TOBACCO CONTROL ACT

(Dollars in Thousands)	FY 2017 Final	FY 2017 Actual	FY 2018 Annualized CR	FY 2019 President's Budget	FY 2019 +/- FY 2018
Family Smoking Prevention and Tobacco Control	**596,338**	**754,076**	**592,288**	**662,043**	**69,755**
Center (UF Only)	581,438	742,641	577,489	647,493	70,004
Field (UF Only)	14,900	11,435	14,799	14,550	-249
FTE	**886**	**886**	**886**	**982**	**96**

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 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.

The following selected accomplishments demonstrate FDA's delivery of its regulatory and public health responsibilities.

Compliance

As of December 31, 2017, FDA had contracts for tobacco retailer compliance check inspections in 57 states, territories, and tribal jurisdictions. During these checks, contractors commissioned as FDA inspectors determine if retailers are complying with regulations pertaining to the marketing, sales, and distribution of tobacco products, to include compliance with age and ID verification requirements. Since the program's inception in October 2010 through December 31, 2017, FDA has commissioned more than 2,500 officers and conducted more than 874,000 compliance check inspections at tobacco retail establishments.

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 (such as e-cigarettes and vape pens), cigars, hookah (waterpipe) tobacco, pipe tobacco and nicotine gels, among others.

This rule helps implement 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.

On July 28, 2017, FDA Commissioner Gottlieb announced a new comprehensive plan for tobacco and nicotine regulation that will serve as a multi-year roadmap to protect kids 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.

For example, FDA noted that almost 90 percent of adult smokers start smoking by the age of 18,[81] and that nearly 2,500 youth smoke their first cigarette every day in the United States.[82] By

[81] 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.

[82] Substance Abuse and Mental Health Services Administration (SAMHSA). Results from the 2015 National Survey on Drug Use and Health: Detailed Tables. Rockville, MD: U.S. Department of Health and Human Services, SAMHSA, Center for Behavioral Health Statistics and Quality;

lowering nicotine levels in cigarettes to non-addictive levels, FDA explained that we could decrease the likelihood that future generations become addicted to cigarettes and allow more currently addicted smokers to quit. Therefore, FDA has begun a public dialogue about lowering nicotine levels in combustible cigarettes to non-addictive levels through achievable product standards. 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 adverse effects of limiting nicotine in cigarettes to minimally or non-addictive levels.

Further, FDA indicated that it is seeking public input on other complex issues to help ensure that the Agency has the proper science-based policies in place to meaningfully reduce the harms caused by tobacco use. 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 announced on March 23, 2018an 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 is extending the premarket application deadlines described in the deeming rule for certain products. Specifically, the FDA is deferring enforcement of deadlines to submit tobacco product review applications for newly regulated tobacco products that were on the market as of August 8, 2016. Under these revised timelines, applications for newly regulated combustible products, such as cigars, pipe tobacco and hookah tobacco, would be submitted by August 8, 2021, and applications for non-combustible products such as ENDS would be submitted by August 8, 2022.

Substantial Equivalence

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 reviewed following three marketing pathways:

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

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.

2016. https://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabs-2015/NSDUH-DetTabs-2015/NSDUH-DetTabs-2015.pdf. Accessed September 9, 2016

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[83] 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[84] 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 requirements in the statute
- notification and predicate eligibility phase – the applicant is notified that scientific review will begin, and a date for the start of review is provided
- substantive scientific review phase and issuance of a decision.

All regular SE Reports received are immediately entered into review. As of December 31, 2017:

- 2,652 regular reports have been received
- 2,411 or 91% of regular reports have been resolved[85]
- 241 regular reports are pending. 240 have begun scientific review and 198, or 83%, have been issued a deficiency letter after a cycle of scientific review was completed.

In FY 2015, FDA implemented performance measures, including timeframes for review of regular SE Reports. FDA has been able to develop these goals because of the increased knowledge of scientific evidence and data gathering needed to adequately review these SE Reports. CTP met 4 out of 8 performance goals[86] for the FY 2016 cohort. Three of the four missed goals involved a program where FDA ceased certain activities pending an August 2016 decision on an October 2015 lawsuit. Subsequent to implementation of program changes to comply with the court's decision, FDA intends to meet all these performance measures in the future.

