Tobacco Control Act

<table>
<thead>
<tr>
<th></th>
<th>FY 2013</th>
<th>FY 2014</th>
<th>FY 2015</th>
<th>FY 2015</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Final</td>
<td>Actual</td>
<td>Enacted</td>
<td>President's Budget</td>
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<td>Family Smoking Prevention and Tobacco Control Act</td>
<td>458,580</td>
<td>848,807</td>
<td>501,476</td>
<td>531,527</td>
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<tr>
<td>Center (UF Only)</td>
<td>449,644</td>
<td>835,090</td>
<td>486,487</td>
<td>515,640</td>
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<tr>
<td>Field (UF Only)</td>
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<td>13,717</td>
<td>14,989</td>
<td>15,887</td>
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<tr>
<td>FTE</td>
<td>496</td>
<td>640</td>
<td>773</td>
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Allocation Methods: Competitive Grants; Contracts; Direct Federal/Intramural

Program Description and Accomplishments

The Center for Tobacco Products oversees the implementation of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). FDA executes its regulatory and public health responsibilities in three 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. Some of these authorities include:

- requiring tobacco product manufacturers, importers, and distributors to register with FDA
- requiring manufacturers and importers to provide a list of tobacco products they sell
- requiring industry to report harmful and potentially harmful constituents
- inspecting tobacco product manufacturing establishments and tobacco retailers to assure compliance with FDA laws and tobacco product regulations
- prohibiting tobacco product labeling or advertising or other marketing that is inaccurate, false, or misleading
- establishing tobacco product standards to protect the public health
- issuing regulations with respect to the marketing and advertising of tobacco products
- strengthening health warnings for cigarettes and smokeless tobacco products
- enforcing violations of the Tobacco Control Act.

The following selected accomplishments demonstrate FDA’s delivery of its regulatory and public health responsibilities within the context of current priorities.

Reduce Initiation of Tobacco Product Use
FDA works to prevent youth from using FDA-regulated tobacco products, including cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and encourages young tobacco users to quit. These authorized activities involve planning, developing, producing, and delivering national multimedia public education campaigns in FY 2014, which are designed to reduce tobacco initiation and use among young people aged 12 to 17. More recently FDA launched its first ever national youth tobacco prevention campaign, “The Real Cost,” launched on February 4, 2014.

These sustained, multi-media campaigns will enable FDA to educate the public, particularly vulnerable youth populations, about the harms and risks of regulated tobacco products in order to help prevent initiation. Specifically, these campaigns will equip the public with important facts about:

- the health risks of regulated tobacco products
- the addictiveness of regulated tobacco products
- harmful and potentially harmful constituents in regulated tobacco products
- the public health basis for marketing restrictions on regulated tobacco products, such as those on using the descriptors “light,” “mild,” or “low.”

FDA is committed to a science-based approach that addresses the public health issues raised by menthol cigarettes. On July 23, 2013, FDA issued an advance notice of proposed rulemaking (ANPRM) seeking comments and data, research, and other information that may inform regulatory actions FDA might take with respect to menthol in cigarettes. FDA also conducted a preliminary independent scientific evaluation of existing data and research on menthol cigarettes. The Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol Versus Nonmenthol Cigarettes addresses the association between menthol cigarettes and various outcomes, including initiation, addiction, and cessation. The preliminary scientific evaluation, along with other relevant scientific information on the topic of menthol, was included in the docket for the ANPRM.

The FDA tobacco compliance and enforcement program ensures that industry and retailers follow existing laws and regulations designed to reduce the health burden of tobacco use on the American public and protect America’s youth. To ensure compliance with the law, FDA works to prevent youth access to tobacco products and the influence of marketing by reviewing print and online advertising, monitoring promotional activities, and inspecting tobacco retail establishments.

