

# Report to Congress

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

U.S. Department of Health and Human Services  
Food and Drug Administration

/Stephen Hahn/

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Date

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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 the 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 new law. This report, which satisfies the requirements of section 106(a) of the Tobacco Control Act, provides an assessment of FDA's efforts to implement that act from June 1, 2013 to December 31, 2019.

Among the major accomplishments achieved during this time is the growth and development of CTP. Significantly, FDA also:

- Issued a final rule (referred to as the “Deeming Rule”) to extend FDA’s tobacco regulatory authority to additional tobacco products;
- Announced and implemented a comprehensive, Agency-wide plan entitled the Comprehensive Plan for Tobacco and Nicotine Regulation to serve as a multi-year roadmap to better protect youth, to help addicted adult smokers quit smoking, and to significantly reduce tobacco-related disease and death in the United States in the years to come;
- Announced and implemented a Youth Tobacco Prevention Plan focused on stopping youth use of tobacco products, in particular electronic nicotine delivery systems (ENDS);
- Issued a proposed rule for cigarette health warning requirements;<sup>1</sup>
- Developed award-winning tobacco public education campaigns;
- Continued to build a tobacco regulatory science research program, which includes funding over 500 research projects since the program began in fiscal year 2010, resulting in over 1,400 peer-reviewed publications;
- Prevented up to 587,000 youth from initiating cigarette smoking and saving more than \$53 billion in smoking-related costs through "The Real Cost" public education campaign;
- Issued the first marketing order for new tobacco products through the premarket tobacco application pathway;
- Issued the first authorization under the modified risk tobacco product application pathway;
- Continued to build a national enforcement program to ensure compliance with the marketing, sale, and distribution laws and regulations of tobacco at retail locations by contracting with states, territories, and tribes;
- Reached the milestone of more than one million compliance check inspections of tobacco retailers utilizing state and territorial contractors; and
- Issued two user fee final rules to ensure collections of monies required to pay the costs of FDA’s tobacco regulation activities.

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.

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<sup>1</sup> In March 2020, FDA finalized this rule.



## 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 secondhand smoke, which is more than the number of deaths due to alcohol, illegal drug use, homicide, suicide, car accidents, and HIV/AIDS combined.<sup>2</sup> More than 16 million people in the United States live with a serious illness caused by smoking.<sup>3</sup>

In 2009, the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act or TCA) was enacted, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act), granting authority to the Food and Drug Administration (FDA or the 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. In addition, the Tobacco Control Act provided FDA with immediate authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. The Tobacco Control Act also granted FDA authority to extend its tobacco regulatory authorities, by issuing a regulation, to additional tobacco products.

On May 10, 2016, FDA finalized a rule (referred to as the “Deeming Rule”)<sup>4</sup> that extended FDA’s tobacco authority to all tobacco products (except accessories of deemed products), including 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. The Deeming Rule took effect on August 8, 2016.

Since 2016, FDA has taken a number of steps to regulate ENDS products, including actions to address the epidemic of youth use of e-cigarettes. In addition, starting in 2019, FDA worked with the Centers for Disease Control and Prevention (CDC), state and local health departments, and clinical and public health partners to investigate a national outbreak of e-cigarette, or vaping, product use-associated lung injury (EVALI). Vitamin E acetate is strongly linked to the EVALI outbreak. However, evidence is not sufficient to rule out the contribution of other chemicals of concerns, including chemicals in either THC or non-THC products, in some of the reported EVALI cases. FDA continues to collect data and information related to EVALI.

FDA’s ongoing oversight and educational efforts related to e-cigarettes have been critical to the Agency’s public health mission and, especially, to protecting youth from the dangers of nicotine addiction and tobacco-related disease and death.

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

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<sup>2</sup> 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](https://www.cdc.gov/tobacco/data_statistics/fact_sheets/health_effects/tobacco_related_mortality/index.htm).

<sup>3</sup> Smoking & Tobacco Use: Health Effects. Centers for Disease Control and Prevention. [https://www.cdc.gov/tobacco/basic\\_information/health\\_effects/index.htm](https://www.cdc.gov/tobacco/basic_information/health_effects/index.htm).

<sup>4</sup> 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).

*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.*

## **II. PROGRESS OF FDA IN IMPLEMENTING THE TOBACCO CONTROL ACT**

The Center for Tobacco Products (CTP or the Center) has continued to grow since its creation in 2009. This section of the report provides updates on FDA's priorities and major accomplishments, including objective measures of progress, during this reporting period (i.e., from June 1, 2013, to December 31, 2019).

### **A. The Center's Strategic Priorities**

The Center'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 Strategic Priorities.<sup>5</sup> These long-term strategic priorities include the following:

- Product Standards – Advancing a product standard strategy that yields strong standards to improve the public health;
- Comprehensive FDA Nicotine Regulatory Policy – Establishing an integrated, FDA-wide policy on nicotine-containing products that is public health-based;

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<sup>5</sup> CTP's Key Strategic Priorities. FDA. <https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/ctps-key-strategic-priorities>.

- Premarket and Postmarket Controls: Regulations and Product Reviews – Exploring the development of 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 enforcement actions when appropriate;
- Public Education – Educating at-risk audiences on the dangers of tobacco use; 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.

## **B. Comprehensive Plan for Tobacco and Nicotine Regulation**

In July 2017, FDA announced a comprehensive plan for tobacco and nicotine regulation.<sup>6</sup> The plan serves as a multi-year roadmap centered on the following categories:

- Regulatory policies on addiction, appeal, and cessation;
- Youth Tobacco Prevention Plan; and
- Science-based review of tobacco products.

Actions taken as part of the comprehensive plan are numerous. In September 2017, the Office of the Commissioner formed the Agency-wide Nicotine Steering Committee. The committee has been tasked with re-evaluating and modernizing FDA’s approach to the development and regulation of nicotine replacement products. As part of the committee’s work, FDA hosted public meetings on youth tobacco cessation in January and May of 2019. The purpose of the January public hearing was to discuss FDA’s efforts to eliminate youth e-cigarette use as well as other tobacco product use, with a focus on the potential role of drug therapies to support youth e-cigarette cessation and the issues impacting the development of such therapies. The purpose of the May public hearing was to discuss the unique challenges associated with youth tobacco addiction and cessation, the current science regarding youth tobacco use and addiction, and treatment strategies to support youth tobacco cessation.

## **C. Youth Tobacco Prevention Plan**

Preventing youth tobacco use is one of FDA’s most important responsibilities. FDA announced the Youth Tobacco Prevention Plan in April 2018. The plan’s three strategies have focused on preventing youth access, curbing the marketing of tobacco products aimed at youth, and educating teens and their families. FDA has taken numerous actions as part of this plan. Many of these efforts are described in the compliance and enforcement and public education sections below.

## **D. Regulations and Guidance Documents**

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<sup>6</sup> FDA announces comprehensive regulatory plan to shift trajectory of tobacco-related disease, death. FDA. <https://web.archive.org/web/20180125072233/https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm568923.htm>.

FDA works to protect Americans from tobacco-related death and disease by regulating the manufacture, distribution, and marketing of tobacco products and by educating the public, including underage youth, about tobacco products and the dangers their use poses. FDA's mission is accomplished by issuing regulations and guidance documents that explain FDA's expectations to regulated industry and the public. These regulations and guidance documents also serve to implement the Tobacco Control Act.

### *1. The Deeming Rule*

The Tobacco Control Act gave FDA the immediate authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. The Tobacco Control Act also gave FDA the authority to regulate additional tobacco products through the issuance of a regulation. On May 10, 2016, FDA finalized the Deeming Rule,<sup>7</sup> which, as mentioned earlier, extended FDA's tobacco authorities to all tobacco products (except accessories of deemed products), including ENDS, cigars, hookah (waterpipe) tobacco, pipe tobacco, nicotine gels, dissolvables that did not previously fall under FDA's authority, and future tobacco products. The Deeming Rule, as well as FDA's regulation of these products, took effect on August 8, 2016.