FDA is also continuing scientific review of provisional SE Reports.[87] As of December 31, 2017:

- 3,597 provisional reports have been received
- 1,047 or 29% of provisional reports have been resolved[88]

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

[84] 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.

[85] Resolved includes refuse-to-accept, withdrawn, substantially equivalent (SE), not substantially equivalent (NSE), and closure due to administrative issues.

[86] A ninth goal had no submissions in the FY16 cohort.

[87] 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.

[88] 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.

- 2,550 provisional reports are pending. 702 have begun scientific review and 612, or 87%, have been issued a deficiency letter after a cycle of scientific review was completed.
- Approximately 1,848 of the pending provisional reports have not started scientific review

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.

Public Education

FDA is using a comprehensive public education approach to work in concert with regulatory action to reduce use of tobacco products and improve public health. As authorized by the Tobacco Control Act, these activities include planning, developing, producing, and delivering national multimedia public education campaigns.

Multimedia campaigns enable FDA to educate the public about the harms and risks of regulated tobacco products. Specifically, the campaigns will equip the public with important facts about:

- health risks of regulated tobacco products
- addictiveness of regulated tobacco products
- harmful and potentially harmful constituents in regulated tobacco products.

The Real Cost

Launched in February 2014, FDA's award-winning youth tobacco prevention campaign, "The Real Cost," continues to educate at-risk teens aged 12 to 17 about the harmful effects of tobacco use. The goal is 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.

Figure 18 "The Real Cost" campaign logo

Initial advertising focused on cigarette smoking prevention, and results from a two-year outcome evaluation published in January 2017 indicate the campaign is succeeding in meeting this goal. "The Real Cost" campaign prevented an estimated 350,000 U.S. youth from smoking from February 2014 to March 2016, exceeding FDA's goals for the campaign. Considering that most tobacco dependence begins during adolescence, these results demonstrate that youth-focused tobacco prevention campaigns like "The Real Cost" can have long-term effects on future rates of tobacco-related morbidity and mortality.

FDA has refreshed the campaign with new advertising every year to keep its at-risk youth target audience engaged with the campaign. This strategy is based on target audience research that suggests that the personality trait of sensation-seeking, which is closely linked with risk taking behavior, is associated with a preference for novel messaging. FDA refreshed the campaign with a third wave of TV advertising in October 2016 and launched two new digital ads in March and April 2017. Additional advertising is planned for launch in 2018.

FDA also expanded "The Real Cost" brand in April 2016 by launching advertising designed to prevent and reduce smokeless tobacco use among youth aged 12 to 17 who live in rural areas and are at risk for smokeless tobacco initiation. This campaign messaging aims to shift rural teen boys' knowledge, attitudes, and beliefs about the dangers of smokeless tobacco.

In August 2017, FDA announced it would pursue a new, strategic public health education effort designed to prevent youth from using e-cigarettes and other electronic nicotine delivery systems (ENDS). In support of this goal, the agency expanded "The Real Cost" public education campaign in October 2017 to educate teens about the dangers of nicotine to the developing brain. The new campaign materials include digital images and online video and radio ads. Additionally, FDA is planning to launch a full-scale media campaign to prevent youth ENDS use in 2018.

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. The campaign previously won a 2015 gold Effie in the Disease Awareness and Education category. The campaign also received a 2016 Shorty Award for Best Overall Tumblr Presence. The Shorty Awards honor the best of social media by recognizing the top influencers, brands and organizations on Facebook, Twitter, Tumblr, YouTube, Instagram and Snapchat.

Fresh Empire

The "Fresh Empire" campaign, launched on May 12, 2015, targets youth who identify with the hip-hop peer crowd – an innovative and promising segmentation approach that focuses on youth who share the same core ideals, have similar life experiences and common interests, and may be at higher risk for tobacco use.

Figure 19 "Fresh Empire" campaign logo

"Fresh Empire" is FDA's first public education campaign designed to 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. Nearly 5 million multicultural youth are open to smoking or are already experimenting with cigarettes—meaning they have already smoked up to 100 cigarettes in their lifetime[89]—highlighting a critical need for stronger, more targeted youth tobacco prevention efforts.

