

## TOBACCO CONTROL ACT

(Dollars in Thousands)	FY 2016 Final	FY 2016 Actuals	FY 2017 Annualized CR	FY 2018	
				President's Budget	President's Budget +/- FY 2017 CR
Family Smoking Prevention and Tobacco Control Act.....	564,117	476,525	563,045	625,646	62,601
Center (UF Only).....	547,454	466,776	546,413	611,096	64,683
Field (UF Only).....	16,663	9,749	16,631	14,550	-2,081
<b>FTE.....</b>	<b>780</b>	<b>780</b>	<b>910</b>	<b>930</b>	<b>20</b>

**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. FDA 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 FDA 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 March 31, 2017, FDA had contracts for tobacco retailer compliance check inspections in 55 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. Since the program's inception in October 2010 through March 31, 2016, FDA conducted more than 758,000 compliance check inspections at tobacco retail establishments and has commissioned more than 2,500 officers and employees from the states, territories, and their political subdivisions.

## 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 regulation. On May 10, 2016, FDA finalized a rule – Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act – which extends FDA's authority to all tobacco products, including the regulation of 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 bipartisan 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.



Under the final deeming rule, manufacturers of newly deemed tobacco products are required to:

- register establishments with FDA
- report product and ingredient listings
- report harmful and potentially harmful constituents
- market new tobacco products only after receiving authorization from FDA
- make direct and implied claims of reduced risk only after receiving a risk or exposure modification order from FDA
- not distribute free samples.

Also under the final deeming rule, the following provisions, which already applied to the originally regulated tobacco products, now apply to newly “deemed” tobacco products:

- minimum age and identification restrictions to prevent sales to underage youth
- requirements to include health warnings

- prohibition of vending machine sales, unless in a facility that never admits youth.

This final rule went into effect on August 8, 2016.

FDA also understands that newly regulated entities will need assistance in complying with the FD&C Act and FDA regulations. As a result, FDA is working to educate newly regulated industry through multiple means, including:

- Issuing several guidances on the deeming rule to help industry and the public understand FDA's current thinking on provisions in the rule
- Publishing the Small Entity Compliance Guide for Deeming to help small businesses understand and comply with the final deeming rule
- Hosting a two day public seminar in October 2016 to help industry understand the requirements for a new tobacco product application and the submission process
- Publishing 15 deeming related compliance webinars on the CTP website
- Redesigning the tobacco regulation portion of the FDA website and creating specific sections dedicated to assisting manufacturers and retailers
- Setting up a call center to answer questions from consumers, retailers, manufacturers, and importers. As of March 31, 2017, CTP has responded to more than 5,000 inquiries.

### **Substantial Equivalence**

Manufacturers may submit Substantial Equivalence (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.

A substantially equivalent tobacco product is a product 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 demonstrates that the new product does not raise different questions of public health. A predicate tobacco<sup>81</sup> product 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 of these criteria are met, FDA issues a written order permitting the product to be legally marketed in the United States. A manufacturer cannot legally market a new tobacco product if they have not received marketing authorization from FDA<sup>82</sup>.

FDA has prioritized the review of regular<sup>83</sup> SE submissions 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

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<sup>81</sup> <http://www.fda.gov/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/SubstantialEquivalence/ucm304517.htm#3>

<sup>82</sup> If a new tobacco product was commercially marketed after February 15, 2007 but before March 22, 2011; and a Substantial Equivalence Report was submitted by March 22, 2011, then this new tobacco product may continue to be marketed unless FDA issues an order that the new product is not substantially equivalent to an appropriate predicate product.

<sup>83</sup> 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.

- 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 March 31, 2017:

- 76 percent of all full<sup>84</sup> regular SE reports received to date have been resolved by a final decision<sup>85</sup>.
- FDA completed acceptance reviews of 5,757 of the 5,870 SE submissions received to date.
- FDA issued a Scientific Advice and Information Request Letter or a Preliminary Finding Letter for 88 percent of the pending full regular SE reports.

These letters communicate to the manufacturer the deficiencies in a SE Report that preclude either further scientific review or issuance of an SE Order.

In FY 2015, FDA implemented performance measures, including timeframes for review of regular SE reports and review of Exemption from SE requests.<sup>86</sup> 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.

