TOBACCO CONTROL ACT

(Dollars in Thousands)	FY 2018 Enacted	FY 2018 Actuals	FY 2019 Annualized CR	FY 2020 President's Budget	FY 2020 +/- FY 2019 Annualized CR
Tobacco	**626,663**	**625,406**	**626,663**	**761,739**	**135,076**
Center	**611,979**	**614,794**	**611,979**	**747,055**	**135,076**
Family Smoking Preventionb and tobacco Control Act	611,979	614,794	611,979	647,055	35,076
Expand tobacco product (Proposed)	---	---	---	100,000	100,000
Field	**14,684**	**10,612**	**14,684**	**14,684**	**---**
Family Smoking Preventionb and tobacco Control Act	14,684	10,612	14,684	14,684	---
FTE	**874**	**874**	**991**	**1,053**	**62**

Authorizing Legislation: Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321-399); The Family Smoking Prevention and Tobacco Control Act of 2009 (P.L. 111-31); The Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333); Public Health Service Act of 1944 (42 U.S.C. 201); Federal Advisory Committee Act of 1972, as amended.

Allocation Methods: Competitive Grants; Contracts; Direct Federal/Intramural

PROGRAM DESCRIPTION AND ACCOMPLISHMENTS

The Center for Tobacco Products (CTP) oversees the implementation of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). 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 executes its regulatory and public health responsibilities in program areas that support the following objectives:

- reducing initiation of tobacco product use
- decreasing the harms of tobacco products
- encouraging cessation among tobacco product users.

To achieve its goals, FDA relies on statutory authorities to regulate the manufacturing, marketing, and distribution of tobacco products. The Tobacco Control Act requires domestic tobacco product manufacturers to register and provide a list of tobacco products they manufacture, and tobacco product manufacturers and importers are required to submit a listing of ingredients in their products. Industry must report harmful and potentially harmful constituents and the Tobacco Control Act prohibits inaccurate, false, or misleading tobacco product labeling and marketing.

Some of FDA's authorized activities include:

- inspecting tobacco product manufacturing establishments and tobacco retailers to ensure compliance with laws and regulations
- establishing tobacco product standards to protect public health
- issuing regulations on the marketing and advertising of tobacco products
- strengthening health warnings for tobacco products
- taking enforcement action for violations of the Tobacco Control Act and implementing regulations.

FDA's comprehensive plan for tobacco and nicotine regulation serves as a multi-year roadmap to protect youth and significantly reduce tobacco-related disease and death. The approach places nicotine, and the issue of addiction, at the center of the agency's tobacco regulation efforts. The goal is to ensure that the FDA has the proper scientific and regulatory foundation to efficiently and effectively implement the Tobacco Control Act. Key features of the comprehensive plan include:

- regulatory policies on addiction, appeal and cessation
- Youth Tobacco Prevention Plan: announced April 24, 2018, to reduce access to - and use of - tobacco products, particularly e-cigarettes
- science-based review of tobacco products.

Almost 90% of adult smokers start smoking by the age of 18,[96] and nearly 2,500 youth smoke their first cigarette every day in the United States.[97] By lowering nicotine levels in cigarettes to minimally addictive or non-addictive levels, we could decrease the likelihood that future generations become addicted to cigarettes and allow more currently addicted smokers to quit.

REDUCE THE BURDEN OF ADDICTION CRISES THAT ARE THREATENING AMERICAN FAMILIES

The following selected accomplishments demonstrate FDA's commitment to reducing the burden of the addiction crises that are threatening American families by protecting youth and helping addicted adult smokers quit, and by significantly reducing tobacco-related disease and death in the U.S. in the years to come.

Regulation

The Tobacco Control Act gave FDA 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 a rule – Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act (FD&C Act) – which extended FDA's tobacco authorities to all tobacco products, including electronic nicotine delivery systems (ENDS) - such as e-cigarettes and vape pens - cigars, hookah (waterpipe) tobacco, pipe tobacco and nicotine gels.

This rule helps implement the goals of the Tobacco Control Act and allows FDA to improve public health and protect future generations from the dangers of tobacco use through a variety of steps, including restricting the sale of these tobacco products to minors nationwide.

[96] U.S. Department of Health and Human Services (USDHHS). The Health Consequences of Smoking - 50 Years of Progress. A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 2014.

[97] undefined

Figure 17

As part of the Agency's comprehensive plan for regulation of nicotine and tobacco, FDA has begun a public dialogue about lowering nicotine levels in combustible cigarettes to minimally addictive or non-addictive levels through a tobacco product standard regulation. On March 16, 2018, FDA published an Advance Notice of Proposed Rulemaking (ANPRM) to seek input on the potential public health benefits and any possible unintended consequences of limiting nicotine in cigarettes to minimally-addictive or non-addictive levels.

Further, FDA indicated that it is seeking public input on other tobacco regulatory issues. On March 21, 2018, FDA published an ANPRM to seek public comment on the role that flavors in tobacco products - including menthol - play in attracting youth, as well as the role some flavors may play in helping some smokers switch to potentially less harmful forms of nicotine delivery. FDA also published on March 26, 2018, an ANPRM to solicit additional comments and scientific data related to the patterns of use and resulting public health impacts from "premium" cigars.

To encourage innovations that have the potential to make a notable public health difference and to put foundational rules in place to provide increased clarity and efficiency for industry, the Agency extended the premarket application deadlines described in the deeming rule for certain products. Specifically, in August 2017, the FDA posted a revised guidance, Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule, which deferred enforcement of deadlines to submit tobacco product applications for newly regulated tobacco products that were on the market as of August 8, 2016.[98] Under these revised timelines, applications for newly regulated combustible products, such as cigars, pipe tobacco and waterpipe tobacco, would be submitted by August 8, 2021, and applications for non-combustible products such as ENDS would be submitted by August 8, 2022.