FDA expanded the "Fresh Empire" campaign to markets throughout the U.S. in October 2015 and launched new advertising in market in January 2017 to keep the target audience engaged with campaign messages.

The 2017 Telly Awards named the "Fresh Empire" campaign the Silver winner in the Motivational category for Video / Shows / Segments, and a Bronze winner in the Public Interest & Awareness category for Promotional Pieces. The Telly Awards honor excellence in video and television.

This Free Life

On May 3, 2016, FDA launched a public education campaign aimed at preventing and reducing tobacco use among lesbian, gay, bisexual, and transgender (LGBT) young adults aged 18 to 24. 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. Of the more than 2 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

[89] Based on 2013 data from NYTS on experimentation and openness to smoking among youth and 2014 youth population estimates from the U.S. Census Bureau.

signage, and local events to help prevent tobacco-related death and disease in the LGBT community.

The campaign won a significant multicultural award of excellence at the 18th Annual Association of National Advertisers (ANA) Multicultural Marketing & Diversity Conference in October 2016. The awards seek to raise awareness of the outstanding work in African-American, Asian, Audio, B-to-B, Digital, Experiential, Hispanic, LGBT, People with Disabilities, Print, and Total Market advertising. "This Free Life" won an ANA Multicultural Excellence Award in the LGBT category.

Figure 20 "This Free Life" campaign logo

The 2017 Telly Awards also named the "This Free Life" campaign the Bronze winner in the Cultural category for Video / Shows / Segments. Additionally, the 2017 Ad POPs (Pride in Online and Print) Awards named the "This Free Life" campaign the Gold winner in the Non-Profit category for print ads. The Ad POPs reward the best representations of LGBT individuals in online and print advertising in regional LGBT media.

Enhance Oversight

FDA's Tobacco Program is carried out by issuing regulations and guidance that explain FDA's expectations to the regulated industry and to 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 youth through the use compliance inspections, warning letters, civil money penalties, and no-tobacco-sale-orders.

Maintaining a Strong Science Base

FDA invests in priority tobacco regulatory research areas to address gaps and add to the evidence base in order to inform FDA's tobacco regulatory activities and help assess the impact of regulatory actions. In FY 2017, FDA invested more than $239 million in scientific research. Through research, FDA better understands patterns of tobacco use, the harms caused by tobacco use, and where regulatory intervention consistent with FDA's statutory authority is most needed.

FDA research supports regulatory and public education efforts to improve public health. In addition to conducting independent research to support regulatory science, the Center for Tobacco Products partners with FDA's National Center for Toxicological Research (NCTR) 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 Partnerships

FDA avoids duplication of resources and enhances scientific research capability by collaborating with NIH and tapping into its well-established infrastructure. In FY 2017, FDA funded 140 research projects via NIH. These research projects include grants, intramural projects, and

contracts which will address important FDA research priorities. Below are some of CTP's areas of research.

FDA funds NIH's Tobacco Regulatory Science Program (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 2016, FDA funded new grants to research toxicity and addictiveness of waterpipes, abuse liability of reduced nicotine content cigarettes, and tobacco regulatory science projects for new investigators.

In FY 2017, FDA funded new grants to support regulatory science research on tobacco products in the fields of biomedical, behavioral, and social sciences.

FDA continues to fund the Center for Evaluation and Coordination of Training and Research (CECTR) in Tobacco Regulatory Science via NIH to support evaluation of the CTP-funded research projects and facilitate coordination and communications of research and scientific training among those projects.

FDA collaborates with NIH to fund the 14 Tobacco Centers of Regulatory Science (TCORS). The objective of the Centers is to conduct multidisciplinary research that will inform FDA's regulatory actions related to the manufacture, distribution, and marketing of tobacco products. FDA will collaborate with NIH to fund new TCORS and a Center for Coordination of Analytics, Science, Enhancement and Logistics (CASEL) in FY 2018.

Figure 21 Population Assessment of Tobacco and Health logo

FDA funds the Population Assessment of Tobacco and Health (PATH) Study via NIH's National Institute on Drug Abuse (NIDA) and works collaboratively with them on the scientific aspects of the study. The PATH Study is a longitudinal cohort study launched in 2013 with a national sample of U.S. civilian, non-institutionalized persons ages 12 and older. The study follows approximately 46,000 never, current, and former users of tobacco products.