During FY 2013, FDA issued its 10,000th tobacco retailer warning letter. Although many retailers are actively trying to keep tobacco away from kids, some continue to violate the law. In order to help reduce these violations, FDA established the State Enforcement Program that awards contracts to States and Territories to assist with inspections of tobacco retail establishments. FDA awarded one new State contract in FY 2013 for a total of 45 States, territories, and the District of Columbia in the program.

To ensure compliance with the Tobacco Control Act, FDA conducts surveillance, investigations, inspections, sample collections, and detention and refusal of tobacco products.

In FY 2013, FDA conducted approximately 109,900 tobacco retailer inspections, resulting in about 6,000 Warning Letters being issued and over 530 Civil Monetary Penalties being imposed related to violations of the Tobacco Control Act.

FDA established and maintains a testing laboratory at FDA’s Southeast Regional Laboratory (SRL) with expertise and capacity to analyze tobacco products. The SRL laboratory has been acquiring specific testing equipment, such as mass spectrometers and smoke machines and is working to develop multi-residue flavor analysis methods.
**Decrease the Harms of Tobacco Products**

FDA is dedicated to reducing tobacco harms by engaging in and supporting numerous research and scientific endeavors. Research results will expand the scientific evidence needed to implement several authorities specified in the Tobacco Control Act and will also help assess the impact of regulatory actions. This research is also consistent with the Department of Health and Human Services (HHS) Strategic Plan and the Secretary’s strategic initiatives which seek to prevent and reduce tobacco use through accelerated research to expand the science base and monitor progress.

During FY 2013, FDA partnered with the National Institutes of Health (NIH) to create 14 Tobacco Centers of Regulatory Science (TCORS). The TCORS program brings together investigators from across the country to aid in the development and evaluation of tobacco product regulations. Each TCORS application identified a targeted research goal. Taken together, the TCORS sites will increase knowledge across the full spectrum of basic and applied research on tobacco and addiction. The program also provides new investigators with training opportunities to ensure the development of the next generation of tobacco regulatory scientists.

Throughout FY 2013, FDA and NIH also collaborated to stimulate investigator-initiated research and to release targeted Funding Opportunity Announcements to study:

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

FDA also worked with the Centers for Disease Control and Prevention (CDC) on laboratory research of tobacco products, as well as national cross-sectional surveys. Data from these surveys will allow FDA to monitor awareness of, susceptibility to, and experimentation with the use of a wide range of tobacco products.

In FY 2014, FDA will award research contracts and expand funding for tobacco regulatory science research within FDA and in alliance with NIH and CDC.

FDA has developed systems and procedures for the review and evaluation of tobacco industry submissions. In June 2013, FDA began issuing substantially equivalent (SE) marketing orders and not substantially equivalent orders for new tobacco products. FDA has also started issuing Refusal to Accept letters for exemption from SE requests. As part of its ongoing SE review process, FDA has communicated with many manufacturers about the status of their product submissions.

FDA sent “Advice and Information Request” letters to many manufacturers whose SE reports were missing administrative and scientific information, requesting clarification or the submission of the missing information. FDA held three public workshops in 2013 to gather information regarding third-party governance of industry-sponsored tobacco product research, tobacco product analysis, and electronic submission of tobacco product applications and other information.

As of December 31, 2013, FDA authorized the marketing of 17 new tobacco products and denied the marketing of 13 others. In addition, the first cycle of scientific review was completed for over 400 regular SE reports and Scientific Advice, and Information letters were issued for all regular SE reports received as of November 2012. FDA also formally withdrew 84 regular SE Reports at the request of the applicants and refused to accept 22 SE exemption requests because the manufacturers did not meet the requirements for such an exemption.
**Encourage Tobacco Product Cessation**

FDA is promoting public health and encouraging tobacco product cessation by leading comprehensive, science-based efforts to educate the nation about the dangers of tobacco products. Consistent with the HHS Strategic Plan and High-Priority Performance Goals, FDA seeks to prevent and reduce tobacco use.

