a final draft/final rule.

⁷⁰ The date listed reflects either the date of issuance or the date published in the *Federal Register*.

Type ^{67, 68, 69}	Title	Date ⁷⁰
Final Rule	Tobacco Products, Exemptions from Substantial Equivalence Requirements	07/05/2011
Final Rule	Amendments to General Regulations of the Food and Drug Administration	11/30/2010
Final Rule	Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents	03/19/2010
Proposed Rule	Tobacco Product Standard for N-nitrosornicotine Level in Finished Smokeless Tobacco Products	01/23/2017
Proposed Rule	Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents (Amends Brand Name Provision (1140.16(a)))	11/17/2011
Advanced Notice of Proposed Rulemaking (ANPRM)	Regulation of Premium Cigars	03/26/2018
ANPRM	Regulation of Flavors in Tobacco Products	03/21/2018
ANPRM	Tobacco Product Standard for Nicotine Level of Combusted Cigarettes	03/16/2018
ANPRM	Nicotine Exposure Warnings and Child-Resistant Packaging for Liquid Nicotine, Nicotine-Containing E-Liquid(s), and Other Tobacco Products; Request for Comments	07/01/2015
ANPRM	Menthol in Cigarettes; Tobacco Products; Request for Comments	07/24/2013
ANPRM	Non-Face-to-Face Sale and Distribution of Tobacco Products and Advertising, Promotion, and Marketing of Tobacco Products	09/09/2011
ANPRM	Request for Comment on Implementation of the Family Smoking Prevention and Tobacco Control Act (Outdoor Advertising Provision)	03/19/2010
Guidance	Tobacco Product User Fees: Responses to Frequently Asked Questions	12/08/2021

Type ^{67, 68, 69}	Title	Date ⁷⁰
Guidance	Submission of Plans for Cigarette Packages and Cigarette Advertisements (Revised)	07/09/2021
Guidance	Required Warnings for Cigarette Packages and Advertisements: Small Entity Compliance Guide (Revised)	07/09/2021
Guidance	FDA Deems Certain Tobacco Products Subject to FDA Authority, Sales and Distribution Restrictions, and Health Warning Requirements for Packages and Advertisements (Revised)	10/16/2020
Guidance	Enforcement Priorities for Electronic Nicotine Delivery System (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised)	04/30/2020
Guidance	Compliance Policy for Limited Modifications to Certain Marketed Tobacco Products	11/26/2019
Guidance	Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (ENDS)	06/12/2019
Guidance	Interpretation of and Compliance Policy for Certain Label Requirement; Applicability of Certain Federal Food, Drug, and Cosmetic Act Requirements to Vape Shops	03/25/2019
Guidance	Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule (Revised)	03/08/2019
Guidance	Listing of Ingredients in Tobacco Products (Revised)	11/06/2018
Guidance	Compliance Policy for Certain Labeling and Warning Statement Requirements for Cigars and Pipe Tobacco	08/09/2018
Guidance	Compliance Policy for Required Warning Statements on Small-Packaged Cigars (Revised)	08/09/2018
Guidance	Submission of Warning Plans for Cigars (Revised)	08/09/2018
Guidance	Tobacco Retailer Training Programs (Revised)	08/09/2018

Type ^{67, 68, 69}	Title	Date ⁷⁰
Guidance	Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments (Revised)	12/08/2017
Guidance	Health Document Submission Requirements for Tobacco Products (Revised)	10/18/2017
Guidance	Prohibition of Distributing Free Samples of Tobacco Products	10/12/2017
Guidance	Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers (Revised)	12/15/2016
Guidance	Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers Responses to Frequently Asked Questions (Revised)	12/15/2016
Guidance	Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Revised)	12/12/2016
Guidance	Investigational Use of Deemed, Finished Tobacco Products That Were on the U.S. Market on August 8, 2016, During the Deeming Compliance Periods	10/12/2016
Guidance	“Harmful and Potentially Harmful Constituents” in Tobacco Products as Used in Section 904(e) of the Federal Food, Drug, and Cosmetic Act (Revised)	08/31/2016
Guidance	Meetings with Industry and Investigators on the Research and Development of Tobacco Products (Revised)	07/15/2016
Guidance	Tobacco Product Master Files	05/10/2016
Guidance	Small Entity Compliance Guide: Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products (Revised)	05/10/2016
Guidance	Small Entity Compliance Guide: National Environmental Policy Act; Environmental Assessments for	10/26/2015

Type ^{67, 68, 69}	Title	Date ⁷⁰
	Tobacco Products; Categorical Exclusions	
Guidance	Enforcement Policy for Certain (Provisional) Tobacco Products that FDA Finds Not Substantially Equivalent	09/14/2015
Guidance	Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance with an Order	08/28/2015
Guidance	Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007	09/29/2014
Guidance	Compliance with Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents	08/22/2013
Guidance	Small Entity Compliance Guide: Further Amendments to General Regulations of the Food and Drug Administration to Incorporate Tobacco Products	03/28/2012
Guidance	Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products	01/06/2011
Guidance	Use of “Light,” “Mild,” “Low,” or Similar Descriptors in the Label, Labeling, or Advertising of Tobacco Products	06/10/2010
Guidance	Enforcement Policy Concerning Certain Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco	05/07/2010
Guidance	General Questions and Answers on the Ban of Cigarettes that Contain Certain Characterizing Flavors (Edition 2)	12/23/2009
Draft Guidance	Validation and Verification of Analytical Testing Methods Used for Tobacco Products	12/21/2021
Draft Guidance	Tobacco Products: Principles for Designing and Conducting Tobacco Product Perception and Intention Studies	10/28/2020
Draft Guidance	Enforcement Policy for Certain Marketed Tobacco Products	03/01/2019

Type ^{67, 68, 69}	Title	Date ⁷⁰
Draft Guidance	Use of Investigational Tobacco Products (Revised)	02/21/2019
Draft Guidance	Substantial Equivalence Reports: Manufacturer Requests for Extensions or to Change the Predicate Tobacco Product	07/15/2014
Draft Guidance	Modified Risk Tobacco Product Applications	04/03/2012
Draft Guidance	Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under Section 904(a)(3) of the Federal Food, Drug, and Cosmetic Act	04/03/2012
Draft Guidance	Submission of Warning Plans for Cigarettes and Smokeless Tobacco Products	09/09/2011
Draft Guidance	The Scope of the Prohibition Against Marketing a Tobacco Product in Combination with Another Article or Product Regulated under the Federal Food, Drug, and Cosmetic Act	10/05/2009
Established List	Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke	04/03/2012
Enforcement Action Plan	Promotion and Advertising Restrictions	10/01/2010