It is intended to yield data to inform CTP's regulatory activities including:

- comprehensive data on tobacco product use, attitudes, associated health outcomes
- biomarkers of tobacco exposure and potential harm.

Data collection for Wave 4 launched in December 2016 and Wave 5 will launch December 2018. 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 will be on youth and will begin December 2017. Wave 1 Biomarker data was released in July 2017. Wave 2 questionnaire data was released to the public in June 2017.

CDC Partnerships

FDA is partnering 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 HPHCs.

CDC is also providing the analyses of tobacco exposure biomarkers from research data collected in the PATH Study. In order 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. Data from this survey will allow FDA to monitor awareness of, susceptibility to, experimentation with, and use of, a wide range of tobacco products.

FDA National Center for Toxicological Research (NCTR) Partnership

NCTR will continue research on:

- the toxicology of compounds and cigarette smoke
- biomarker discovery
- the toxic and addictive potential of tobacco products via cell culture and animal models
- developmental bioinformatics projects.

Other Research Collaborations

FDA conducts research via research contract organizations, and includes research studies focused on studying chemistry and engineering, addiction, toxicity and carcinogenicity, health consequences, behavior, communications, and marketing. For example, there are studies that help inform the development of surveys and questionnaires, evaluate the impact of various tobacco product constituents on exposure, physiological responses, and use behavior, and assess user and non-user beliefs about emerging tobacco products.

In FY 2016, CTP contracted with the Institute of Medicine – now called the Health and Medicine Division of the National Academy of Sciences – to conduct an evaluation of health effects from e-cigarettes and identify gap areas for future federally funded research in this area.

In FY 2017, CTP partnered with National Cancer Institute (NCI), NIH 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.

Enforcement of the Tobacco Control Act

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

Tobacco Retailer Inspections

As of December 31, 2017, FDA had contracts for tobacco retailer compliance check inspections in 57 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 August 2016, FDA began including deemed products in the scope of its retail inspections. As of December 31, 2017, FDA had issued more than 10,000 warning letters to tobacco retailers for selling newly-regulated tobacco products such as e-cigarettes, e-liquids, and cigars to minors in retail stores and online.[90]

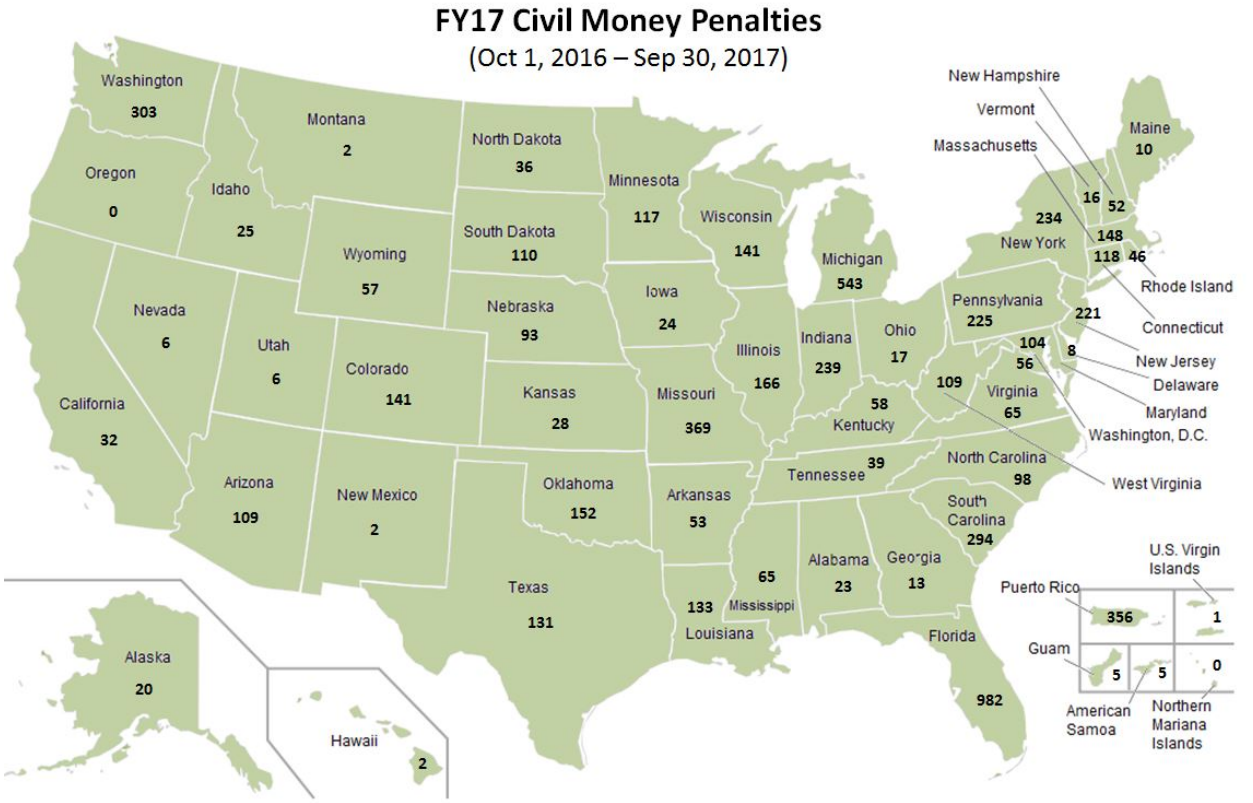
Since the Tobacco Retailer Inspection Program's inception in October 2010 through December 31, 2017, FDA has commissioned more than 2,500 officers and employees from the states, territories, and their political subdivisions, and provides a training program for those that perform inspections. FDA currently utilizes more than 700 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-Order, when violations are found. The following table lists the different enforcement actions that have resulted from these inspections.

