TOBACCO CONTROL ACT

(Dollars in Thousands)	FY 2015 Final	FY 2015 Actuals	FY 2016 Enacted	FY 2017 President's Budget	FY 2017 +/- FY 2016
Family Smoking Prevention and Tobacco Control Act	**531,527**	**554,469**	**564,117**	**596,338**	**32,221**
Center (UF Only)	515,640	544,999	547,454	581,438	33,984
Field (UF Only)	15,887	9,470	16,663	14,900	-1,763
FTE	**699**	**708**	**882**	**960**	**78**

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), established in 2009, 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 its 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 CTP'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 cigarettes and smokeless 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, 2015, FDA had contracts in 55 states, territories, and tribal jurisdictions to conduct compliance check inspections at tobacco retail establishments. Compliance check inspections pertain to tobacco marketing, sales, and distribution of tobacco products at retail locations. From the beginning of the program in October 2010 through December 2015, FDA has conducted more than 549,300 compliance check inspections at tobacco retail establishments.

Regulation
On April 24, 2014, FDA issued a proposed rule - the "deeming rule" - to deem additional products that meet the statutory definition of a "tobacco product," to be subject to FDA's regulatory authority. This includes e-cigarettes, nicotine gels, some or all cigars, hookah, and pipes. The draft final rule was submitted to the Office of Management and Budget (OMB) on October 19, 2015, for review.

Under the proposed rule, manufacturers of newly deemed tobacco products would be 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 proposed rule, these provisions would 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.

After Administration review, the final rule can be issued.

FDA continues to invest in scientific research to better understand regulated tobacco products and patterns of tobacco use. In FY 2015, FDA funded 114 research projects via the National Institutes of Health (NIH). These research projects include grants, intramural projects, and contracts which will address important FDA research priorities.

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 rigorous, science-based process to review these SE Reports to determine whether the new product is substantially equivalent.

A substantially equivalent (SE) 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[87] 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 will issue 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[88].

FDA has prioritized the review of regular SE submissions and has made progress in each of the three phases in the SE review process:

- administrative review phase – FDA makes a decision to either accept or refuse the application based on requirements in the statute
- notification phase – the scientific review team assembles and answers any outstanding predicate eligibility questions
- substantive scientific review phase and issuance of a decision.

FDA no longer has a backlog of regular[89] SE reports. All regular SE reports received are immediately entered into review.

As of December 31, 2015:

- 71 percent of all full[90] regular SE reports received to date have been resolved by a final decision[91]
- FDA completed administrative reviews of 5,492 of the 5,650 SE submissions received to date
- FDA issued a Scientific Advice and Information Request Letter or a Preliminary Finding Letter for 75 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.

---

[87] http://www.fda.gov/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/NewTobaccoProductReviewand Evaluation/Substantial Equivalence/ucm304517.htm

[88] 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.

[89] 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.

[90] 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.

[91] Final decisions include refuse-to-accept, withdrawn, substantially equivalent (SE), not substantially equivalent (NSE)

In FY 2015, FDA implemented performance measures, including timeframes for review of regular SE reports and review of Exemption from SE requests.[92] 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.[93] Since the products covered by these reports are already on the market, FDA is prioritizing their review based on an initial Public Health Impact (PHI) review of their potential to raise different questions of public health. Those Provisional SE reports with the highest potential are placed in the highest tier and reviewed first.

Once FDA has had more experience addressing provisional SE reports, we expect to better understand the time required for review. At that time, we intend to set performance measures for provisional SE reports.

As of December 31, 2015:

- FDA has begun scientific review of 857 provisional SE Reports
- Fourteen percent of full provisional SE reports have been resolved by a final decision.[94]

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 more than 90 percent of the target audience every quarter since launch.

The campaign is designed to reduce the number of youth aged 12 to 17 who smoke. To keep the target audience engaged with its messaging, FDA refreshed the campaign with a second full wave of advertising in June 2015. Additional advertising is in development. The campaign also recently won an advertising industry award in June 2015 – a gold Effie Award in the Disease Awareness and Education category – for its insightful communications strategy, outstanding creative, and success in market.

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

[92] 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.
[93] 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.
[94] Final decisions include refuse-to-accept, withdrawn, substantially equivalent (SE), not substantially equivalent (NSE).

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.

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 strong implementation of the Tobacco Program is carried out with the use of regulations and guidance that clarify regulatory authority and 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, and civil monetary penalties.

Maintaining a Strong Science Base for Oversight Actions

FDA reduces tobacco harms by investing in research to inform regulations and help assess the impact of regulatory actions. In FY 2015, FDA invested more than $232 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 Southeast Regional Lab (SRL), 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.