When Commissioner Gottlieb announced FDA's comprehensive plan for tobacco and nicotine regulation in 2017, the deadlines for certain deemed products were extended, in part, so FDA could issue guidance and foundational rules for submission of product applications and to allow manufacturers more time to prepare product applications. Commissioner Gottlieb made clear FDA's concerns about kids' use of e-cigarettes, especially those products marketed with obviously kid-appealing flavors. At the time, however, the trends in youth use appeared to be changing in the right direction – reported e-cigarette use among high school students, which peaked at 16.0 percent in 2015, had decreased to 11.3 percent in 2016 and held steady in 2017. What FDA did not predict was that, in 2018, youth use of e-cigarettes and other ENDS products

[98] https://www. fda. gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM557716. pdf

would become an epidemic. According to findings from the 2018 National Youth Tobacco Survey (NYTS), there has been a dramatic increase in youth use of e-cigarettes and other ENDS: from 2017 to 2018, there was a 78 percent increase in current e-cigarette use among high school students and a 48 percent increase among middle school students.[99]

Therefore, on November 15, 2018, Commissioner Gottlieb outlined updates to our policy framework to address the large increase in youth use of tobacco products. Our focus is on what appear to be the central issues—youth appeal and youth access to flavored tobacco products. FDA will be taking steps on the following product categories:

- flavored ENDS products (other than tobacco, mint, and menthol flavors or non-flavored products) that are not sold in an age-restricted, in-person location;
- flavored ENDS products (other than tobacco, mint, and menthol flavors or non-flavored products) that are sold online without heightened age verification processes;
- flavored cigars;
- ENDS products that are marketed to kids; and
- menthol in combustible tobacco products, including cigarettes and cigars.

FDA intends to provide additional details, including what the agency might consider an "age-restricted" location, what it might consider "heightened" age-verification online, and timelines for when FDA intends to implement these policies. This policy reflects FDA's aim of striking the right balance between closing the on ramp for kids to become addicted to nicotine while maintaining access to potentially less harmful forms of nicotine delivery for adult smokers seeking to transition away from combustible tobacco products.

FDA's Tobacco Program is accomplished by issuing regulations and guidance that explain FDA's expectations to regulated industry and the public. FDA invests in tobacco regulatory research to inform regulatory activities and assess the impact of regulatory actions. Furthermore, FDA ensures industry compliance by enforcing warning label and advertising requirements, and restricting sales and marketing of tobacco products to underage youth through the use of compliance inspections, warning letters, civil money penalties, and no-tobacco-sale-orders.

Product Review and Evaluation

FDA's authority to regulate tobacco products includes premarket review of new tobacco products to determine if their marketing is appropriate for the protection of the public health, or if they are substantially equivalent to existing products. Tobacco products are inherently dangerous. FDA's responsibility is to review new tobacco products to determine if they meet the appropriate statutory standard for marketing.

New products and product changes are submitted for FDA review under one of these three marketing pathways:

- premarket tobacco product application (PMTA)
- report demonstrating substantial equivalence (SE Report) to certain commercially marketed products
- request for exemption from demonstrating substantial equivalence (Ex Req).

[99] https://www. fda. gov/NewsEvents/Newsroom/PressAnnouncements/ucm625917. htm

On October 22 and 23, 2018, FDA held a public meeting to improve public understanding and seek feedback on the policies and processes for the submission and review of tobacco product marketing applications, including the general scientific principles relevant to various application pathways, in order to assist applicants considering submitting marketing applications for tobacco products.

PMTA and Substantial Equivalence

Under the PMTA pathway, manufacturers must demonstrate to FDA that the marketing of the new tobacco product would be appropriate for the protection of the public health. This standard requires FDA to consider the risks and benefits to the population, including users and non-users of tobacco products.

Alternatively, manufacturers may submit SE Reports to seek FDA authorization to legally market a new tobacco product. FDA has made significant progress in this important area and has built a science-based process to review these SE Reports to determine whether the new product is substantially equivalent to a valid predicate product.

A substantially equivalent tobacco product is a product that FDA has determined has the same characteristics as a predicate tobacco product or has different characteristics than the predicate tobacco product, but the information submitted by the applicant demonstrates that the new product does not raise different questions of public health. A predicate tobacco product[100] is one that was commercially marketed in the United States – other than in a test market – as of February 15, 2007, or a product previously found to be substantially equivalent by FDA.

FDA reviews these SE Reports to determine if the new tobacco product is substantially equivalent and is in compliance with the requirements of the law. If both criteria are met, FDA issues a written order permitting the product to be legally marketed in the United States.

FDA has prioritized the review of regular[101] SE Reports and has made progress in each of the three phases in the SE review process:

- acceptance review phase – FDA makes a decision to either accept or refuse the application based on regulatory and statutory requirements
- notification and predicate eligibility phase – for provisional SE Reports only the applicant is notified when scientific review will begin
- substantive scientific review phase and issuance of a decision.

All regular SE Reports received are immediately entered into review. In FY 2018, FDA met all performance goals for Regular SE Reports and Exemption Requests. Additionally, as part of a re-examination of the review queue of "Provisional SE Reports," FDA announced new performance measures for these reports which will take effect in FY 2019. These performance measures are similar to those used for Regular SE Reports but are tailored for the unique circumstances of provisional SE reports.

[100] http://www.fda.gov/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/SubstantialEquivalence/ucm304517.htm#3

[101] SE Reports received after March 22, 2011 are "regular" reports and products covered by those reports cannot be marketed unless FDA first issues a finding of substantial equivalence.

On July 19, 2018, FDA issued for the first time SE orders on regular SE Reports for two non-combusted cigarettes tobacco products, demonstrating that the SE premarket review pathway is viable for non-combustible cigarettes. In addition, each of these products could serve as predicate products for future SE Reports.

FDA is also actively continuing scientific review of provisional SE Reports.[102] FDA announced on April 5, 2018, removal of certain provisional SE applications from review because those products are less likely to raise different questions of public health. Over 1,100 reports have been removed from review, but FDA estimates 1,500 provisional products may ultimately be removed from review, depending on additional information provided by the applicant. This new approach allows for increased efficiency, better use of resources, and greater transparency - while ensuring those products with the greatest potential to raise different questions of public health undergo a full multi-disciplinary scientific review.

Products removed from review can continue to be legally marketed so long as they do not undergo further changes or do not fall under certain other exceptions that would pull the products back into the review queue. As part of re-examining the review queue of "Provisional SE Reports," FDA also announced performance measures for these reports. These new performance measures will guide FDA's efforts and allow for all interested stakeholders to stay up-to-date on progress in reviewing these applications as of FY 2019.