FDA is also continuing scientific review of provisional SE reports.<sup>87</sup>

As of March 31, 2017:

- FDA has begun scientific review of 1,270 provisional SE Reports.
- 23 percent of full provisional SE reports have been resolved by a final decision.<sup>88</sup>

FDA expects the time required for review of SE submissions 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's first ever national public education campaign to help prevent youth tobacco use – “The Real Cost” – continues to exceed paid media reach and frequency goals by reaching at least 86 percent of the target audience every quarter since launching February 11, 2014.

The campaign is designed to reduce the number of youth aged 12 to 17 who smoke, and results announced in January, 2017 from a two-year outcome evaluation indicate the campaign is succeeding in meeting this goal. So far, “The Real Cost” campaign prevented over 345,000 U.S.



<sup>84</sup> In March 2015, FDA issued guidance permitting companies to submit “streamlined” SE reports under certain conditions. Review of these streamlined reports is ongoing and is not counted here.

<sup>85</sup> Final decisions include refuse-to-accept, withdrawn, substantially equivalent (SE), not substantially equivalent (NSE)

<sup>86</sup> Exemption from SE is an alternative to substantial equivalence in which the only change is to an additive, the product change is minor and a full substantial equivalence report is not necessary to ensure that permitting the tobacco products to be marketed is appropriate for the protection of public health.

<sup>87</sup> SE reports received before March 23, 2011 for products introduced to market or changed between February 16, 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.

<sup>88</sup> Final decisions include refuse-to-accept, withdrawn, substantially equivalent (SE), not substantially equivalent (NSE).

youth from smoking from 2014 to 2016, exceeding our goals for the campaign. Considering most tobacco dependence begins during adolescence, youth-focused tobacco prevention campaigns like “The Real Cost” can have long-term effects on future rates of tobacco-related morbidity and mortality.

To keep the target audience engaged with its messaging, FDA refreshed the campaign with a third wave of advertising in October 2016. This strategy is based on target audience research that suggests the personality trait of sensation-seeking, which is closely linked with risk taking behavior, is associated with a preference for novel messaging. As such, FDA has launched new advertising every year to keep these high sensation-seeking youth engaged with the campaign. Additional advertising is planned for launch in 2017.

Additionally, the campaign won 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.

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 deliver facts about the dangers of smokeless tobacco use to drive shifts in the beliefs of rural teens to ultimately create attitude and behavior change.

On May 12, 2015, FDA launched the first phase of its “Fresh Empire” campaign in four Southeast markets in the United States: Atlanta, GA; Birmingham, AL; Charlotte, NC; and Raleigh, NC. The campaign is designed to prevent and reduce tobacco use among at-risk multicultural youth aged 12 to 17 including African American, Hispanic, and Asian American/Pacific Islander youth.



The campaign 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. FDA expanded the “Fresh Empire” campaign to markets throughout the U.S. in October 2015 and plans to launch new advertising in market in 2017.



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 the occasional or “social” smokers to help prevent tobacco-related death and disease in the LGBT community.

The campaign won a significant multicultural award of excellence at the 18<sup>th</sup> 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.

### **Enhance Oversight**

FDA is committed to regulating the manufacture, marketing, and distribution of tobacco products to protect public health and to reduce tobacco use, especially among youth. FDA’s implementation of the Tobacco Program is carried out with the use of regulations and guidance that explain FDA’s expectations to the regulated industry and the public.

FDA has established a framework for industry registration, product listing, and submission of information concerning ingredients and harmful and potentially harmful constituents (HPHCs) in tobacco products and tobacco smoke. Furthermore, FDA ensures industry compliance by enforcing warning label and advertising requirements, and by restricting access and marketing of cigarettes and smokeless tobacco products to youth through the use of compliance inspections, warning letters, civil money penalties, and no-tobacco-sale-orders.

### **Maintaining a Strong Science Base for Oversight Actions**

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 2016, FDA invested more than \$193 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), Center for Devices and Radiological Health (CDRH), and Southeast Regional Lab, 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 resources 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 2016, FDA funded 106 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.



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 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 nationally representative 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 related disease.

Data collection for Wave 2 of the PATH Study was completed October 2015, and Wave 3 began October 2015 and was completed October 2016. Wave 4 launched in December 2016. Starting in FY 2017, FDA will collect 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.

#### 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, and 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.

#### **FDA Center for Devices and Radiological Health (CDRH) Partnership**

In FY 2016, CDRH began research on effects of atomizer temperature on electronic cigarette aerosol.