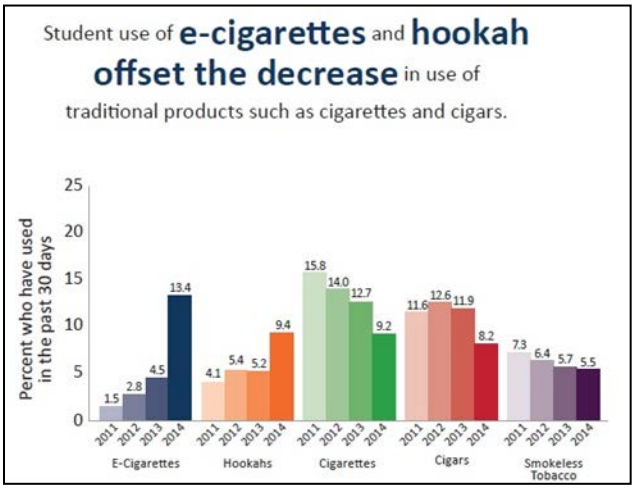
NIH Partnerships

FDA avoids duplication of resources and enhances scientific research capability by collaborating with NIH and tapping into its well-established infrastructure. Below are some of CTP's areas of research.

FDA and NIH's Tobacco Regulatory Science Program (TRSP) collaborates 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 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 2015, FDA expanded existing grant funded research for toxicological assessments of flavors in e-cigarettes and cigars and for the public display of Harmful and Potentially Harmful (HPHC) information.

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 TCORS is to conduct multidisciplinary research that will inform FDA's regulatory actions related to the manufacture, distribution, and marketing of tobacco products.

FDA partners with NIH to fund The Population Assessment of Tobacco and Health (PATH) Study. PATH is a longitudinal cohort study 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 for adults.

Data collection for Wave 2 of the PATH Study was completed October 2015, and Wave 3 began October 2015 and will be completed October 2016.

<u>CDC Partnerships</u>

FDA is partnering with the Division of Laboratory Sciences at CDC on research projects which use laboratory-based approaches to expand knowledge of how best to regulate 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 the impact of tobacco regulation on populations, FDA collaborates with 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.

NCTR Partnership

NCTR will continue research on:

- the toxicology of compounds and cigarette smoke
- biomarker discovery
- the toxic and addictive potential of tobacco products
- developmental bioinformatics projects.

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 cigarettes and smokeless tobacco products to youth. As of December 31, 2015, FDA had contracts in 55 states, territories, and Tribal jurisdictions to conduct compliance check inspections at tobacco retail establishments. 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.

Although most retailers comply after receiving a warning letter, in FY 2015 alone, FDA issued more than 3,200 civil money penalties.

From the beginning of the program in October 2010 through December 2015, FDA has conducted more than 549,300 compliance check inspections at tobacco retail establishments, resulting in FDA issuing over 38,800 warning letters, 6,400 civil money penalties, and 8 No-Tobacco-Sale Order (NTSO) complaints. 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.

Since the program's inception, FDA has commissioned more than 2,300 officers and employees from the states, territories, and their political subdivisions, and provides a training program for those that perform inspections.

FDA exceeded the FY 2015 target goal and conducted 162,873 retail inspections, exceeding the target of 105,000 inspections. FDA also conducted 89%, or 49 of 55, of the target goal for manufacturer inspections. Even though FDA overestimated the number of registered manufacturing facilities that would require inspection in FY 2015, FDA met its plan to inspect half of the actual registered manufacturing facilities (keeping FDA on track to inspect registered manufacturing facilities biennially).

FDA regularly inspects registered establishments that manufacture or process tobacco products to determine compliance with existing laws and regulations. FDA conducts investigations that include sponsorship events and free sample events, and also conducts surveillance of websites, social media, and magazines and other publications that promote and sell regulated tobacco products in the U.S. market. FDA issued over 320 warning letters as a result of these surveillance activities (over 100 of them were issued in FY 2015).

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 control access to 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 application (PMTA) pathway. The marketing orders are for eight PMTA applications received in March 2015. FDA uses a rigorous 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 is currently conducting substantive reviews on ten MRTP applications received in June 2014. These MRTP applications were made available to the public in August 2014, 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. FDA continues to review these applications and intends to issue a decision when the substantive scientific review is complete.

FDA informs small businesses of existing guidances, regulations, and submission pathways through publications and online webinars. These materials aim to provide easily accessible educational opportunities.

Promote Informed Decisions

"The Real Cost" and Public Education Campaigns

FDA is leveraging 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. NIH's 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.

The CDC indicates that tobacco prevention campaigns that reach 75 to 85 percent of the target audience within one year can expect to produce attitude and behavior change within two years if the time in market is adequately sustained.[95] FDA is positioned to sustain "The Real Cost" campaign at the reach, frequency, and time in-market recommended by CDC to achieve behavior change and improve public health.

FDA is implementing a large, two-year outcome evaluation study of "The Real Cost" campaign. The study design is longitudinal, meaning the study will attempt to follow the same youth over time. In FY 2015, short-term outcome evaluation findings for "The Real Cost" suggest that approximately 90 percent of the target audience is aware of the campaign and its messaging. The awareness level is a precursor to positive behavior change. Ultimately, results will be used to determine if exposure to the campaign is associated with a decrease in smoking among youth aged 12 to 17.