When the Deeming Rule took effect in August 2016, many of the regulatory and legal requirements that had been in place for manufacturers of cigarettes, smokeless tobacco, cigarette tobacco, and roll-your-own tobacco since 2009 became applicable to makers of all newly deemed products, including ENDS products. These requirements have included:

- Registering domestic establishments and submitting lists of products manufactured at those establishments, including all labeling and representative samples of advertisements;
- Submitting tobacco health documents;
- Submitting ingredient listings;
- Marketing new tobacco products only after FDA authorization; and
- Marketing products with direct or implied claims of reduced risk only if FDA confirms that scientific evidence supports the claim and determines that providing a marketing authorization for the product will, among other things, benefit the health of the population as a whole.

In addition, under the Deeming Rule, the following regulatory provisions apply to deemed tobacco products, including ENDS products:

- Minimum age restrictions and identification requirements to prevent sales to underage youth;
- Requirements to bear certain health warnings on packages and advertisements (including certain ENDS components, such as e-liquids), such as, "WARNING: This product contains nicotine. Nicotine is an addictive chemical."; and
- Prohibition of vending machine sales unless the machine is located in a facility that does not admit youth.

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<sup>7</sup> See *supra* note 4.

Some of the requirements, such as the federal minimum age of sale, were enforced immediately when the Deeming Rule took effect on August 8, 2016, while, through an exercise of enforcement discretion, FDA deferred enforcement of other provisions (such as premarket review of “new tobacco products”<sup>8</sup>).

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

## **E. User Fee Collection**

FDA assesses user fees as directed by section 919 of the FD&C Act for individual domestic manufacturers and importers based on their respective market share in each tobacco product class.<sup>9, 10</sup> Previously, the U.S. Department of Agriculture (USDA) was authorized to collect similar assessments under the Fair and Equitable Tobacco Reform Act of 2004. USDA’s authority to collect assessments ended on September 30, 2014. Section 919(b)(7) of the FD&C Act required FDA to begin making determinations necessary for assessing tobacco product user fees no later than the beginning of fiscal year (FY) 2015.

On July 10, 2014, FDA issued a final rule<sup>11</sup> that applies to domestic manufacturers and importers of the following four classes of tobacco products: cigarettes, snuff, chewing tobacco, and roll-your-own tobacco. Beginning in October 2014, the rule required each domestic manufacturer or importer of these four product classes to submit to FDA specific information regarding the units of product placed into the chain of commerce and the federal excise taxes paid for each class of tobacco product. This final rule specified that FDA will continue to follow the same method as was used by USDA for allocating the total fees among classes of tobacco products.

On May 10, 2016, FDA issued a final rule<sup>12</sup> that applies to domestic manufacturers and importers of two additional classes of tobacco products that are subject to requirements for submission of data that are needed to calculate user fees—namely, cigars and pipe tobacco. As a result, domestic manufacturers and importers of cigars and pipe tobacco were required to begin submitting data to FDA in August 2016.

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<sup>8</sup> 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).

<sup>9</sup> In specifying how to determine these assessments for domestic manufacturers and importers of listed classes of tobacco products other than cigars, section 919 of the FD&C Act references subsections of the Fair and Equitable Tobacco Reform Act of 2004 (Pub. L. 108-357) (7 U.S.C. 518 et seq.). Assessments for domestic manufacturers and importers of cigars are determined separately under section 919(b)(5) of the FD&C Act.

<sup>10</sup> Tobacco User Fees. FDA. <https://www.fda.gov/tobacco-products/manufacturing/tobacco-user-fees>.

<sup>11</sup> Tobacco Products, User Fees, Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products. 79 FR 39302 (July 10, 2014).

<sup>12</sup> Requirements for the Submission of Data Needed To Calculate User Fees for Domestic Manufacturers and Importers of Cigars and Pipe Tobacco. 81 FR 28707 (May 10, 2016).

FDA continues to refine and strengthen the tobacco user fee program. This includes work to establish more formal partnerships with U.S. Customs and Border Protection (CBP) and the Department of Treasury's Alcohol and Tobacco Tax and Trade Bureau to ensure a timely exchange of quality data to complete the annual reconciliation process.

## **F. Efforts to Better Understand the Regulated Products**

### *1. Expand the Science Base for Regulatory Action*

A strong science base is a key underpinning of the tobacco regulatory framework and FDA's ability to develop product standards, to review product applications, to support compliance and enforcement actions, and to 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.

### *2. Tobacco Science and Research*

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

- Chemistry and Engineering – Understanding the chemical constituents in tobacco products and the methods for measuring them 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 both users and non-users (i.e., through secondary exposure) and evaluating and considering the inclusion of animal and cell culture models, as well as novel alternative toxicology approaches, to test the toxicity of tobacco smoke, aerosols, or specific constituents in tobacco;
- Addiction – Understanding the effect of tobacco product characteristics on addictions and on abuse liabilities across populations;
- Health Effects – Understanding the short- and long-term health effects of tobacco products across populations of special relevance, as appropriate. Priority areas to build our knowledge base include cardiovascular or respiratory health effects, including inflammation;
- Behavior – Understanding the knowledge, attitudes, and behaviors related to tobacco product use and changes in tobacco product characteristics across populations, as appropriate;
- Communications – Understanding how to effectively communicate to the public regarding the health effects of tobacco products and nicotine (including addiction) through media campaigns and digital media;
- Marketing Influences – Understanding (1) the impact of marketing on an individual's susceptibility to using tobacco products (both classes of products and products within classes) and (2) transitions between experimentation, initiation to regular use, and dual use among different populations. Topics may include tobacco industry marketing such as advertising, digital media, and promotions; and

- Impact Analysis – Understanding the potential impact of FDA’s regulatory actions.

FDA has encouraged research studies to include, when appropriate, populations of special relevance, including youth, socioeconomically disadvantaged populations, racial/ethnic minorities, underserved rural populations, people with co-morbid mental health conditions and/or substance use disorders, military/veteran populations, pregnant women or women of reproductive age, and sexual and gender minorities.

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. In FY 2019, FDA CTP invested more than \$181 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. In addition to conducting independent research to support regulatory science, CTP collaborated with other Centers and Offices, including the National Center for Toxicological Research, Center for Food Safety and Nutrition, 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 FY2010, CTP has funded more than 500 research projects, resulting in more than 1,400 peer-reviewed publications across the research program.

A cornerstone of the CTP tobacco regulatory science research program is the Tobacco Regulatory Science Program (TRSP), a unique collaboration between CTP 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 is the establishment of the Tobacco Centers of Regulatory Science (TCORS). TCORS are made up of scientists with a broad range of expertise (e.g., 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. From FY 2013 to FY 2018, NIH awarded 14 research centers<sup>13</sup> with FDA funds to generate critical research that informs tobacco product regulation in the original TCORS program. Currently, there are nine research centers funded for FY 2018 to FY 2022 as part of the TCORS 2.0 program.<sup>14</sup>

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 from NIH’s National Institute on Drug Abuse, with both agencies collaborating on the scientific aspects of the study, such as the appropriate inclusion of biomarkers to assess tobacco exposure

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<sup>13</sup> Tobacco Centers of Regulatory Science (TCORS) (*archived*). FDA. <https://web.archive.org/web/20180725113926/https://www.fda.gov/TobaccoProducts/PublicHealthScienceResearch/Research/ucm369005.htm>.

<sup>14</sup> Tobacco Centers of Regulatory Science (TCORS). FDA. <https://www.fda.gov/tobacco-products/research/tobacco-centers-regulatory-science-tcors>.

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, age 12 and older. Research topics include evaluating patterns of tobacco use over time, such as switching products and using multiple products, as well as seeking to understand perceptions, knowledge, and attitudes.

Since data collection started in FY 2013, four data collection waves have been made available to the public. Data from two additional collections is forthcoming. PATH Study data has resulted in more than 100 peer-reviewed publications by FDA, NIH, and other scientists. Studies have examined 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 in tobacco use.

In June 2018, CTP issued a report on the Tobacco Regulatory Science Research Program for fiscal years 2010 – 2017. The report includes additional information about the research programs described above.<sup>15</sup>

### 3. *Tobacco Products Scientific Advisory Committee*

Mandated by the FD&C Act, the 12-member Tobacco Products Scientific Advisory Committee (TPSAC) 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.