#### **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, use behavior, and the assessment of user and non-user beliefs about emerging tobacco products.

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

#### **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 March 31, 2017, FDA had contracts for tobacco retailer compliance check inspections in 55 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 newly deemed products in the scope of its retail inspections. As of March 31, 2017, FDA had issued more than 4,600 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.<sup>89</sup>

Since the Tobacco Retailer Inspection Program's inception in October 2010 through March 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

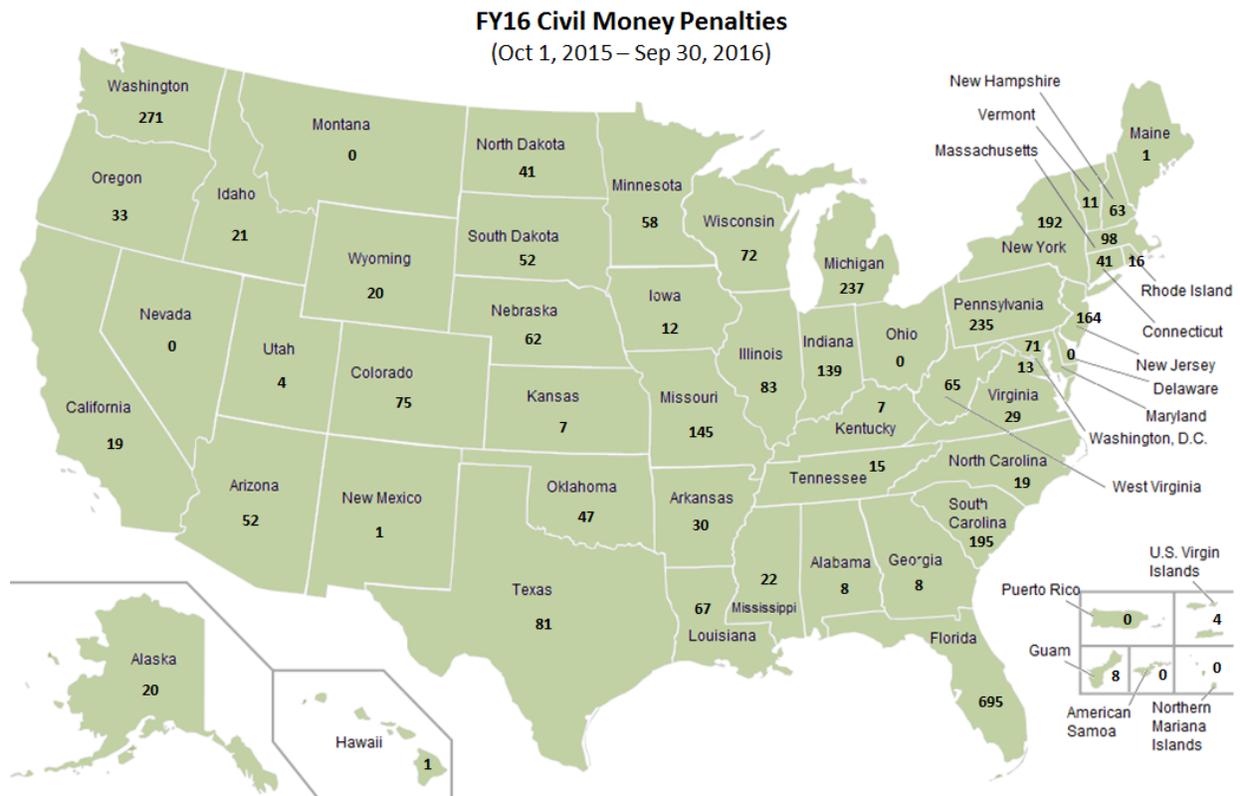
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<sup>89</sup> These warning letters are included in the total number of warning letters reported in the "CTP Tobacco Retailer Inspection Program" table.

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**

<b>Enforcement Action</b>	<b>FY 2015 Actuals</b>	<b>FY 2016 Actuals</b>	<b>Total Since the Program's Inception on 10/1/2010 (as of 3/31/2017)</b>
Retailer Inspections	162,865	165,098	758,871
Warning Letters	16,521	13,921	56,901
Civil Money Penalties	3,290	3,630	11,877
No-Tobacco-Sale-Orders <sup>90</sup>	0	31	47



Although most retailers comply after receiving a warning letter, FDA issued 3,630 civil money penalties in FY 2016 (Oct 1, 2015 – Sep 30, 2016).