CTP Tobacco Retailer Inspection Program

Action	FY 2016 Actuals	FY 2017 Actuals	Total Since the Program's Inception on 10/1/2010 (as of 12/31/2017)
Retailer Inspections	165,089	168,696	874,578
Warning Letters	13,921	14,735	67,722
Civil Money Penalties	3,618	6,408	16,067
No-Tobacco-Sale-Orders	34	61	99

[90] These warning letters are included in the total number of warning letters reported in the "CTP Tobacco Retailer Inspection Program" table.



Although most retailers comply after receiving a warning letter, FDA has issued 6,408 civil money penalties in FY 2017 (Oct 1, 2016 – Sep 30, 2017).

Figure 22 The number of Civil Money Penalty Complaints filed by the Center for Tobacco Products in FY 2017 by state.

Tobacco Manufacturer Inspections

FDA regularly inspects registered establishments that manufacture or process tobacco products to determine compliance with existing laws and regulations. Tobacco manufacturers of deemed products were required to register by October 12, 2017. 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 December 31, 2017, CTP conducted more than 350 inspections of vape shops to verify whether they were engaged in manufacturing activities, and ORA conducted more than 300 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 in the U.S. market. In FY 2016, FDA began surveillance of websites that sell newly deemed tobacco products, including regulated electronic nicotine delivery system (ENDS) products and took compliance actions when violations were found. Since the program's inception in October 2010, FDA has issued over 500 warning letters as a result of these surveillance activities. In FY 2017, 140 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. In FY 2016 and 2017, OSBA published 18 tobacco compliance webinars on its website, 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.

Improve and Safeguard Access to FDA-Regulated Products to Benefit Health

The Tobacco Control Act gives FDA the authority to determine whether new and modified risk products can be marketed-including reviewing and evaluating applications before the products are allowed to be marketed. Under the premarket tobacco application (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 as a whole, including users and non-users of tobacco products.

As of December 31, 2017, FDA has:

- received 392 PMTAs and refused-to-accept, or refused-to-file 372
- issued marketing orders for eight products and denied zero marketing orders. Nine PMTAs are currently under review.[91]

Although a refuse-to-accept or refuse-to-file decision closes all activity for the application, an applicant may always resubmit a new application with the missing items. By providing timely responses to applications that cannot be accepted, FDA provides manufacturers with more time to resubmit with the information that is required.