On August 14, 2018, FDA announced the agency is improving transparency regarding certain review documents for provisional SE tobacco products. FDA will proactively provide applicants certain reviews with underlying data to facilitate understanding of a provisional Not Substantially Equivalent (NSE) decision. Applicants are no longer required to file a Freedom of Information Act request to obtain these documents following a decision.

FDA expects the time required for review of SE Reports to decrease as CTP continues to improve the efficiency of its review process and companies continue to improve the completeness and quality of their applications.

Modified Risk Products

In addition to the three marketing pathways, before marketing legally marketed tobacco products with claims that explicitly or implicitly represent the product is for use to reduce harm or the risk of tobacco-related disease, manufacturers must submit a Modified Risk Tobacco Product Application (MRTPA) and receive an FDA order authorizing that the product reduces harm or the risk of tobacco-related disease.

The following table is a summary of tobacco product applications received through October 31, 2018.

[102] SE Reports received before March 23, 2011 for products introduced to market or changed between February 15, 2007, and March 22, 2011 are "provisional" reports and products covered by those reports can continue to be marketed until FDA issues a finding of not-substantial equivalence.

Application Status	Product Class	Cumulative through 10/31/2018			
		Regular SE Reports	**Provisional SE Reports**	**Premarket Tobacco Applications**	**Modified Risk Tobacco Applications**
Received	Cigarettes	1,184	2,351	6	10
	RYO	976	642	3	0
	Smokeless	332	588	14	19
	Other	274	18	(Deemed) 373	(Deemed) 8
	Total	**2,766**	**3,599**	**396**	**37**
Pending	Cigarettes	44	669	3	3
	RYO	23	67	0	0
	Smokeless	36	185	6	7
	Other	3	0	(Deemed) 4	(Deemed) 0
	Total	**106**	**921**	**13**	**10**
>Closed[103]	Cigarettes	1,140	1,682	3	7
	RYO	953	575	3	0
	Smokeless	296	403	8	12
	Other	271	18	(Deemed) 369	(Deemed) 8
	Total	**2,660**	**2,678**	**383**	**27**

Research

FDA invests in research to inform regulatory actions by addressing gaps and adding to the evidence base. The regulatory research informs FDA's tobacco regulatory activities and helps FDA better understand tobacco use and associated risks which supports FDA's mandate to reduce the public health burden of tobacco product use in the United States. In FY 2018, FDA invested more than $182 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. Research priorities address the following Scientific Domains:

- Toxicity: understanding how tobacco products and changes to tobacco product characteristics affect their potential to cause morbidity and mortality
- Addiction: understanding the effect of tobacco product characteristics on addiction and abuse liability
- Health Effects: understanding the short- and long-term health effects of tobacco products

[103] Closed includes refuse-to-accept, refuse-to-file, remove from review, issuance of an order, special advice/information request, response, withdrawn, or closure due to administrative issues.

- Behavior: understanding the knowledge, attitudes, and behaviors related to tobacco product use and changes in tobacco product characteristics
- Communications: understanding how to effectively communicate to the public and vulnerable populations (including underage youth) regarding nicotine and the health effects of tobacco products, including media campaigns and digital media
- Marketing Influences: understanding why people become susceptible to using tobacco products (both classes of products and products within classes) and to transitions between experimentation and initiation to regular use and dual use
- Impact Analysis: understanding the impact of potential FDA regulatory actions.

In addition to conducting independent research to support regulatory science, CTP partners with several other FDA Centers including the National Center for Toxicological Research (NCTR) and Center for Food Safety and Nutrition (CFSAN), and FDA's Southeast Tobacco Laboratory, as well as other governmental agencies, including the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC). By leveraging the expertise of other Federal agencies, FDA brings science-based regulation to the manufacturing, marketing, and distribution of tobacco products.

NIH Tobacco Regulatory Science Program (TRSP)

FDA avoids duplication of resources and enhances scientific research capability by collaborating with NIH and tapping into its well-established infrastructure. In FY 2018, FDA funded 114 research projects via NIH. These research projects include grants and contracts which will address important FDA research priorities.

FDA funds NIH TRSP and works with TRSP to stimulate tobacco regulatory research and fund projects to study:

- the impact of marketing and communications on tobacco use behavior
- perceptions, knowledge, attitudes, and beliefs regarding tobacco products
- toxicity, carcinogenicity, and health risks of tobacco products
- varying nicotine levels and other constituents' effects on initiation, dependence, and quitting.

FDA also funds research via NIH that includes studying the impact of flavor and sweetness of different tobacco products on use behaviors such as experimentation and initiation among youth and young adults.

In FY 2018, FDA funded 53 new grants to support regulatory science research on tobacco products in the fields of biomedical, behavioral, and social sciences.

FDA collaborates with NIH to fund the Tobacco Centers of Regulatory Science (TCORS). In September 2018, nine TCORS grants were awarded. This second round of funding covers FY 2018-2022. The objective of the Centers is to conduct multidisciplinary research that will inform and assess FDA's prior, ongoing, and potential regulatory activities. TCORS investigators also have the flexibility and capacity to respond to FDA's research needs as issues are raised in today's rapidly evolving tobacco marketplace.

FDA also collaborates with NIH to fund the Center for Coordination of Analytics, Science, Enhancement and Logistics (CASEL). Its objective is to facilitate synthesis, coordination, and communications of research and career enhancement within the scientific program by FDA.

FDA funds the Population Assessment of Tobacco and Health (PATH) Study via NIH's Nation

Figure 18 Population Assessment of Tobacco and Health logo

al Institute on Drug Abuse (NIDA) and works collaboratively with them on the scientific aspects of the study. The PATH Study is an ongoing national, longitudinal, cohort study of users of tobacco products and those at risk for tobacco use with a national sample of U.S. civilian, non-institutionalized persons ages 12 and older. It follows approximately 46,000 never, current, and former users of tobacco products. Research topics in the PATH study related to reducing harm include evaluating patterns of tobacco use such as switching products and using multiple products, as well as seeking to understand perceptions, knowledge, attitudes and use of modified risk tobacco products.