### 4. *Safety Reporting Portal*

Since January 2014, consumers, health care providers, and other members of the public who have suspected a problem with a tobacco product have been able to use the Safety Reporting Portal (SRP),<sup>16</sup> an online standardized reporting system that was updated to include tobacco products. The portal has enabled surveillance of product quality problems and unexpected adverse experiences that occur with the use of various tobacco products.

FDA is interested in reports from consumers about tobacco products that are damaged, defective, contaminated, or smell or taste “wrong.” FDA wants to know about unexpected health or safety problems that may have been caused by being exposed to a tobacco product.

FDA has reviewed all tobacco-related SRP reports to identify new and concerning trends. (A total of 1,219 new reports were submitted to the SRP between January 1, 2014 and December 31, 2019.) For example, beginning in 2018, FDA observed a slight but noticeable increase in voluntary adverse experience reports mentioning seizures and e-cigarette use. In a follow-up to

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<sup>15</sup> <https://www.fda.gov/media/114538/download>

<sup>16</sup> Safety Reporting Portal for Tobacco Products. FDA. <https://www.fda.gov/tobacco-products/tobacco-science-research/safety-reporting-portal-tobacco-products>.

these reports, the Agency has encouraged the public to report cases of individuals who have used e-cigarettes and had a seizure to FDA via the SRP. This reporting has helped FDA monitor potential emerging safety issues.

## G. Compliance and Enforcement

### 1. Retailer Compliance Check Program

FDA estimates that there are currently 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 carry out 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. Alternatively, the Agency may conduct investigations using FDA personnel.

FDA has contracts for tobacco retailer compliance check inspections in 50 states and territories and tribal jurisdictions. The FDA Tobacco Retail Inspection Contracts webpage<sup>17</sup> contains pertinent information about each jurisdiction where FDA has contracted, 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.

Although most tobacco retailers comply with FDA's tobacco laws and regulations, FDA conducts compliance check inspections and issues advisory and enforcement actions such as warning letters, civil money penalties (CMPs), and No-Tobacco-Sale-Orders (NTSOs) when violations are found. The table below lists CMP amounts current as of December 31, 2019.<sup>18</sup>

<b>Number of Regulation Violations</b>	<b>CMP Amount<sup>19</sup></b>
1	\$0, warning letter issued
2 within a 12-month period	\$292
3 within a 24-month period	\$584
4 within a 24-month period	\$2,340

<sup>17</sup> FDA Tobacco Retail Inspection Contracts. FDA. <https://www.fda.gov/tobacco-products/retail-sales-tobacco-products/fda-tobacco-retail-inspection-contracts>.

<sup>18</sup> CTP Compliance & Enforcement. FDA. <https://www.fda.gov/tobacco-products/compliance-enforcement-training/ctp-compliance-enforcement>.

<sup>19</sup> 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).

5 within a 36-month period	\$5,849
6 within a 48-month period	\$11,698

Accomplishments of FDA’s tobacco retail inspection program from October 1, 2012, through September 30, 2019 (i.e., FY 2013 to FY 2019), include the following:

- Issued over 88,000 warning letters (over 10,000 pertained to sales of ENDS products to minors) to retail establishments where violations were found during compliance check inspections;
- Issued over 23,000 CMP administrative actions (over 1,500 pertained to sales of ENDS to minors) to retail establishments where subsequent violations were found during follow-up compliance check inspections;
- Initiated FDA’s first NTSO complaints to retailers in October 2015 and subsequently issued over 160 NTSO complaints to retail establishments where repeated violations<sup>20</sup> were found during follow-up compliance check inspections;
- Enhanced FDA’s public searchable database of tobacco retail compliance check inspection results to increase transparency by including additional information on both the administrative or enforcement action taken and the product(s) purchased during inspections that resulted in a violation; and
- In March and April of 2019, FDA sent letters to 13 large national retail chains that had violation rates exceeding 15 percent or more (since the inception of the tobacco retailer inspection program in 2010). In these letters, FDA outlined its concerns with each retail chain’s violative history and asked these retailers to submit their plans describing how they would address and mitigate illegal sales to minors in their retail establishments.

## 2. Retailer Education

In the fall of 2017, FDA launched a voluntary retailer education program, “This Is Our Watch,” to complement FDA’s tobacco sales compliance work. This program—through program messages, materials, and communications activities—has aimed to raise retailers’ awareness and understanding of FDA’s tobacco regulations to encourage these retailers’ voluntary compliance with the law as well as to highlight the importance of compliance and their critical role in achieving it. “This is Our Watch” materials, including an age verification paper calendar, were mailed to retailers across the country and were available to order at no charge through CTP’s Exchange Lab<sup>21</sup>—CTP’s online digital repository of health education materials. In June 2019, a new digital version of the age verification calendar was mailed to retailers across the United States to replace the paper version of the calendar.<sup>22</sup>

<sup>20</sup> The phrase *repeated violations* is defined as “at least 5 violations of particular requirements over a 36-month period at a particular retail outlet.” TCA, § 103(q)(1)(A).

<sup>21</sup> Center for Tobacco Products Exchange Lab. FDA. <https://digitalmedia.hhs.gov/tobacco/>.

<sup>22</sup> FDA In Brief: FDA provides free digital calendars to retailers as part of voluntary educational program aimed at preventing illegal sales of e-cigarettes and other tobacco products to minors [news release]. Silver Spring, MD: FDA. June 18, 2019. <https://www.fda.gov/news-events/fda-brief/fda-brief-fda-provides-free-digital-calendars-retailers-part-voluntary-educational-program-aimed>.

FDA's Age Calculator mobile application (app) was developed to help retailers, through the use of their personal smartphone, determine if the purchaser is of legal sales age. This app has allowed users to update it to reflect the change of the federal minimum age of sale of tobacco products from 18 to 21 years that became effective on December 20, 2019.

FDA will continue its proactive engagement strategy working with public health, corporate, and municipal stakeholders to ensure that retailers are aware of the Agency's retailer education program and the availability of free resources that support the importance of complying with federal regulations.

### 3. *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. Surveillance has occurred on the Internet, including social media; publications; promotional events; and through other compliance and enforcement activities. FDA may send letters to companies requesting information about their specific products or activities that may cause concern. When violations are observed through these surveillance and investigation activities, FDA has generally issued a warning letter. These proactive compliance and enforcement activities can help protect the public health by preventing the sale and distribution of misbranded and adulterated tobacco products, including those with marketing and advertising materials that violate the FD&C Act.

Accomplishments of FDA in this area from October 1, 2012, through September 30, 2019 (i.e., FY 2013 to FY 2019), include the following:

- Reviewed smokeless tobacco warning plans and smokeless tobacco warning plan supplements in accordance with the Comprehensive Smokeless Tobacco Health Education Act, as amended by section 204 of the Tobacco Control Act;
- Received and reviewed over 370 original cigar rotational warning plans. FDA approved over 300 cigar warning plans;<sup>23</sup>
- Reviewed more than 100 notices of the use of other media, which included online media, for advertising and promotion of tobacco products;
- Identified thousands of websites where regulated tobacco products might be sold, distributed, or advertised. From October 1, 2013, and December 31, 2018, FDA monitored more than 20,000 websites;
- Conducted surveillance of thousands of unique publications;
- Identified and evaluated thousands of advertisements of regulated tobacco products in the U.S. market to determine compliance with advertising and promotion requirements; and

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<sup>23</sup> At this time, FDA does not intend to enforce the health warning requirements for cigar and pipe tobacco products. The U.S. District Court for the District of Columbia issued an order on July 5, 2018, enjoining FDA from enforcing the health warning requirements for cigars and pipe tobacco until 60 days after the final disposition of the plaintiffs' appeal of the court's order on the health warning requirements. On February 3, 2020, the court vacated the health warning requirements for "premium" cigars and remanded that portion of the Deeming Rule to FDA for further proceedings. The warning requirements remain in effect for other product categories (including ENDS products, hookah tobacco, and cigarette tobacco) and roll-your-own tobacco products.