<sup>90</sup> Under the law, the FDA may pursue an NTSO against retailers that have a total of five or more repeated violations of those restrictions during compliance inspections within 36 months.

### **Tobacco Manufacturer Inspections**

FDA regularly inspects registered establishments that manufacture or process tobacco products to determine compliance with existing laws and regulations. FDA conducted approximately 55 tobacco manufacturing inspections in FY 2016. Tobacco Manufacturers of newly deemed tobacco products are required to register in FY 2017 and FDA expects the number of registered establishments will significantly increase.

### **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 systems (ENDS) products and took enforcement actions when violations were found. Since the program's inception in October 2010 through March 31, 2017, FDA has issued over 500 warning letters as a result of these surveillance activities. In 2016, 110 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.

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

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 in accordance with FDA's authorities.

New products and product changes are reviewed following three marketing pathways:

- premarket tobacco product application (PMTA)
- reports demonstrating substantial equivalence (SE) to commercially marketed products
- exemption from demonstrating substantial equivalence.

On November 10, 2015, FDA announced that for the first time it has authorized the marketing of new tobacco products through the premarket tobacco product application (PMTA) pathway. As of November 30, 2016, FDA has issued marketing orders for eight PMTA applications and refused to file four PMTAs for statutorily regulated products.

In addition, two other PMTAs for statutorily regulated products have been submitted and are being reviewed to determine whether they meet the requirements for filing. FDA has also refused to accept 362 of the 364 PMTAs received for newly deemed products because they did not meet statutory requirements.

Currently, CTP reviews for acceptance determine if the application falls under our jurisdiction and addresses environmental considerations, both required by statute. If these two factors are not met, CTP must issue a Refuse to Accept (RTA) letter.

The RTA decision closes all activity for the application. However, 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. FDA uses a scientific review to determine if new tobacco products should come to market under this pathway.

Furthermore, before making marketing claims that imply modified risk, manufacturers must submit a Modified Risk Tobacco Product (MRTP) application, and receive an FDA order authorizing a claim that the product reduces harm or the risk of tobacco-related disease.

FDA continued substantive reviews on ten MRTP applications received in June 2014. These MRTP applications were made available to the public and a docket was opened for public comment. A meeting of FDA's Tobacco Product Scientific Advisory Committee was held on April 9-10, 2015, to review these applications and provide recommendations to FDA. The docket was reopened in July 2015, to solicit comments on amendments that were submitted. There are complex scientific and legal questions related to issuing letters since these are the first MRTP applications to reach this stage in review. On December 14, 2016, following science-based review, FDA took action on the first applications reviewed through the MRTP pathway, denying one claim and deferring final action for the remaining claims.

CTP's OSBA informs small businesses of existing guidances, regulations, and submission pathways through publications and online webinars. In FY 2016, OSBA published 15 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.

### **Promote Informed Decisions**

#### **Public Education Campaigns**

FDA is using sustained, comprehensive public education campaigns 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 involve 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.

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 has 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. The study designs are longitudinal, meaning the studies 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.<sup>91</sup>

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 12 to 17 who smoke by preventing over 345,000 U.S. youth from smoking from 2014 to 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 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 MRTTP
- expand research capabilities
- support inspection efforts
- enforce the deeming regulation
- draft regulations and guidances.

### **FUNDING HISTORY**

<b>Fiscal Year</b>	<b>Program Level</b>	<b>Budget Authority</b>	<b>User</b>
<b>FY 2014 Actual</b>	\$570,536,000	\$0	\$570,536,000
<b>FY 2015 Actual</b>	\$554,469,000	\$0	\$554,469,000
<b>FY 2016 Actuals</b>	\$476,525,000	\$0	\$476,525,000
<b>FY 2017 Annualized CR</b>	\$563,045,000	\$0	\$563,045,000
<b>FY 2018 President's Budget</b>	\$625,646,000	\$0	\$625,646,000

### **BUDGET REQUEST**

The FY 2018 Budget Request is \$625,646,000, all from user fees. This amount is the FY 2018 level authorized in the Tobacco Control Act less the amounts for GSA Rent and FDA

<sup>91</sup> <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0144827>

Headquarters, which are shown in their own sections of the budget request. This amount is an increase of \$29,308,000 above the FY 2017 President's Budget.