Data is collected in "Waves" and the questionnaire data is released to the public and to researchers. Starting in FY 2017, FDA began collecting data on the full cohort every two years instead of every year to allow for sub-studies in the off years to address high priority areas. The first sub-study on youth was launched in December 2017. Additionally, a sub-study of adult e-cigarette users was launched in December 2017 to better understand their e-cigarette use; data collection for this study was completed in August 2018.

Laboratory Analyses

FDA partners with CDC to address priority research needs and with the Division of Laboratory Sciences at CDC on research projects which use laboratory-based approaches to expand knowledge to inform regulation of tobacco products. These research projects include:

- analyses of tobacco products and mainstream smoke
- method development for biomarkers
- exposure assessments under actual use conditions
- further method development for harmful and potentially harmful constituents (HPHCs).

CDC is also providing the analyses of tobacco exposure biomarkers from research data collected in the PATH Study.

CTP partners with NCTR to research:

- the toxicology of compounds and cigarette smoke
- the toxicity of tobacco products via cell culture and animal models
- developmental bioinformatics projects.

In FY 2017, CTP partnered with CFSAN to develop an in vitro buccal (mouth) membrane model to determine absorption of HPHCs found in smokeless tobacco.

National Surveys

To provide critical data on youth use and perceptions of tobacco products, FDA collaborates with the Office of Smoking and Health, CDC to conduct the National Youth Tobacco Survey (NYTS) on an annual basis. FDA funding has expanded the scope and increased the frequency of data collection for the NYTS. The NYTS is a large annual survey of a nationally representative sample of middle and high school students that focuses exclusively on tobacco. On November

15, 2018, data published from this survey indicated a 78 percent increase in current e-cigarette use among high school students and a 48 percent increase among middle school students from 2017 to 2018. NYTS survey data allows FDA to monitor youth awareness of, susceptibility to, experimentation with, and use of, a wide range of tobacco products.

FDA has worked with CDC National Center for Health Statistics (NCHS) and other federal partners to develop and include non-cigarette tobacco use questions on the National Health Interview Survey (NHIS).

In FY 2017, CTP partnered with the NIH's National Cancer Institute (NCI) to co-sponsor the Tobacco Use Supplement to the Current Population Survey (TUS-CPS) via an interagency agreement with U.S. Census Bureau. TUS-CPS is a nationally representative tobacco survey of adults with links to social and economic Census Bureau and Bureau of Labor Statistics data and health data from the National Longitudinal Mortality Study.

Compliance and Enforcement

FDA has a comprehensive compliance and enforcement program to monitor industry compliance with regulatory requirements, and to restrict access and marketing of tobacco products, including e-cigarettes and vape products, to youth.

As part of the Youth Tobacco Prevention Plan, FDA has recently taken the following actions to stop youth use of, and access to, JUUL and other e-cigarette products:

- conducted multiple nationwide blitzes to crack down on the sale of e-cigarettes to minors at both brick-and-mortar and online retailers
- issued more than 1,300 warning letters and civil money penalty complaints to retailers who illegally sold e-cigarette products to minors
- partnered with the Federal Trade Commission (FTC) to issue warning letters to e-liquid manufacturers whose products used misleading, kid-appealing imagery such as candy
- requested e-cigarette manufacturers submit documents that will help FDA better understand the reportedly high rates of youth use and youth appeal of e-cigarette products
- issued letters to the manufacturers of five top-selling vape product brands asking each company to submit plans addressing youth access and use of their products
- investigated 21 e-cigarette companies that may be illegally marketing their products to youth
- took steps to foreclose online sales of e-cigarette products to minors.

Figure 19 Example of misleadingly labeled e-liquids resembling kid-friendly food products

Tobacco Retailer Inspection

As of October 31, 2018, FDA had contracts for tobacco retailer compliance check inspections in 56 states, territories, and tribal jurisdictions. Compliance check inspections pertain to tobacco marketing, sales, 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 commissions and trains these officials to conduct inspections on the Agency's behalf. FDA currently utilizes more than 800 commissioned inspectors.

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, and No-Tobacco-Sale-Orders when violations are found. The following table lists the different enforcement actions that have resulted from these inspections.

CTP Tobacco Retailer Inspection Program

Enforcement Action	FY 2018 Actuals	FY 2019 (as of 10/31/2018)	Total Since the Program's Inception (as of 10/31/2018)
Retailer Inspections	146,398	10,841	1,000,029
Warning Letters	14,032	1,153	79,630
ENDS Products Only	2,929	39	6,126
Civil Money Penalties	3,537	368	19,195
ENDS Products Only	460	17	781
No-Tobacco-Sale-Orders	48	0	143