- Issued more than 200 warning letters to companies for selling or distributing MRTPs, including those products with “low,” “light,” or “mild” claims, without a marketing authorization order from FDA. (Some warning letters covered multiple websites.);
- Issued an additional 500 warning letters for other violations of the law related to tobacco product sales, advertising, and labeling online, in print, and at promotional events. Examples of these warning letters include:
  - In May 2018, FDA issued 17 warning letters—most in partnership with the Federal Trade Commission (FTC)—to manufacturers, distributors, and retailers for selling e-liquids used in ENDS products with false or misleading labeling and/or advertising that caused them to resemble kid-friendly food products such as juice boxes, candy, or cookies, some of them with cartoon-like imagery. These products are no longer being sold with the offending labeling and advertising by the companies that received the May warning letters. Since that time, FDA has issued dozens of warning letters to additional e-liquid manufacturers and online retailers whose products used misleading, kid-appealing imagery that caused the products to appear ingestible by imitating food products such as candy.
  - In October 2018, CTP coordinated with FDA’s Center for Drug Evaluation and Research to issue a joint warning letter to a firm for various violations of the FD&C Act, including selling two e-liquids containing the prescription drugs tadalafil and/or sildenafil. These products were also marketed with images of FDA-approved prescription drugs that treat erectile dysfunction and/or anti-obesity medications. As a result, FDA determined that the company was selling or distributing its e-liquid products in ways that conveyed, or misled consumers into believing, that FDA had approved those tobacco products, when it had not.
  - In September 2019, FDA issued a warning letter to JUUL Labs Inc. for marketing unauthorized MRTPs by engaging in labeling, advertising, and/or other activities directed to consumers. The warning letter stated that FDA had determined that JUUL marketed its products as MRTPs without an appropriate FDA order in effect. FDA also sent a letter to the company expressing concern and requesting documents and information about several issues regarding JUUL’s outreach and marketing practices.

More information and additional examples of this work can be found in FDA’s tobacco *Compliance and Enforcement Report, 2013-2018*.<sup>24</sup>

#### 4. *Manufacturers’ Compliance and Enforcement Activities*

FDA has conducted biennial inspections of registered tobacco product establishments that manufacture regulated tobacco products in the U.S. market. These inspections have been designed to determine compliance with requirements of the FD&C Act. Such requirements include registration, product and ingredient listing, packaging, labeling, and advertising, as well as marketing authorization for new tobacco products or MRTPs. FDA has also conducted other

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<sup>24</sup> Compliance and Enforcement Report. FDA. <https://www.fda.gov/tobacco-products/compliance-enforcement-training/compliance-and-enforcement-report>.

types of inspections, including inspections of manufacturing facilities cited in a premarket tobacco product application (PMTA).

FDA has conducted inspections of vape shop establishments, many of which mix and/or sell flavored ENDS products. During these inspections, FDA has sought to determine the types of activities that were performed at the establishment and the establishment's compliance with applicable requirements under the FD&C Act.

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, 2019, FDA had five active tobacco import alerts. Import alerts inform FDA's field staff and the public that the Agency has had enough evidence to allow for the detention of 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); and regulated tobacco products for non-payment of user fees.

Accomplishments of FDA's tobacco enforcement and manufacturing program from October 1, 2012, through September 30, 2019 (i.e., FY 2013 to FY 2019), include the following:

- Conducted 650 inspections of registered tobacco product facilities;
- Conducted 19 premarket manufacturing and bioresearch monitoring inspections associated with PMTAs;
- Conducted more than 2,000 vape shop inspections;
- Conducted 27 investigations that included sponsorship events and distribution of free sample events;
- Reviewed over 185,000 lines of imported tobacco product entries and processed an additional 660,000 lines of imported tobacco product entries in collaboration with CBP, using their information technology systems for import reviews;
- Issued more than 1,200 letters notifying retailers about the legal status of tobacco products that have received an NSE order;
- Sent letters to over 100 companies seeking information on over 130 brands, including ENDS products, to determine whether those products were not marketed as of August 8, 2016, and therefore not subject to any previous FDA compliance policy;
- Issued warning letters to eight ENDS companies notifying them of the need to remove a combined total of more than 200 products from the market; and
- Issued six warning letters to manufacturers/importers for failure to pay required user fees.

##### *5. Potential Tobacco Product Violation Reports*

Any stakeholder, including a consumer, may report to FDA—via FDA’s Potential Tobacco Product Violation Reports<sup>25</sup>—a potential violation of the tobacco laws that the Agency enforces. 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.

From October 1, 2012, through September 30, 2019 (i.e., FY 2013 to FY 2019), FDA received over 8,800 potential tobacco product violation reports, many of which were for (1) potential violations related to deemed tobacco products such as flavored cigars and ENDS; (2) issues such as sales to minors; (3) the unlawful distribution of free samples of tobacco products; (4) illegal marketing and advertising, such as describing tobacco products as safer or less harmful without an FDA order; (5) distributing promotional or novelty items with brand names of cigarette or smokeless tobacco products; (6) sponsoring events using the brand name of a tobacco product; (7) the placement of cigarette or smokeless tobacco product vending machines in prohibited areas; (8) the sales of cigarettes in packages of less than 20; and (9) products lacking the required premarket authorization.

#### 6. *CTP’s Office of Small Business Assistance*

FDA’s Office of Small Business Assistance<sup>26</sup> (OSBA) within CTP 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 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 has received approximately 22,700 inquiries from October 1, 2012, through September 30, 2019 (i.e., FY 2013 to FY 2019). All inquiries received have been tracked to ensure timely and appropriate responses. In addition, these inquiries have become topics for OSBA’s compliance training webinars and other outreach efforts.

#### 7. *Compliance Training and Assistance*

In 2011, CTP’s Office of Compliance and Enforcement (OCE) began hosting a series of webinars designed to provide FDA tobacco compliance education and information to retailers and to small business manufacturers to encourage compliance with FDA’s tobacco laws and regulations. From October 1, 2012, through September 30, 2019 (i.e. FY 2013 to FY 2019),

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<sup>25</sup> Report Potential Tobacco Product Violation. FDA. <https://www.fda.gov/tobacco-products/compliance-enforcement-training/report-potential-tobacco-product-violation>.

<sup>26</sup> Small Business Assistance for Tobacco Product Industry. FDA. <https://www.fda.gov/tobacco-products/compliance-enforcement-training/small-business-assistance-tobacco-product-industry>.

more than 45 webinars had been developed and posted on FDA’s website. FDA continues to update and provide new webinars (totaling more than 70) to assist regulated industry, such as its 2019 “Introduction to Tobacco Product Recalls” webinar and its webinar series on CMP and NTSO complaints.

After the Deeming Rule was finalized, many of the webinars focused on this rule and its impact to make tobacco retailers, importers, and manufacturers aware of the steps they must take to comply with the Deeming Rule’s requirements for the marketing and sale of tobacco products.

## **H. Public Education**

### *1. Cigarette Health Warnings*

The TCA included a mandate to issue regulations that would "require color graphics depicting the negative health consequences of smoking" on cigarette packages and in advertisements (Tobacco Control Act, Pub. L.111-31, 101(b), 123 Stat. 1776, 1845 (2009), § 201, codified in 15 U.S.C. 1333(d)).

In June 2011, the Agency published a final rule requiring color graphics depicting the negative health consequences of smoking to accompany nine textual health warning statements specified in the TCA. However, the final rule was challenged in court by several tobacco companies and was ultimately vacated in August 2012 after the U.S. Court of Appeals of the District of Columbia held that the rule violated the First Amendment.<sup>27</sup> In March 2013, the federal government announced its decision not to seek further review of the court’s ruling and reported FDA’s intention to undertake research to support new health warning rulemaking consistent with the Tobacco Control Act.

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 August 16, 2019, FDA issued a proposed rule<sup>28</sup> to require new health warnings on cigarette packages and in advertisements to promote a greater public understanding of the negative health consequences of smoking. This proposed rule, now finalized, will require the warnings to appear prominently on cigarette packages and in advertisements.