The Center for Tobacco Products amount in this request is \$611,096,000.

In FY 2018, CTP plans to continue its efforts on six current strategic priorities:

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

Specifics on CTP's FY 2018 strategic priorities and its many other efforts are provided below.

### **Strategic Priorities**

#### **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-wide Comprehensive Nicotine Regulatory Policy**

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 reality that people use tobacco for the nicotine but die from the toxins in the tobacco and in tobacco smoke. Beyond finalizing the "deeming rule," related activities include:

- developing jurisdiction policy on nicotine-containing products across FDA
- working with CDER and CDRH to determine how regulation of therapeutic nicotine products – Rx, OTC, drugs, devices – should evolve
- considering regulatory guidance on premarket review policy based on the principle of relative toxicity and risk.

#### **Premarket and Postmarket Controls: Regulations and Product Reviews**

FDA's reviews act as a gatekeeper between tobacco products and consumers. FDA ensures that new products cannot be commercially sold without review by requiring manufacturers to seek FDA authorization before:

- marketing new tobacco products
- marketing new tobacco products demonstrating substantial equivalence<sup>92</sup> to certain commercially marketed products
- modifying existing tobacco products.

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<sup>92</sup> 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 speed application review by FDA staff. In addition to developing rules and guidances, CTP will continue to establish 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 cigarettes or open to it, multicultural including African American, Hispanic, Asian/Pacific Islander, and American Indian/Alaska Native youth, rural youth, and lesbian, gay, bisexual, and transgender (LGBT) young adults.

### **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.

### **Additional FY 2018 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 TCORS and other research grants via NIH
- fund research projects via NIH to address FDA time-sensitive research.

In FY 2018, 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 2018. Continued planned activities include:

- conducting compliance check inspections via the Tobacco Retailer Inspection Program<sup>93</sup>
- coordinating with ORA to conduct inspections of tobacco manufacturing facilities

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<sup>93</sup> The results of the Tobacco Retailer Inspection Program can be found on FDA's website at [http://www.accessdata.fda.gov/scripts/oc/inspections/oc\\_insp\\_searching.cfm](http://www.accessdata.fda.gov/scripts/oc/inspections/oc_insp_searching.cfm)

- 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 2018, FDA will further develop and continue public health education efforts to reach at-risk populations, particularly youth, with messages about the dangers of tobacco use.

FDA will:

- continue outcome evaluation for "The Real Cost" smokeless campaign, the "Fresh Empire" campaign, and the "This Free Life" campaign
- continue its tobacco education campaigns targeting discrete at-risk and underserved audiences
- 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.

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2017 Target	FY 2018 Target	FY 2018 +/- FY 2017
<u>280005</u> : Total number of compliance check inspections of retail establishments in States under contract. <i>(Outcome)</i>	FY 2016: 165,098 Target: 110,000 (Target Exceeded)	125,000	140,000	+15,000
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). <i>(Output)</i>	FY 2016: 63% Target: 60% (Target Exceeded)	70%	80%	+10%
<u>280007</u> : Educate at-risk general market 12-17 year olds about the harmful effects of tobacco use. <i>(Output)</i>	FY 2016: 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 165,000 compliance check inspections of retail establishments in FY 2016. Although this number was much higher than the expected FY 2016 full year target of 110,000, 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.

FDA is on target to meet or exceed the FY 2017 full year goal of 125,000 compliance checks. It is important to note however, that some contracts are expiring and will need to be renewed in FY 2017 in order for these efforts to continue. Although 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 2017 and 2018 targets consider these challenges, but have still been increased.

**PROGRAM ACTIVITY DATA TABLE**

<b>CTP Workload and Outputs</b>	<b>FY 2016 Actuals</b>	<b>FY 2017 Annualized CR</b>	<b>FY 2018 President's Budget</b>
<b>Tobacco Retailer Inspections</b>			
Number of Inspections	165,098	125,000	140,000
<b>Tobacco Manufacture Inspections</b>			
Number of Inspections <sup>1</sup>	52	52	200
<b>Substantial Equivalence Reviews</b>			
Number of Regular Full SE Reports <sup>2</sup>	122	100	100

<sup>1</sup> Outyear estimates are based on the number of firms registered with FDA. FDA inspects each registered firm biennially.

<sup>2</sup> Limited to Regular Full SE Reports received for currently regulated products.

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