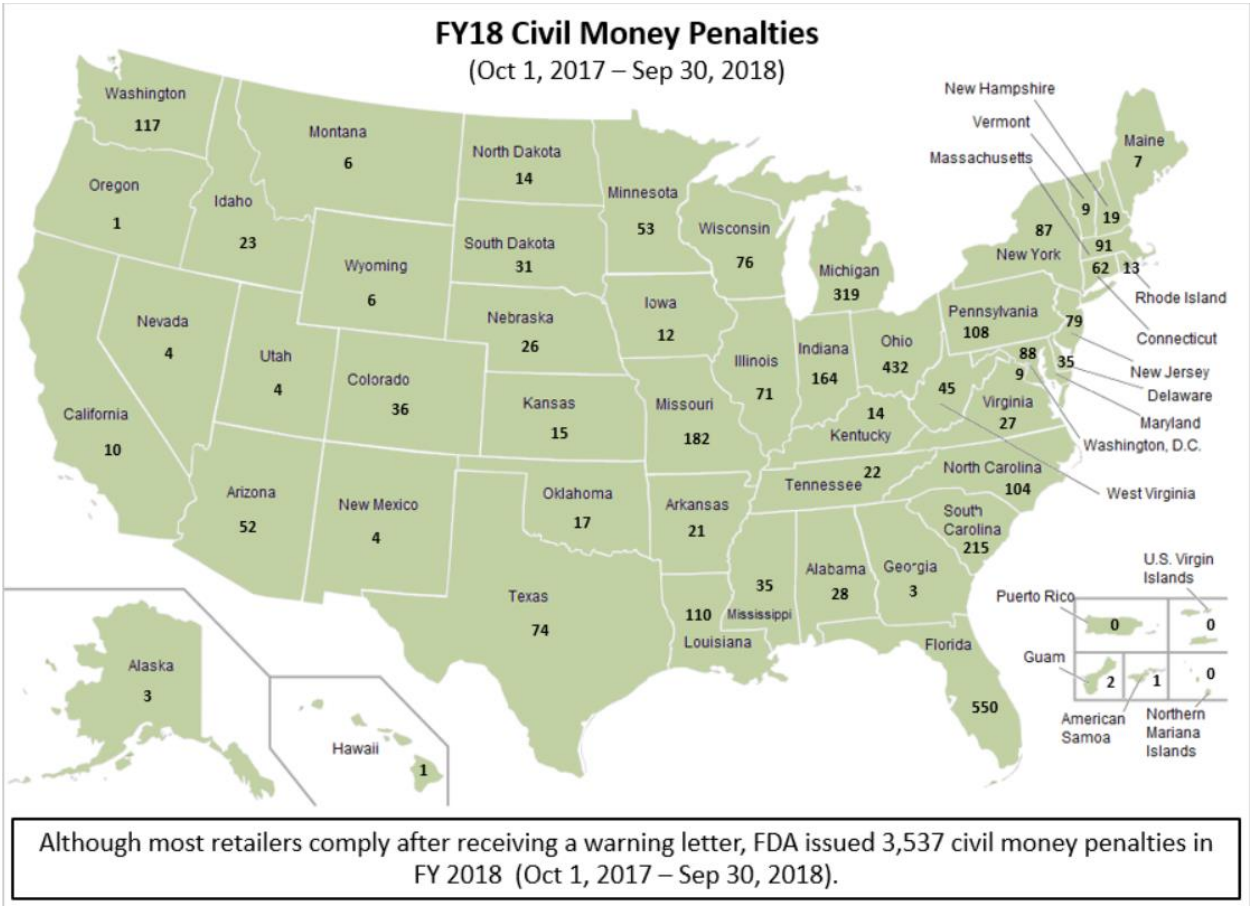

Figure 20 The number of Civil Money Penalty Complaints filed by the Center for Tobacco Products in FY 2018 by state.

Tobacco Retailer Education Program

"This Is Our Watch," is a voluntary national retailer education program designed to educate retailers on how to comply with federal tobacco laws, including deemed tobacco products. The program includes a free set of resources, such as a programmable calendar, designed to support retailers' efforts to educate staff on enforcing federal laws and regulations.

Tobacco Manufacturer Inspections

FDA regularly inspects registered establishments that manufacture or process tobacco products to determine compliance with existing laws and regulations. CTP's coordination with the Office of Regulatory Affairs (ORA) has increased considerably as the scope of these activities continues to expand to include manufacturers and importers of deemed tobacco products and additional provisions in the final Deeming rule. As of October 31, 2018, CTP has overseen the completion of more than 900 inspections of vape shops to verify whether they were engaged in manufacturing activities, and ORA has completed over 400 routine biennial inspections of tobacco manufacturers.

Promotion, Advertising, and Labeling Activities

FDA conducts surveillance of websites, social media, and magazines and other publications that promote and sell regulated tobacco products, including e-cigarettes and other ENDS products, in the U.S. market, and takes enforcement action when violations are found. As of October 31,

2018, FDA has issued over 690 warning letters as a result of these surveillance activities. In FY 2018, more than 115 warning letters were issued. FDA also conducts investigations of events where free samples of tobacco are distributed and events sponsored by the tobacco industry to ensure compliance with the Tobacco Control Act.

Office of Small Business Assistance (OSBA)

CTP's OSBA informs small businesses of existing guidances, regulations, and submission pathways through publications and online webinars. CTP has produced over 65 compliance training webinars that explain in detail important requirements for industry manufacturers, importers, and retailers with topics ranging from imported product regulations to health warning statement requirements. OSBA also answers questions from regulated industry, including small tobacco product manufacturers and retailers, consumers of regulated tobacco products, and the general public. OSBA responds to thousands of calls, emails, and correspondence every year to assist in answering specific questions about requirements of small businesses and how to comply with the law.

Public Education Campaigns

FDA's public education campaigns help educate the public—especially youth—about the dangers of regulated tobacco products. Achieving the FDA's mission to reduce tobacco-related death and disease requires a comprehensive, scientific, and innovative approach. FDA's tobacco use prevention campaigns focus on changing knowledge, attitudes and beliefs that lead to tobacco use, by following an evidence-based process to develop messages and tactics, including:

- identifying the problem to address
- researching the target audience and the best way to reach them
- testing messages and materials with the target audience
- sharing the messages using a variety of media
- assessing how effectively the messages reached the target audience and changing the messages if necessary.

FDA's current public education campaigns:

Campaigns	Launch date	Description
"The Real Cost" Campaign	February 2014	Educate at-risk youth aged 12 to 17 about the harmful effects of tobacco use.
"The Real Cost" Smokeless Campaign	April 2016	Educate at-risk 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	May 2015	Prevent and reduce tobacco use among at-risk multicultural youth ages 12-17 who identify with hip-

		hop culture, 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	Encourages cigarette smokers to quit through messages of support that underscore the health benefits of quitting. Targets smokers ages 25-54 who have attempted to quit smoking in the last year but were unsuccessful.

The Real Cost

FDA's award-winning youth tobacco prevention campaign, "The Real Cost," continues to seek to prevent youth who are open to tobacco from trying it and to reduce the number of youth who move from experimenting with tobacco to regular use.

In its first two years, research shows the campaign has achieved its stated goals: "The Real Cost" prevented an estimated 350,000 teens ages 11 to 18 from initiating smoking between 2014 and 2016, half of whom might have gone on to become established adult smokers. Ultimately, preventing these kids from becoming established smokers has saved them, their families, and the country more than $31 billion by reducing smoking-related costs like early loss of life, costly medical care, and lower productivity.

Figure 21 "The Real Cost" campaign logo

These results not only reinforce the importance of our public education efforts in reducing the public health and financial burden of tobacco use, but also highlight the importance of investing in tobacco-related education campaigns. Investment in tobacco prevention can have huge returns: the campaign has a cost savings of $128 for every dollar invested in the first two years of the campaign. The campaign continues to air nationally across TV, radio, print, web, and social media, and new advertising will launch in January 2019.