Now finalized, this rule fulfills a requirement in the TCA and would complement additional important work the FDA is undertaking to advance the health of America’s families.<sup>29</sup>

### *2. Public Education Campaigns*

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<sup>27</sup> *R.J. Reynolds Tobacco Company, et al. v. Food & Drug Administration, et al.* (D.C. Cir. 2012).

<sup>28</sup> Tobacco Products; Required Warnings for Cigarette Packages and Advertisements. 84 FR 42754 (August 16, 2019).

<sup>29</sup> In March 2020, FDA finalized this rule.

FDA has used comprehensive public education campaigns to work in concert with regulatory actions to reduce the use of tobacco products and improve the public health. FDA's public education campaigns have helped educate the public—especially youth—about the dangers of regulated tobacco products. Achieving FDA's mission to reduce tobacco-related death and disease has required a comprehensive, scientific, and innovative approach. FDA's tobacco public education campaigns have focused on changing the knowledge, attitudes, and beliefs that lead to tobacco use and have followed an evidence-based process to develop messages and tactics, including:

- Identifying the problems to address;
- Testing messages and materials with the target audience;
- Sharing these messages using a variety of media; and
- Assessing how effectively these messages reach the target audience and changing the messages if necessary.

Below is a list of FDA’s current public education campaigns:

<b>Campaigns</b>	<b>Launch Date</b>	<b>Description</b>
“The Real Cost” Cigarette Campaign	February 2014	Educate at-risk youth aged 12 to 17 about the harmful effects of cigarette use.
“The Real Cost” Smokeless Campaign	April 2016	Educate at-risk rural, male youth aged 12 to 17 about the harmful effects of smokeless tobacco use.
“The Real Cost” E-Cigarette (ENDS) Campaign	September 2018	Educate at-risk youth aged 12 to 17 about the harmful effects of e-cigarette use.
“Fresh Empire” Campaign	October 2015	Prevent and reduce tobacco use among at-risk multicultural youth aged 12 to 17, specifically African American, Hispanic, and Asian American/ Pacific Islander youth.
“This Free Life” Campaign	May 2016	Prevent and reduce tobacco use among Lesbian, Gay, Bisexual, and Transgender (LGBT) young adults aged 18 to 24.
“Every Try Counts” Campaign	January 2018	Through messages of support that underscore the benefits of increased quit attempts, encourage adult cigarette smokers aged 25 to 54 who have attempted to quit smoking in the last year but were unsuccessful.

### 3. “The Real Cost” – Cigarette Prevention

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

Initial advertising focused on cigarette smoking prevention. Results<sup>30</sup> from an independent third-party research firm showed that in its first 2 years, the campaign prevented up to 587,000 youth aged 11 to 19 from initiating cigarette smoking—half of whom might have gone on to become established smokers. By preventing hundreds of thousands of youth from becoming established adult smokers, “The Real Cost” has saved more than \$53 billion for youth, their families, and society at large by reducing smoking-related costs such as premature loss of life, costly medical care, lost wages, lower productivity, and increased disability. For every dollar spent to prevent teen smoking, FDA achieved a return on investment of \$180.

Since “The Real Cost” launched, the campaign has been leveraging a robust media strategy to effectively reach teens and to change their tobacco-related knowledge, attitudes, beliefs, and behaviors. The campaign continues to air nationally across TV, radio, print, web, and social media.

The Effies are the advertising industry’s awards that recognize marketing ideas that are innovative and have demonstrated effectiveness. As a nationally recognized campaign, “The Real Cost” won a gold Effie in the Disease Awareness and Education category in 2015 and a bronze Effie in the Youth Marketing category in 2017. The campaign also won a 2016 Shorty Award for Best Overall Tumblr Presence. The Shorty Awards honor the best of social media tactics and advertisements. In 2019, “The Real Cost” received a BrandBlazer Award from Verizon Media and a silver Clio Award; both of these awards recognize excellence from brands in the advertising field. Also, “The Real Cost” was named the 2019 grand prix winner for the Campaign of the Year by the Festival of Media North American Awards for the campaign’s youth marketing and branded gaming advertising.

#### 4. “The Real Cost” – E-Cigarette Prevention

After finalizing the Deeming Rule, FDA began the research and creative development to reach teens across the United States with critical prevention messaging about ENDS. Since the initial launch of FDA’s “The Real Cost” e-cigarette prevention work in 2017, the campaign has steadily increased its budget as the epidemic of youth e-cigarette use has grown. To date, the campaign has spent approximately \$65 million, and in 2020, the campaign will invest over \$85 million, totaling \$150 million committed to prevent teen vaping. The increase in budget will demonstratively improve FDA’s ability to reach teenagers with its advertising, which is one important way to stem the epidemic of youth vaping.

“The Real Cost” youth e-cigarette prevention campaign targets the over 10 million U.S. teens who have either used e-cigarettes or are open to trying them and urges them to “know the real

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<sup>30</sup> Duke, JC, MacMonegle, AJ, Nonnemaker, JM, et al. Impact of *The Real Cost* Media Campaign on Youth Smoking Initiation. *American Journal of Preventive Medicine*. Nov. 1, 2019; 57(5):645-651.

cost of vaping.” 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 3.6 billion views from teen exposure and high online engagement. Across social media platforms, FDA has engaged teen audiences with more than 950,000 likes, over 132 shares, and over 54,000 comments. Additionally, on the campaign’s social media channels approximately 10% 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. Since the web content launched in July 2019, there have been nearly 1 million page views with visitors spending almost 3 minutes per page to learn how to quit vaping and overcome nicotine cravings.

FDA has joined forces with Scholastic, the global children’s publishing, education, and media company, to distribute posters to the nation’s 31,000 high schools in 2018 and 2019; these posters contained e-cigarette prevention messages for display in school bathrooms, the epicenter for teen vaping. In addition, in 2018, FDA developed information for fact sheets and lesson plans that were sent to over 750,000 high school administrators and teachers. In the fall of 2019, FDA expanded its collaboration with Scholastic to include resources for middle school educators, as well as new resources for high school educators. In mid-November 2019, these resources were distributed to 1.3 million educators. The materials included lesson plans and activity sheets to help teachers start educational conversations about the harms of youth e-cigarette use as well as videos designed to enhance learning. These materials, as well as a teacher resource guide and youth addiction and cessation materials, are still available online at no cost.<sup>31</sup>

##### 5. *“The Real Cost” – Smokeless Tobacco Prevention*

Under “The Real Cost” brand, FDA also has a smokeless prevention campaign to reach rural male youths, designed to shift their knowledge, attitudes, and beliefs about the dangers associated with dipping. In January 2019, FDA, with a primarily digital campaign, expanded this smokeless prevention campaign and extended its reach from 35 counties reaching 600,000 at-risk rural male teens to a 20-state approach reaching nearly 3 million at-risk rural male teens.

While analysis of the smokeless campaign evaluation data is still underway, preliminary data from an independent third-party research firm indicate that 85.9 percent of the target audience is aware of at least one of the campaign’s videos. Data also show increased agreement with specific campaign-targeted attitudes and beliefs that are correlated with reduced odds of smokeless use. High levels of awareness and an increased attitudinal agreement with campaign messages are indicators for media campaigns to influence positive health behaviors.

“The Real Cost” smokeless campaign earned a silver Effie in 2019 in the Youth Marketing category, which recognizes innovation and effectiveness.

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<sup>31</sup> The Real Cost of Vaping. Scholastic. [scholastic.com/youthvapingrisks](https://www.scholastic.com/youthvapingrisks).

## 6. “Fresh Empire”

In 2015, FDA launched "Fresh Empire," a campaign designed to educate the nearly five million multicultural youth (specifically African American, Hispanic, and Asian American/Pacific Islander) who are open to tobacco, or are already experimenting with tobacco, about the harms of tobacco use. The campaign uses broadcast television, radio, print, digital, social media and local events in select markets to reach the target audience. Since the launch, it has been seen over 6 billion times, with over 12 million social media interactions (e.g., likes, comments, shares) on the campaign's social media channels, and nearly 10 million visitors to [FreshEmpire.gov](http://FreshEmpire.gov). Additionally, results<sup>32</sup> from an independent third-party research firm show that campaign advertisements elicited positive audience reactions and were successful at effectively reaching this at-risk multicultural youth audience—a traditionally hard-to-reach population.