In addition to the three marketing pathways, before making marketing products with claims that imply modified risk, manufacturers must submit a Modified Risk Tobacco Product Application (MRTPA), and receive an FDA order authorizing a claim that the product reduces harm or the risk of tobacco-related disease.

As of December 31, 2017, FDA has:

- received 36 MRTPAs and refused-to-accept, or refused-to-file 14
- 17 MRTPAs pending final action[92], including nine currently under review and eight with final action deferred pending response from the applicant.

[91] Does not include three PMTAs that were closed for administrative reasons such as withdrawal.

[92] MRTPAs pending final action does not include five MRPTAs closed for administrative reasons such as withdrawal.

Promote Informed Decisions

Public Education Campaigns

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 National Cancer Institute 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 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. In FY 2015, published outcome evaluation findings for "The Real Cost" showed that over 90 percent of the target audience is aware of the campaign and its messaging - a key precursor to behavior change.[93]

Additional findings published in FY 2017 show that increasing levels of campaign exposure are associated with positive changes in campaign-related beliefs – for example, if I smoke I will get wrinkles – and that "The Real Cost" 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.

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

Strengthen Organizational Excellence

FDA provides the infrastructure necessary to support the Agency's responsibilities and authorities of the Tobacco Control Act. Examples include:

- strategic IT systems which support industry applications
- compliance inspections
- scientific data analysis
- collection of tobacco user fees.

In addition, FDA is hiring additional staff to:

- conduct reviews of product applications, including SE, PMTA, and MRTP
- expand research capabilities
- support inspection efforts
- enforce the deeming regulation
- draft regulations and guidances.

[93] http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0144827

FUNDING HISTORY

Fiscal Year	Program Level	Budget Authority	User Fees
FY 2015 Actual	$554,469,000	---	$554,469,000
FY 2016 Actual	$476,525,000	---	$476,525,000
FY 2017 Actual	$754,076,000	---	$754,076,000
FY 2018 Annualized CR	$592,288,000	---	$592,288,000
FY 2019 President's Budget	$662,043,000	---	$662,043,000

BUDGET REQUEST

The FY 2019 Budget request is $662,043,000 all from user fees. This amount is the FY 2019 level authorized in the Tobacco Control Act less the amounts for GSA Rent and FDA Headquarters, which are shown in their own sections of the budget request. This amount is an increase of $69,755,000 above the FY 2018 Annualized CR.

The Center for Tobacco Products amount in this request is $647,493,000.

In FY 2019, CTP plans to continue implementing its Plan for Tobacco and Nicotine Regulation as announced by Commissioner Gottlieb on July 28, 2017, which CTP has incorporated into its six strategic priorities:

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

Specifics on CTP's FY 2019 efforts follow the Agency-wide plan below.

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. FDA plans to seek public comment on the reduction of nicotine in combusted cigarettes to minimally addictive or nonaddictive levels, while encouraging innovation to reduce harm by establishing a strong regulatory framework for newer products, such as e-cigarettes. FDA also plans 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 adult smokers switch to potentially less harmful forms of nicotine delivery. In addition, FDA plans to solicit additional comments and scientific data related to the patterns of use and resulting public health impacts from cigars.

As part of this plan, FDA has taken several steps, including:

- issuing guidance in September 2017 extending timelines for submitting tobacco product review applications for newly regulated products that were on the market as of August 8, 2016

- forming a Nicotine Steering Committee, in conjunction with CDER and FDA's Office of the Commissioner, to examine the science behind the Agency's evaluation of nicotine replacement therapies (NRTs), including the types of safety and efficacy studies FDA requires and how these products are used and labeled (with public hearing to obtain feedback on public health, regulatory, and legal considerations relating to NRT products and their use for cessation to be held on January 26, 2018)
- considering regulatory guidance on premarket review policy based on the principle of relative toxicity and risk
- preparing for publication of Advance Notices of Proposed Rulemaking (ANPRMs) on nicotine in cigarettes, flavors in tobacco products, and premium cigars
- preparing for publication a proposed rule on Substantial Equivalence, as well as pursuing proposed rules on Premarket Tobacco Product Applications (PMTAs) and Modified Risk Tobacco Products (MRTPs)
- pursuing product standards for Electronic Nicotine Delivery Systems (ENDS) and other products, as appropriate, to establish basic standards and inform and drive innovation in the direction of harm reduction.