"The Real Cost" smokeless campaign aims to shift rural teen boys' knowledge, attitudes, and beliefs about the dangers of smokeless tobacco. The campaign most recently launched new advertising in August 2018.

While evaluation of the smokeless campaign is still underway, preliminary data indicates that 85.9% of the target audience is aware of at least one of the campaign's videos. Data are also showing increased agreement with specific campaign targeted attitudes and beliefs that are correlated with reduced odds of smokeless use. For instance, agreement with several negative health consequence attitude and belief statements about smokeless tobacco are moving in the desired direction.

In September 2018, FDA expanded "The Real Cost" campaign to educate the nearly 10.7 million youth aged 12-17 who have ever used e-cigarettes or are open to trying them about the potential

risks of e-cigarette use. Campaign messages focus on educating youth that using e-cigarettes, just like cigarettes, puts them at risk for addiction and other health consequences.

Advertising and other prevention materials are delivered where teens spend most of their time—online and in school—including:

- online video ads
- additional content on "The Real Cost" campaign's youth-targeted website
- digital and social media content
- materials for use in high schools nationwide (e.g., posters for school bathrooms).

A nationally recognized campaign, "The Real Cost" earned a bronze Effie in the Youth Marketing category at the 2017 North American Effie Awards. The Effies are the advertising industry's most prestigious award, recognizing marketing ideas that work and have demonstrated effectiveness.

Fresh Empire

"Fresh Empire" educates the nearly five million multicultural youth are open to sm

oking or are already experimenting with cigarettes about the harms of tobacco use. FDA launched new advertising in market in August 2018 to keep the target audience engaged with campaign messages.

Figure 22 "Fresh Empire" campaign logo

The 2018 Telly Awards named the "Fresh Empire" campaign the Bronze winner for both the Motivational category for Video / Shows / Segments, and Campaign for Social Responsibility categories. The Telly Awards honor excellence in video and television. In addition, the campaign earned the 2018 Platinum award for Event Marketing, and a Gold award for the effectiveness of its website. The Hermes is an international competition that honors excellence in communications and marketing.

This Free Life

FDA's "This Free Life" campaign targets LGBT young adult tobacco users because

they 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. Of the more than two million young adults who identify as LGBT, more than 800,000 smoke occasionally and are at risk of progressing to regular tobacco use. The "This Free Life" campaign is designed to reach occasional or "social" smokers through print and digital advertising, social media, outdoor signage, and local events to help prevent tobacco-related death and disease in the LGBT community.

Figure 23 "This Free Life" campaign logo

New advertising launched in Spring 2018, focusing on the 7,000 toxic chemicals found in cigarette smoke and how smoking harms nearly every part of your body.

The 2018 Telly Awards also named the "This Free Life" campaign the Gold winner in the Public Interest and Awareness category, and a Bronze winner in the Public Service and Activism category. Additionally, the campaign earned Platinum awards in three categories: YouTube video, social video and social marketing campaign.

Every Try Counts

In January 2018, FDA launched its first adult cessation campaign, "Every Try Counts." Approximately two out of three adult smokers, more than 22 million people, say they would like to quit.[104]

Figure 24 "Every Try Counts" campaign logo

However, in 2015, of the 55% of adult smokers who made a quit attempt, only seven percent were successful.[105] The "Every Try Counts" campaign is aimed at encouraging cigarette smokers to quit through messages of support that underscore the health benefits of quitting. These messages will be displayed in and around gas stations or convenience stores – retail locations where smokers face a multitude of triggers and that typically feature cigarette advertisements. The "Every Try Counts" campaign targets smokers ages 25-54 who have attempted to quit smoking in the last year but were unsuccessful. Ongoing research is planned for use in local campaign markets. Select campaign print ads are also available for use via the Centers for Disease Control and Prevention (CDC)'s Media Campaign Resource Center (MCRC). The MCRC provides access to advertisements for use by states and/or other public health organizations and agencies.

Outcome Evaluations

A critical factor in reducing youth tobacco use is to produce and maintain effective levels of campaign awareness within the target population. Studies have specifically confirmed the effectiveness of media campaigns in reducing youth tobacco use. The NIH NCI and Community Preventive Services Task Force have conducted comprehensive scientific reviews of studies on the effectiveness of media campaigns to reduce tobacco use. The reviews concluded that media campaigns to prevent and control tobacco use are effective.

FDA is implementing multi-year outcome evaluation studies of its public education campaigns. For example, the study design for the original Cohort and now Cohort 2 of "The Real Cost" campaign is longitudinal, meaning the study will attempt to follow the same individuals over time to track changes in targeted tobacco-related knowledge, attitudes, beliefs, intentions, and behaviors.

"The Real Cost" Cohort 1 advertising exceeded its ultimate goal of reducing the number of youth aged 11 to 18 who smoke by preventing an estimated 350,000 U.S. youth from smoking from February 2014 to March 2016, ultimately saving these kids, their families, and the country more

[104] Centers for Disease Control and Prevention (CDC). Quitting smoking among adults – United States, 2000-2015. Morbidity and Mortality Weekly Report. 2017;65(52):1457-1464.

[105] Centers for Disease Control and Prevention (CDC). Quitting smoking among adults – United States, 2000-2015. Morbidity and Mortality Weekly Report. 2017;65(52):1457-1464.

than $31 billion by reducing smoking-related costs like early loss of life, costly medical care, lost wages, lower productivity, and increased disability.

FDA is also conducting separate outcome evaluations of "The Real Cost" smokeless campaign messaging, the "Fresh Empire" campaign, the "This Free Life" campaign, and the "Every Try Counts" campaign to measure whether exposure to campaign messaging creates positive changes in tobacco-related knowledge, attitudes, beliefs, and intentions among the target audiences.

FUNDING HISTORY[106]

Fiscal Year	Program Level	Budget Authority	User Fees
FY 2016 Actual	$476,525,000	---	$476,525,000
FY 2017 Actual	$754,076,000	---	$754,076,000
FY 2018 Actual	$625,406,000	---	$625,406,000
FY 2019 Annualized CR	$626,663,000	---	$626,663,000
FY 2020 President's Budget	$761,739,000	---	$761,739,000

BUDGET REQUEST

The FY 2020 Budget request is $761,739,000 all from user fees. This amount is $100 million above the FY 2020 level authorized in the Tobacco Control Act less the amounts for GSA Rent, FDA Headquarters, FDA White Oak Consolidation, and Other Rent and Rent Related, which are shown in their own sections of the budget request. This amount is $135,076,000 above the FY 2019 Annualized CR.