The Association of National Advertisers (ANA) named “Fresh Empire” a 2017 winner in the Experiential category at the Multicultural Excellence Awards. In addition, the 2017 Telly Awards, which honor excellence in video and television, named “Fresh Empire” the silver winner in the Motivational Category for Video/Shows/Segments and the bronze winner in the Public Interest and Awareness category for Promotional Pieces. In 2019, the “Fresh Empire” campaign received a platinum and gold Hermes Award for the social marketing and Twitter categories respectively. Hermes is an international competition that honors excellence in communications and marketing.

## 7. “This Free Life”

In May 2015, FDA launched “This Free Life,” a campaign designed to reach LGBT young adults at risk for occasional smoking to prevent escalation to regular smoking. LGBT young adults are nearly twice as likely to use tobacco as other young adults, ultimately resulting in the loss of tens of thousands of LGBT lives to tobacco use each year. This campaign advertises across digital platforms and social media with local events in select markets. Since the launch, it has been seen over 2.5 billion times by the target audience, with nearly 6 million social media interactions (e.g., likes, comments, shares) on social media channels, and over 3 million visitors to [ThisFreeLife.gov](http://ThisFreeLife.gov).

Assessment of the public health impact of “This Free Life,” using an independent third-party research firm, is currently in progress. This study will measure whether exposure to campaign messaging creates positive changes in tobacco-related knowledge, attitudes, beliefs, and intentions among the target audiences.

The campaign won an award of excellence at the 18<sup>th</sup> Annual ANA in 2016, earning a Multicultural Award in the LGBT category. In 2017, the campaign earned a bronze Telly Award in the Cultural category for Video/Shows/Segments and was named a gold winner in the Non-Profit category for print ads by the National LGBT Media Association Ad Pop Awards (Pride in

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<sup>32</sup> Guillory, J, Henes, A, Farrelly, MC, et al. Awareness of and Receptivity to the *Fresh Empire* Tobacco Public Education Campaign Among Hip Hop Youth. *Journal of Adolescent Health*. 2019:1-7.

Online and Print Category). In 2019, the campaign received a gold Hermes Award for its engagement-focused digital and social media content.

#### 8. *“Every Try Counts”*

In January 2018, FDA launched its first adult cessation campaign, “Every Try Counts,” which is designed to reach adult smokers who have intentions to quit cigarettes. The campaign launched in 35 counties with high smoking rates across the country and uses messages of support that underscore the health benefits of quitting to encourage smokers to quit. These messages are displayed as posters, billboards, and other out-of-home advertising units designed to engage audiences in and around gas stations or convenience store—locations where smokers face a multitude of triggers and that typically feature cigarette advertisements. Select campaign print ads are available for use via both CTP’s content sharing platform, the Exchange Lab,<sup>33</sup> and CDC’s Media Campaign Resource Center (MCRC). The Exchange Lab and MCRC provide access to “Every Try Counts” materials for use by states and/or other public health organizations and agencies.

Assessment of the public health impact of the “Every Try Counts” campaign, using an independent third-party research firm, is currently in progress. This study will measure whether exposure to campaign messaging creates positive changes in tobacco-related knowledge, attitudes, beliefs, and intentions among the target audiences.

#### 9. *American Indian/Alaska Native Campaign*

FDA is developing a tobacco prevention campaign designed to reach American Indian and Alaska Native (AI/AN) youth aged 13 to 17. AI/AN youth initiate smoking cigarettes earlier and at higher rates than non-AI/AN youth. The campaign is still under development in formative research with the audience to determine the most promising messaging areas.

#### 10. *Public Outreach and Stakeholder Engagement*

FDA is committed to establishing and maintaining meaningful relationships with key stakeholders across all functions and entities of the tobacco control landscape—public health, regulated industry, and other government organizations.

FDA has built a deep working knowledge of tobacco product manufacturing, marketing, and distribution through interactions with industry stakeholders. These stakeholders have included manufacturers, distributors and wholesalers, retailers, and trade associations. These interactions have increased FDA's understanding of the tobacco industry and its members while building the industry's understanding of FDA and the regulatory process.

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 have included youth tobacco prevention strategies, tobacco product testing and safety, and

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<sup>33</sup> See supra note 20.

perspectives on a tobacco product regulatory framework. Since June 1, 2013, FDA has held over 60 listening sessions with a broad array of participants on topics that have included product testing, youth tobacco prevention, and trends in e-cigarette use.

FDA has participated in many tobacco industry and public health conferences and meetings to present information to attendees and conduct outreach activities. As part of CTP's strategic outreach initiatives, the Office of Health Communication and Education (OHCE) has frequently participated in conferences by hosting an exhibit booth. Conference exhibits have provided an opportunity to educate diverse audiences on CTP's 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.

The Agency's diversity and inclusion efforts have included participation in FDA's Innovation Lab to present high-level presentations related to FDA's health education campaigns, outreach efforts with underserved audiences, the retailer education program, and the Exchange Lab, 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. From 2013 to 2019, CTP exhibited at 106 conferences, with more than 1.6 million (estimated) attendees combined.

A novel approach to building awareness and extending FDA's messaging was achieved through a variety of stakeholder outlets, including the U.S. Military, National Association of School Nurses, Society of Health and Physical Educators, and TEDxMidAtlantic. Campaign videos about the harms of tobacco were featured in over 70 military installation movie theaters around the world from 2015 to 2017. Since 2015, FDA has secured three TED Talk opportunities that focused on the harms of tobacco, reduced nicotine cigarettes, and the tobacco continuum of risk. These talks featured the U.S. Surgeon General, the Director of CTP, and the Director of OHCE.

## *11. Tribal Consultation and Engagement*

FDA has participated in tribal consultation, in accordance with its Tribal Consultation Policy, with all federally recognized tribes through "Dear Tribal Leader" letters<sup>34</sup> and All Tribes' Calls in response to significant regulatory actions. These actions have included the Deeming Rule, the "Content and Format of Substantial Equivalence Reports" proposed rule, the "Pre-market Tobacco Product Applications and Recordkeeping Requirements" proposed rule, and the "Tobacco Products; Required Warnings for Cigarette Packages" proposed rule. Additionally, FDA has provided consultation on compliance and enforcement activities, including tobacco manufacturing inspections and contracting with tribes for retailer compliance checks.

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<sup>34</sup> Dear Tribal Leader Letters. FDA. <https://www.fda.gov/federal-state-local-tribal-and-territorial-officials/tribal-affairs/dear-tribal-leader-letters>.

FDA has conducted outreach to AI/AN stakeholders through other channels as well. In addition to regular outreach via conference calls and letters, FDA has hosted ancillary meetings as an opportunity for interaction between AI/AN stakeholders and FDA staff.

## *12. 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 regulatory counterparts, ministries of health, embassies, foreign public health organizations, and multilateral organizations. Through this engagement, FDA has aimed to contribute to global collaboration among tobacco regulators regarding public health initiatives and priorities. Additionally, FDA has continued to gather information on the regulatory experiences of other governments. 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 the successes and failures of international counterparts. In addition, FDA has continued to engage both bilaterally and multilaterally in several ways. For example, FDA has established confidentiality commitments with trusted government partners to permit the sharing of non-public information. Also, FDA has regularly conducted high-level teleconferences and ad hoc email exchanges, as well as hosted international stakeholders for educational visits to the FDA campus.

### **III. IMPEDIMENTS IDENTIFIED BY FDA TO PROGRESS IN IMPLEMENTING THE TOBACCO CONTROL ACT AND IN MEETING STATUTORY TIME FRAMES**

Standing up a new regulatory process, including the premarket review of new tobacco products, hiring qualified technical staff, and gathering the resources needed have all had varying degrees of impact on FDA's progress in implementing the Tobacco Control Act. However, FDA has worked diligently to address these challenges, as evidenced below.