FDA plans to launch additional public education campaigns in 2016 including rural youth at risk of smokeless tobacco initiation and lesbian, gay, bisexual, and transgender (LGBT) young adults.

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
- 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.

[95] Best Practices for Comprehensive Tobacco Control Programs, 2014. http://www.cdc.gov/tobacco/stateandcommunity/best_practices/pdfs/2014/comprehensive.pdf pg.33

FUNDING HISTORY

Fiscal Year	Program Level	Budget Authority	User
FY 2013 Actual	$848,807,000	$0	$848,807,000
FY 2014 Actual	$570,536,000	$0	$570,536,000
FY 2015 Actual	$554,469,000	$0	$554,469,000
FY 2016 Enacted	$564,117,000	$0	$564,117,000
FY 2017 President's Budget	$596,338,000	$0	$596,338,000

BUDGET REQUEST

The FY 2017 Budget Request is $596,338,000, all from user fees. This amount is the FY 2017 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 $32,221,000 above the FY 2016 Enacted level.

The Center for Tobacco Products amount in this request is $581,438,000. The Office of Regulatory Affairs amount is $14,900,000. The Tobacco Control Act requires this funding be used only for FDA tobacco regulatory activities. Conversely, the law prohibits the use of non-tobacco funds for FDA tobacco regulatory activities.

In FY 2017, CTP will continue its efforts on five strategic priorities:

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

Specifics on CTP's FY 2017 five 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
With passage of the Tobacco Control Act, FDA now regulates a broad range of nicotine-delivering products, from cigarettes to medicinal nicotine gum and patch. FDA is establishing 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 Control: 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[96] to certain commercially marketed products
- modifying existing tobacco products.

CTP is exploring developing additional rules and guidances for product review pathways, product standards, Tobacco Product Manufacturing Practices, and registration and product listing. 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.

Additional FY 2017 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 the TCORS and other research grants via NIH
- fund research projects via NIH to address FDA time-sensitive research.

In FY 2017, 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.

[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.

CTP conducts research via research contract organizations to understand consumer perceptions and behaviors of various tobacco products.

Enforcement of the Tobacco Control Act and implementation of regulations are a priority for FY 2017. Continued planned activities include:

- conducting compliance check inspections via the Tobacco Retail Inspection Program[97]
- continuing outreach and education efforts for small tobacco manufacturers and retailers
- responding to inquiries and requests for assistance by tobacco manufacturers and retailers received by CTP's Office of Small Business Assistance
- enforcing warning label requirements, including smokeless tobacco products
- conducting surveillance, investigations, inspections, 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 2017, FDA will further develop public health education efforts to reach at-risk populations, particularly youth, with messages about the dangers of tobacco use. The investment in tobacco education marks a historic first for FDA and is designed to change the trajectory of tobacco-related disease and death to create long lasting public health benefits.

FDA will:

- complete its longitudinal evaluation of the first two years of "The Real Cost" campaign
- measure the effectiveness of the campaign
- continue its tobacco education campaigns targeting discrete at-risk and underserved audiences including general market youth, multicultural youth, rural youth, LGBT young adults, and others
- continue to develop interactive digital communication technologies and products such as CTP's content sharing platform, 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 2016 Target	FY 2017 Target	FY 2017 +/- FY 2016
280005: Total number of compliance check inspections of retail establishments in States under contract. *(Outcome)*	FY 2015: 162,873 Target: 105,000 (Target Exceeded)	110,000	125,000	+15,000

[97] The results of the Tobacco Retail 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 2016 Target	FY 2017 Target	FY 2017 +/- FY 2016
280006: Review and act on original Regular SE Reports within 90 days of FDA receipt.	New Goal	60%	70%	+10%
280007: Educate at-risk general market 12-17 year olds about the harmful effects of tobacco use. *(Output)*	FY 2015: Reached more than 90% 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. In FY 2015, under these state contracts, FDA conducted 162,873 compliance check inspections of retail establishments. Although this number was much higher than the expected FY 2015 full year target of 105,000, 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 2016 full year goal of 110,000 compliance checks. It is important to note however, that some contracts are expiring and will need to be renewed in the next year 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 2016 and 2017 targets consider these challenges, but have still been increased.

PROGRAM ACTIVITY DATA

CTP Workload and Outputs	FY 2015 Actuals	FY 2016 Estimate	FY 2017 Estimate
Tobacco Retailer Inspections			
Number of Inspections	162,873	110,000	125,000
Inspections of Manufacturers Currently Regulated			
Number of Inspections[1]	49	60	60
Substantial Equivalence Reviews			
Number of Regular Full SE Reports[2]	133	100	100

[1] Outyear estimates are based on projected workloads
[2] Limited to Regular Full SE Reports received for currently regulated products

Page intentionally left blank