The Center for Tobacco Products amount in this request is $747,055,000. Currently, the Tobacco Control Act does not provide a means for FDA calculation of user fees for ENDS products and certain other deemed products. These products represent an increasing share of the tobacco marketplace as well as FDA's tobacco regulatory activities. This proposal includes a request to enable FDA to include all deemed products in the tobacco user fee assessments. FDA requests an additional $100 million and requests authority to include manufacturers and importers of all deemed products among the tobacco product classes for which FDA assesses tobacco user fees. To ensure that resources keep up with new tobacco products, the proposal would also index future collections to inflation.

In FY 2020, CTP will continue implementing the FDA-wide Comprehensive Plan for Tobacco and Nicotine Regulation, which the Center has incorporated into its six strategic priorities:

- Comprehensive Nicotine and Tobacco Regulatory Policy
- Premarket and Postmarket Controls: Regulations and Product Reviews
- Product Standards
- Public Education
- Compliance and Enforcement
- Investing in Human Capital

[106] Numbers reflect comparability adjustments for FY 2018, FY 2019, and FY 2020 consistent with budget figures.

FDA-WIDE COMPREHENSIVE PLAN FOR TOBACCO AND NICOTINE REGULATION

FDA regulates a broad range of nicotine-delivering products, from cigarettes to medicinal nicotine gum and patch. FDA is exploring an integrated, agency-wide policy on nicotine-containing products that is public health based and recognizes the continuum of risk among such products. Most recently, in November 2018, Commissioner Gottlieb announced several new steps being taken to advance the comprehensive plan for tobacco and nicotine regulation and protect youth by preventing access to flavored tobacco products and announcing plans to ban menthol in combustible tobacco products, including cigarettes and cigars.

FDA will continue to implement the comprehensive plan by:

- holding a public hearing on January 18, 2019 to discuss our efforts to eliminate youth e-cigarette use, focusing on the potential role of drug therapies to support cessation
- considering regulatory guidance on premarket review policy based on the principle of relative toxicity and risk
- working on foundational rules such as proposed rules on Substantial Equivalence, Tobacco Product Manufacturing Practices, PMTAs and MRTPs.

FDA is continuing efforts with the Nicotine Steering Committee, in conjunction with FDA's Center for Drug Evaluation and Research (CDER) and FDA's Office of the Commissioner to include:

- examining the science behind the Agency's evaluation of nicotine replacement therapies (NRTs)
- examining the types of safety and efficacy studies FDA requires and how these products are used and labeled.

Comprehensive Nicotine and Tobacco Regulatory Policy

FDA will continue pursuing the nicotine work mentioned above, as well as:

- continuing a national dialogue on nicotine to increase knowledge and understanding of the addictive nature of nicotine to better protect the public's health
- developing opportunities for global collaboration to learn from other governments' research, experiences, and challenges to inform our domestic efforts.

Premarket and Postmarket Control: Regulations and Product Reviews

FDA serves as a critical public health gatekeeper between tobacco product manufacturers and consumers by performing a scientific review before new tobacco products are commercially sold. Manufacturers are required to obtain FDA authorization before marketing new[107] tobacco products:

- by demonstrating they are appropriate for protection of public health, or
- by demonstrating substantial equivalence[108] to certain commercially marketed products.

[107] New tobacco product includes products with any modification after February 15, 2007.

[108] An alternative to new product applications where the characteristics are the same as predicate products (which is a product that was commercially marketed in the United States as of February 15, 2007, or a product previously found to be substantially equivalent) or the characteristics are different, but the product does not raise different questions of public health.

To help industry better understand expectations and aid them in preparing complete applications, CTP is exploring developing additional rules and guidances for product review pathways, tobacco product manufacturing practices, and registration and product listing. This will improve transparency and provide consistent submission guidelines which will facilitate industry's preparation of applications and speed application review by FDA staff. In addition to developing rules and guidances, CTP will continue to monitor performance measures for product reviews, including new performance measures added in FY19 for provisional SE Reports. In addition to working on foundational rules for application pathways, CTP is reviewing the process for review of SE Reports to identify areas where process improvements could enhance CTP work efficiencies. CTP is also hiring additional scientific staff to review product applications.

Product Standards

Section 907 of the Federal Food, Drug, and Cosmetic Act gives FDA the authority to issue, via notice-and-comment rulemaking, tobacco product standards that are appropriate for the protection of the public health. This authority is one of the most powerful tools that FDA has to regulate tobacco. CTP is advancing a product standard strategy to yield strong standards to improve public health, by exploring potential standards for addictiveness, toxicity, and appeal.

FDA is actively considering the need for other product standards. In July 2017, Commissioner Gottlieb announced FDA's intent to develop product standards to protect against known public health risks such as ENDS battery issues and concerns about children's exposure to liquid nicotine. FDA also is pursuing a product standard for establishing limits on the level of toxicants and impurities found in certain ENDS ingredients. And in November 2018, FDA announced its intention to move forward with proposed rulemaking to ban menthol in cigarettes and all flavors, including menthol, in cigars, on an expedited timeline.

Public Education

FDA maximizes its impact on public health by focusing public education efforts on at-risk audiences such as general market youth who are already experimenting with tobacco or are open to it; African American, Hispanic, Asian/Pacific Islander, and American Indian/Alaska Native youth; rural youth at risk of using smokeless tobacco, lesbian, gay, bisexual, and transgender (LGBT) young adults who smoke, and adult smokers who want to quit.

Several of these campaigns are also expanding to message on additional regulated tobacco products, such as ENDS. Campaign messaging and outreach tactics for each product type will continue to target discrete audiences and be informed by findings from formative research, results of outcome evaluations and real-time tracking efforts, as well as changes in youth tobacco use trends.