FDA has addressed a variety of challenges that have delayed the hiring of highly qualified staff in the last few years. These challenges have included competition for talent across the FDA Centers and recruiting/retaining scientists with specialized experience in tobacco product review. To address its critical hiring need, FDA requested and received approval of Direct Hire Authority (DHA) from the Office of Personnel Management for scientific, consumer safety officer and information technology positions through October 2021. The DHA approval will significantly increase FDA's ability to hire the talented staff it requires and will mitigate the challenges that reduced staffing has posed to the Center's ability to review tobacco product applications, as well as to perform other key functions required to successfully implement the TCA. To ensure awareness of the open opportunities advertised under the DHA, FDA created a digital advertisement that is displayed in 15 Washington, DC, metro stations; human resources staff attended over 20 career fairs and outreach events; and the Agency has significantly increased the posting of positions to industry and university job boards, as well as to online platforms such as LinkedIn. As a result, the number of applicants per job posting has increased significantly.

As stated earlier, in 2016, FDA deemed additional products, including ENDS, subject to FDA's tobacco authorities. As a result of deeming these products, FDA's inventory of registered tobacco product manufacturers and products listed has increased exponentially. Additionally, e-cigarettes are the most commonly used tobacco product by youth, which requires a dedicated public education program, as well as compliance and enforcement work. To fund these increased efforts, the President's budget included a request for new user fees in the amount of \$100M. The budget proposed that FDA be given the authority to collect user fees in support of its regulatory oversight of new tobacco and nicotine-related products in the future as appropriate. Currently, the Tobacco Control Act does not provide a means for FDA's calculation of user fees for ENDS products and certain other deemed products. These products have represented a significant share of the tobacco marketplace as well as FDA's tobacco regulatory and enforcement activities.

Out of necessity, FDA has redirected existing funding resources to address ENDS use. This additional funding will support actions FDA is taking to combat youth use of tobacco products, including e-cigarettes, through the Youth Tobacco Prevention Plan. Redirecting these resources will also bolster FDA's compliance and enforcement efforts for all tobacco products and support the expansion of FDA's public education campaigns and science and research programs in a changing tobacco product marketplace. Additionally, FDA has requested that the existing cap on tobacco user fees (i.e., \$712M per year) be adjusted for inflation.

#### **A. Areas of the TCA That Have Not Been Fully Implemented**

FDA continues to develop, draft, and issue regulations and guidances for industry to support the public health goals of the Tobacco Control Act. In addition to foundational rules, FDA has yet to issue three rules contained in the TCA 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.<sup>35</sup>

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. DATA ON THE NUMBER OF NEW PRODUCT APPLICATIONS AND MRTPAs AND THE NUMBER OF APPLICATIONS ACTED ON UNDER EACH CATEGORY**

#### **A. Substantially Equivalent (SE) to Certain Commercially Marketed Products**

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<sup>35</sup> 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 subbrand in a format that is understandable and not misleading to a lay person.

The SE pathway is one way in which a manufacturer can seek marketing authorization for a new tobacco product. For a new tobacco product to be SE, FDA must find that it either has the same characteristics as a valid predicate tobacco product or has different characteristics than the *predicate* tobacco product but that these difference(s) in characteristics do not cause the new tobacco product to raise different questions of public health. A *predicate product* is a tobacco product that was commercially marketed in the United States (other than in a test market) as of Feb. 15, 2007, or is a product previously found to be substantially equivalent by FDA and in compliance with the requirements of the Food Drug & Cosmetic Act (FD&C Act).

On April 2, 2019, FDA published a proposed rule<sup>36</sup> that would establish requirements for the content and format of reports manufacturers must send to the Agency to demonstrate the SE of a new tobacco product. This proposed SE rule would also provide information as to how the Agency intends to evaluate these SE reports.

Once finalized, the SE rule would formally set the minimum requirements for submitting SE reports, allowing for greater predictability and efficiency for industry stakeholders. Some of these requirements are currently recommended in Agency guidance documents. It is FDA's intent that the SE rule, when finalized, will bring greater uniformity to the consistency and completeness of SE reports and make the tobacco product review process more effective and efficient for all applicants.

As of October 31, 2019, FDA has received a total of 6,706 SE reports. Of these, 3,645 were provisional SE reports.<sup>37</sup> The remaining 3,061 are regular SE reports for products not currently on the market.

FDA is committed to a thorough and timely review of submissions. As of October 31, 2019:

- Of the 6,706 SE reports received, 89 percent have been closed<sup>38</sup> (n=5,994)
- Of the 3,645 provisional SE reports received, 84 percent have been closed (n=3,074)
  - 262 SE Orders
  - 187 NSE Orders
  - 1,149 Withdrawals
  - 14 Refuse to Accept (RTA)
  - 1,393 Removed from Review (RFR)
  - 69 Administrative Closures
- Of the 3,061 regular SE reports received, 95 percent have been closed (n=2,920)

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<sup>36</sup> Content and Format of Substantial Equivalence Reports; Food and Drug Administration Actions on Substantial Equivalence Reports. 868684 FR 12740 (proposed Apr. 2, 2019) (to be codified at 21 CFR 1107).

<sup>37</sup> *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. A regular SE Report is one that requires FDA authorization to be legally marketed in the United States.

<sup>38</sup> Closed means CTP has taken a final action on an application. Final actions for the SE pathway include Refuse to Accept (RTA), positive marketing order, negative marketing order, withdrawals, Removed from Review (RFR), or administrative closure. 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.

- 977 SE Orders
- 209 NSE Orders
- 958 Withdrawals
- 298 RTA
- 478 Administrative Closures

## **B. Exemption from Demonstrating SE**

The SE exemption (EX) is another pathway to market. To be considered for an exemption, the application must meet the requirements in the statute and regulations. FDA issued a final rule, “Tobacco Products, Exemptions From Substantial Equivalence Requirements,” on July 5, 2011.<sup>39</sup> This rule established procedures for requesting an exemption from the SE requirements.

As of October 31, 2019, FDA has received a total of 603 EX requests. Of the 603 EX requests received, 85 percent have been closed<sup>40</sup> (n=513).

- 338 EX Orders
- 42 NEX Orders
- 55 Withdrawals
- 76 RTA
- 2 Administrative Closures

## **C. Premarket Tobacco Product Applications (PMTA)**

On June 11, 2019, FDA finalized its guidance document<sup>41</sup> for manufacturers submitting new tobacco product applications through the PMTA pathway for ENDS, such as e-cigarettes and the liquid nicotine and nicotine-containing e-liquids used with such products, as part of the Agency’s continued commitment to its oversight of tobacco products.

Following an extensive review of input from the public on the previous draft guidance document, the final guidance document clarifies the PMTA process for ENDS products and FDA’s current thinking about information the Agency recommends applicants include in a PMTA submission for ENDS products. Importantly, the final guidance document also includes recommendations to address public health issues in the design and manufacture of ENDS products, such as accidental nicotine exposure and battery safety.

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<sup>39</sup> Tobacco Products, Exemptions From Substantial Equivalence’ Requirements. 76 FR 38961 (July 5, 2011) (codified at 21 CFR 1107).

<sup>40</sup> Closed means CTP has taken a final action on an application. Final actions for the EX pathway include Refuse to accept (RTA), positive marketing order, negative marketing order, withdrawals, or administrative closure. 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.

<sup>41</sup> *Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems* (June 11, 2019). FDA. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/premarket-tobacco-product-applications-electronic-nicotine-delivery-systems-ends>.

Additionally, the guidance document includes recommendations for conducting constituent or chemical testing, applying existing scientific literature or analyses about products similar to the proposed new tobacco product, including multiple distinct products in a single submission, and referencing tobacco product master files.

On September 25, 2019, FDA, as part of its continued commitment to overseeing e-cigarettes and other tobacco products, published a proposed rule<sup>42</sup> to set forth requirements related to the content and format of, as well as the Agency's review and communications procedures for, PMTAs. When finalized, this proposed rule will help ensure that PMTAs contain sufficient information for FDA's evaluation, including details regarding the physical aspects of a tobacco product and information on the product's potential public health benefits and harms. This proposed rule, when finalized, will also codify the procedures by which the Agency would review PMTAs and establish the requirements for manufacturers to maintain records related to the legal marketing status of their tobacco products.