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.

On January 23, 2017, FDA published a proposed rule - Tobacco Product Standard for N-nitrosonornicotine Level in Finished Smokeless Tobacco Products[94]- that would establish for finished smokeless tobacco products sold in the United States a limit of N-nitrosonornicotine, a potent carcinogen and major contributor to elevated oral cancer risks in smokeless tobacco users.

As with any rulemaking, it is important for the Agency to hear from the public regarding their thoughts on the proposed rule, and participation in the rulemaking process by all interested parties was robust. FDA is currently reviewing and evaluating the comments to determine appropriate next steps.

Comprehensive Nicotine and Tobacco Regulatory Policy

FDA is pursuing the nicotine work mentioned above, as well as:

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

[94] https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm537091.htm

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 seek FDA authorization before marketing new[95] tobacco products:

- by demonstrating they are appropriate for protection of public health, or
- by demonstrating substantial equivalence[96] to certain commercially marketed products.

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 speed application review by FDA staff. In addition to developing rules and guidances, CTP will continue to monitor performance measures for product reviews.

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.

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, hookah, and little cigars. 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.

Investing in Human Capital

FDA invests 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 Employee Viewpoint Survey. FDA also promotes employee diversity and inclusion to cultivate an engaged workforce that reflects the country it serves.

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

[96] 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.

Additional FY 2019 Support Activities

FDA will continue to:

- partner with other agencies, including NIH, CDC, and FDA's National Center for Toxicological Research 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
- collect and analyze PATH Study participant responses and biomarker data to assess tobacco use transitions over time
- conduct priority research with research contract organizations.

In FY 2019, FDA will continue to fund PATH Study analyses and sub-studies via NIH. These sub-studies will enable FDA to gain more in depth insight into a rapidly evolving tobacco market and provide the PATH Study with a way to more comprehensively examine new and emerging issues related to tobacco use behavior and health.

Enforcement of the Tobacco Control Act and implementation of regulations are a priority for FY 2019. Continued planned activities include:

- conducting compliance check inspections via the Tobacco Retailer Inspection Program[97]
- coordinating with ORA to conduct inspections of tobacco manufacturing facilities
- providing outreach, education, and assistance to small tobacco manufacturers and retailers via CTP's Office of Small Business Assistance
- enforcing promotional, advertising, and labeling requirements
- conducting surveillance, investigations, and sample collections
- identifying criminal violations in tobacco-related cases.

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 2019, 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.

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.

[97] 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

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 +/- FY 2018
280005: Total number of compliance check inspections of retail establishments in States under contract. *(Outcome)*	FY 2017: 168,696 Target: 125,000(Target Exceeded)	130,000	140,000	+10,000
280006: Review and act on original Regular SE Reports within 90 days of FDA receipt (applies to cigarettes, cigarette tobacco, smokeless tobacco, and roll-your- own tobacco products) *(Output).*	FY 2017: 93%Target: 70%(Target Exceeded)	80%	80%	Maintain
280007: Educate at-risk general market 12-17 year olds about the harmful effects of tobacco use. *(Output)*	FY 2017: Reached 86% of general market at risk 12-17 year olds with campaign messaging.(Target Exceeded)	Reach 75% of 12-17 year olds with campaign messaging within 1 year.	Reach 75% of 12-17 year olds with campaign messaging within 1 year.	Maintain

Compliance Check Inspections

Highlighted from the above table, 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 168,000 compliance check inspections of retail establishments in FY 2017. Although this number was much higher than the expected FY 2017 full year target of 125,000, 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 2018, 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 2018 and 2019 targets consider these challenges, but have still been increased.

PROGRAM ACTIVITY DATA

CTP Workload and Outputs	FY 2017 Actuals	FY 2018 Annualized CR	FY 2019 President's Budget
Tobacco Retailer Inspections			
Number of Inspections	168,696	130,000	140,000
Tobacco Manufacture Inspections			
Number of Inspections [1]	52	75	200
Substantial Equivalence Reviews			
Number of Regular Full SE Reports	132	100	100

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