In addition to research and enforcement, FDA is committed to communicating to the public the risks associated with the use of tobacco products, which result in more than 480,000 deaths each year. In FY 2020, FDA will:

- continue to implement campaigns designed to reach at-risk and vulnerable populations – especially young people – with messages about the dangers of using tobacco products
- continue to conduct and share findings from its campaign outcome evaluation studies
- continue to develop interactive digital communication technologies and products such as CTP's content sharing platform, the Exchange Lab

- continue to use our communication tools (website, social media, email marketing, and stakeholder outreach) to reach consumers, public health stakeholders, and industry.

Compliance and Enforcement

FDA focuses on the utilization of a national program of inspections, investigations, monitoring, and review of covered tobacco products, sales, manufacturing, and advertising. FDA's compliance programs focus on appropriate enforcement actions that are supported by evidence of violations of the law.

FDA is currently revising its compliance policy that sets a compliance deadline of August 2022 for submission of premarket applications for ENDS. This revision means that ENDS products that are marketed to children and/or appealing to youth will no longer be subject to the compliance policy, and all flavored ENDS products (other than tobacco, mint and menthol flavors or non-flavored products) will no longer be subject to the policy unless they are sold in age-restricted, in-person locations or sold online with heightened age verification processes. The effect of not being subject to this compliance policy is that products must come off the market unless they submit a premarket application and receive marketing authorization from FDA. Continued planned activities include:

- reviewing FDA's current compliance policy to determine whether it can better account for manufacturers that are not successfully preventing widespread youth use of their products
- indefinitely stepping up enforcement actions with a sustained campaign to monitor, penalize, and prevent ENDS sales in convenience stores and other retail sites
- closely evaluating manufacturers' internet storefronts and distribution practices and taking enforcement actions if violations of the restrictions on sales to minors are found
- investigating whether manufacturers of certain ENDS products may be marketing new products that have not gone through premarket review
- conducting compliance check inspections via the Tobacco Retailer Inspection Program[109]
- coordinating with ORA to conduct inspections of tobacco manufacturing facilities
- coordinating inspections of vape shops to determine whether they conduct manufacturing activities
- providing outreach, education, and assistance to small tobacco manufacturers and retailers via CTP's OSBA
- enforcing promotion, advertising, and labeling requirements
- conducting surveillance, inspections, and investigations
- identifying criminal violations in tobacco-related cases.

Investing in Human Capital

FDA will continue to invest in its workforce by continually assessing workloads and identifying strategies to help manage work/life balance, strengthening retention and anticipating future staffing needs, and engaging employees via the annual Federal Employee Viewpoint Survey. FDA also promotes employee diversity and inclusion to cultivate an engaged workforce that reflects the country it serves.

[109] The results of the Tobacco Retailer Inspection Program can be found on FDA's website at http://www.accessdata.fda.gov/scripts/oce/inspections/oce_insp_searching.cfm

Additional FY 2020 Support Activities

FDA will continue to:

- partner with other agencies, including NIH, CDC, and FDA's NCTR to expand the tobacco regulatory science base
- provide priority research support to CDC and NCTR
- fund new research projects via NIH to address FDA time-sensitive research
- fund PATH Study analyses and sub-studies via NIH to more comprehensively examine new and emerging issues related to tobacco use behavior and health
- collect and analyze PATH Study participant responses and biomarker data to assess tobacco use transitions over time
- explore the addition of questions to the National Health Interview Survey cancer control supplemental questionnaire
- conduct priority research with research contract organizations.

PERFORMANCE

The Tobacco Control Act Program's performance measures focus on activities in order to achieve public health goals, as detailed in the following table.

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 +/- FY 2019
280005: Total number of compliance check inspections of retail establishments in States under contract. *(Outcome)*	FY 2018: 146,398 Target: 130,000 (Target Exceeded)	130,000	130,000	Maintain
280006: Review and act on Regular SE Reports within 90 days of FDA receipt (applies to cigarettes, cigarette tobacco, smokeless tobacco, and roll-your-own tobacco products) *(Output).*	FY 2018: 95% Target: 80% (Target Exceeded)	80%	80%	Maintain
280007: Educate at-risk general market 12-17 year olds about the harmful effects of tobacco use. *(Output)*	FY 2018: Reached 75% of general market at risk 12-17 year olds with campaign	Reach 65% of 12-17 year olds with campaign messaging	Reach 65% of 12-17 year olds with campaign messaging	Maintain

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 +/- FY 2019
	messaging. (Target Met)	within 1 year.	within 1 year.	

COMPLIANCE CHECK INSPECTIONS

A key element in enforcing the Tobacco Control Act involves contracts with U.S. state, territory, and tribal agencies, as well as private entities, to conduct retailer compliance checks. Under these contracts, FDA conducted more than 146,000 compliance check inspections of retail establishments in FY 2018. Although this number was much higher than the expected FY 2018 full year target of 130,000, it reflects the high level of variability inherent in this goal that requires estimating the number of compliance checks that each jurisdiction will be able to conduct. Also, some contracts are expiring and being renewed in FY 2019, and while most states, territories, tribes, and private entities are expected to renew their contracts, there are always outside factors that may prohibit them from doing so. The FY 2019 and FY 2020 targets consider these challenges and will therefore remain at the FY 2018 target levels.

REGULAR SE REPORTS

Review and act on includes issuing a Deficiency letter (e.g. Advice/Information Request letter, Preliminary Finding letter), Cancellation, Closure, SE Order or NSE Order.

EDUCATE AT-RISK GENERAL MARKET 12-17 YEAR OLDS

"The Real Cost" reach target has changed for FY 2019 because the e-cigarette prevention campaign is limited to airing on age-verified digital media only, which limits the amount of reach possible. This strategy was driven by research that indicated adult smokers who saw "The Real Cost" e-cigarette ads may be less likely to use e-cigarettes to attempt to quit smoking.

PROGRAM ACTIVITY DATA

CTP Workload and Outputs	FY 2018 Actuals	FY 2019 Annualized CR	FY 2020 President's Budget
Tobacco Retailer Inspections			
Number of Inspections	146,398	130,000	130,000
Tobacco Manufacture Inspections			
Number of Inspections [1]	96	200	300
Substantial Equivalence Reviews			
Number of Regular SE Reports	104	100	100

[1] Outyear estimates are based on the number of firms registered with FDA. FDA works to inspect each registered firm biennially.