Under the PMTA pathway, manufacturers or importers must demonstrate to the Agency, among other things, that marketing of the new tobacco product(s) would be appropriate for the protection of the public health. That statutory standard requires FDA to consider the risks and benefits to the population, including users and non-users of tobacco products. The Agency's evaluation also includes reviewing a tobacco product's components, ingredients, additives, constituents, toxicological profile, and health impact, as well as how the product is manufactured, packaged, and labeled.

As of October 31, 2019, FDA has received a total of 432 PMTAs. Of the 432 PMTAs received, 90 percent have been closed<sup>43</sup> (n=390). Of those 390, there are:

- 12 marketing granted orders
- 368 refuse to accept (RTA)<sup>44</sup>
- 7 refuse to file (RTF)<sup>45</sup>
- 3 withdrawals

Of the 42 PMTAs currently under review, all have been accepted, and 27 have been filed.

Following a rigorous, science-based review, on November 10, 2015, FDA announced that for the first time it authorized the marketing of new tobacco products through the PMTA pathway. On

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<sup>42</sup> Premarket Tobacco Product Applications and Recordkeeping Requirements. 84 FR 50566 (proposed Sept. 25, 2019) (to be codified at 21 CFR 1100).

<sup>43</sup> Closed means CTP has taken a final action on an application. Final actions for PMTA include Refuse to Accept (RTA), Refuse to File (RTF), positive marketing order, negative marketing order, withdrawals, or administrative closure. 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.

<sup>44</sup> The majority of RTA decisions were due to the PMTA's lack of an environmental assessment.

<sup>45</sup> RTF decisions include, but are not limited to, the PMTA's lack of product characterizations (see, e.g., section 910(b)(1)(B) of the FD&C Act) or manufacturing and facility information (see, e.g., section 910(b)(1)(C) of the FD&C Act).

April 30, 2019, FDA issued the first marketing orders for a heated tobacco product system. These actions have permitted these tobacco products to be sold in the United States but do not mean that these products are safe or “FDA approved.” All tobacco products are potentially harmful and addictive, and individuals who do not use tobacco products should continue to abstain from doing so.

#### **D. Modified Risk Tobacco Product Application (MRTPA)**

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 or the risk of tobacco-related disease associated with commercially marketed tobacco products. To authorize an MRTP, FDA evaluates whether a manufacturer has satisfied the standards set forth in section 911, including that the product will, or is expected to, benefit the health of the population as a whole. This evaluation includes considering both users of tobacco products and persons who do not currently use tobacco products. In conducting this evaluation, the Agency must consider, among other things, whether individuals who do not use tobacco products would start using the product and whether existing tobacco users who would have otherwise quit would switch to the MRTP instead.

As of October 31, 2019, FDA has received a total of 42 MRTPAs. Of the 42 MRTPAs received, 69% have been closed<sup>46</sup> (n=29). Of those 29, there are:

- 8 modified risk granted orders
- 10 refuse to accept (RTA)
- 6 refuse to file (RTF)
- 5 withdrawals

Of the 13 MRTPAs currently under review, all have been filed and made publicly available, and 11 have completed the TPSAC process.

On October 22, 2019, FDA authorized<sup>47</sup> eight Swedish Match USA, Inc. snus smokeless tobacco products sold under the “General” brand name<sup>48</sup> to be marketed as MRTPs. This action marked FDA’s first authorizations under the MRTP pathway.<sup>49</sup> With these authorizations, the

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<sup>46</sup> Closed means CTP has taken a final action on an application. Final actions for MRTPA include Refuse to Accept (RTA), Refuse to File (RTF), modified risk granted order, denial of a modified risk order, withdrawals, or administrative closure. 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 does not contain all the items under section 911(d) of the FD&C Act, FDA will issue a refuse-to-file letter.

<sup>47</sup> Swedish Match General Snus, 2015.

<sup>48</sup> These products were previously authorized to be marketed without modified risk information in 2015 based on CTP’s review of their PMTAs.

<sup>49</sup> In 2016, FDA took action on the original General snus MRTPAs that were submitted in 2014, issuing a denial to one request and a response letter to the others. The applicant submitted an amendment to its MRTPA in September 2018 to address deficiencies, including by proposing a revised claim and conducting a new consumer perceptions study.

manufacturer could market these specific products with the claim “Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.” FDA conducted a thorough scientific review that included a multidisciplinary team of scientific reviewers, a public comment period, and a public meeting of the TPSAC.

FDA believes that the MRTP pathway is an important component of its tobacco product review authorities and tool for achieving the Agency’s mission. The first MRTP authorizations are significant, not only because of the expectation that these products will benefit the population’s health but also because these authorizations demonstrate that FDA has developed a practical program to implement the pathway delineated under section 911 of the FD&C Act that is viable for manufacturers.

## **V. DATA ON 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 the Center’s inception, staffing has grown to hundreds of 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, communications specialists, and other professionals needed to design and implement a comprehensive program of tobacco product regulation.

The Center is composed of six offices. They are:

- 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 (FTE) program levels from FY 2009 through FY 2019.

<b>Fiscal Year</b>	<b>Program Level FTEs</b>
2009 Actual	0 <sup>50</sup>
2010 Actual	113

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<sup>50</sup> 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.

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

## VI. CONCLUSION

Given the substantial impact tobacco use and exposure has on America's health, FDA's regulation of tobacco products is a vital step to protecting the public from the harmful effects of tobacco use. By extending FDA's authority to additional tobacco products in 2016, through the Deeming Rule, the Agency has been in an even better position to protect the public health by regulating an ever-changing tobacco marketplace.

In the last 6 years, FDA has made significant strides in establishing and implementing a framework for tobacco product regulation that is based on an expanding repository of available science. Notable efforts have included:

- Applying lessons learned to develop a consistent and transparent review process for tobacco product applications;
- Developing a robust regulatory science research program;
- Promulgating evidence-based regulations and guidance;
- Creating effective public education campaigns; and
- Enforcing compliance with tobacco product requirements.

FDA continues its efforts to reduce the toll that tobacco use and exposure have on our nation's health.

**APPENDIX A: CURRENT REGULATIONS, GUIDANCE DOCUMENTS, AND OTHER REGULATORY DOCUMENTS ISSUED BY FDA RELATED TO THE TOBACCO CONTROL ACT (ORGANIZED BY TYPE)**

Type <sup>51, 52, 53</sup>	Title	Date <sup>54</sup>
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
Final Rule	Tobacco Products, Exemptions From Substantial Equivalence Requirements	07/05/2011
Final Rule	Required Warnings for Cigarette Packages and Advertisements	06/22/2011
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

<sup>51</sup> Rules and Regulations. FDA. <https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/rules-and-regulations>.

<sup>52</sup> Guidance. FDA. <https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/guidance>.

<sup>53</sup> Appendix A does not include guidance documents that have been withdrawn or superseded by a more current version or a final draft/final rule.

<sup>54</sup> The date listed reflects either the date of issuance or the date published in the *Federal Register*.

Proposed Rule	Premarket Tobacco Applications and Recordkeeping Requirements	09/25/2019
Proposed Rule	Tobacco Products; Required Warnings for Cigarette Packages and Advertisements	08/16/2019
Proposed Rule	Content and Format of Substantial Equivalence Reports; Food and Drug Administration Actions on Substantial Equivalence Reports	04/02/2019
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	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	FDA Deems Certain Tobacco Products Subject to FDA Authority, Sales and Distribution Restrictions, and Health Warning Requirements for Packages and Advertisements (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
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	The 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 Tobacco Products; Categorical Exclusions	10/26/2015
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	03/28/2012

	Regulations of the Food and Drug Administration to Incorporate Tobacco Products	
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	Submission of Plans for Cigarette Packages and Cigarette Advertisements	12/30/2019
Draft Guidance	Modifications to Compliance Policy for Certain Deemed Tobacco Products	03/14/2019
Draft Guidance	Enforcement Policy for Certain Marketed Tobacco Products	03/01/2019
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	Applications for Premarket Review of New Tobacco Products	09/28/2011
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	10/05/2009

	Product Regulated under the Federal Food, Drug, and Cosmetic Act	
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