FDA will allocate significant resources to enforce statutory requirements of the Tobacco Control Act, such as health warnings and public education. FDA will review new submissions and supplements involving health warning plans for smokeless tobacco products.

To encourage compliance with the Tobacco Control Act, FDA continues to educate retailers about their responsibilities to protect the Nation’s young people from the harms of tobacco product use. These efforts include outreach to small businesses and to those in minority communities.

In FY 2014, FDA will hold regular compliance education webinars, providing retailers with an opportunity to ask questions about FDA regulatory authorities and activities. FDA will conduct regular compliance education webinars directed towards small manufacturers to provide information about the Tobacco Control Act, FDA regulations, and other activities, including what to expect during an FDA inspection of a manufacturing facility.

**Funding History**

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<thead>
<tr>
<th>Fiscal Year</th>
<th>Program Level</th>
<th>Budget Authority</th>
<th>User Fees</th>
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<tr>
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<td>$277,136,000</td>
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<tr>
<td>FY 2013 Actual</td>
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<tr>
<td>FY 2014 Enacted</td>
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<td>$501,476,000</td>
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<td>FY 2015 Budget Request</td>
<td>$531,527,000</td>
<td>$0</td>
<td>$531,527,000</td>
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**Budget Request**

The FY 2015 Budget for the Tobacco Control Act Program is $531,527,000, of which $515,640,000 is for the Center and $15,887,000 is for the Field. The amount is the same as the FY 2015 level authorized in the Tobacco Control Act less the amounts for GSA rent and FDA headquarters. This amount is an increase of $30,051,000 above the FY 2014 Enacted level. The source of funding for is tobacco user fees, which the Tobacco Control Act requires be used only for FDA tobacco regulatory activities. Conversely, the law prohibits the use of non-tobacco funds for FDA tobacco regulatory activities.

The FY 2015 Budget allows the Program to protect and promote public health by planning, managing, directing, and coordinating major tobacco program objectives to support the implementation of the Tobacco Control Act.

In FY 2015, FDA will continue to implement the Tobacco Retail Inspection Program. This work includes re-awarding contracts to States and territories that are already under contract with FDA to conduct compliance check inspections of retail establishments that sell regulated tobacco products. Efforts will be made to expand the program with additional States and territories to cover more retailer inspections. In addition, FDA will continue to keep the results of the retail inspections public by maintaining a dedicated webpage that publicizes warning letters and civil money penalties issued to violative tobacco retailers and lists all retail establishments that pass FDA inspections.
In FY 2015, the Tobacco Retail Inspection Program will also:

- increase the number of inspections of tobacco retailers within the States and territories
- conduct quality assessments of performance under the State contracts
- maintain effective internal controls that meet the objectives of the Federal Managers’ Financial Integrity Act to ensure effective and efficient operations and compliance with laws and regulations
- issue Warning Letters and Civil Money Penalty actions, and other enforcement actions, against retailers that violate the law and regulations.

FDA will expand its tobacco-related promotion, advertising, and labeling enforcement activities. FDA will enforce warning label requirements, including the review of warning plans for smokeless tobacco products. FDA will evaluate false and misleading claims made in the labeling and advertising of regulated tobacco products to ensure the public does not receive deceptive information from tobacco manufactures and is equipped with accurate information to assist with cessation.

In FY 2015, FDA will expand its enforcement and manufacturing activities by monitoring compliance with registration and listing requirements and will coordinate the activities surrounding the development of Tobacco Product Manufacturing Practice requirements for regulated tobacco manufacturers.

FDA will provide training, educational webinars and other web-based training for small tobacco manufacturers and retailers and to provide information about the Tobacco Control Act and regulations through:

- the Compliance and Enforcement webpage
- compliance training webinars
- responding to inquiries.

FDA will also provide compliance training and outreach to other Federal, State, and local stakeholders involved in tobacco control.

In FY 2015, FDA will develop public health education campaigns and key messages, and support effective design, development, implementation, and evaluation of its public health education efforts.

FDA will regulate the manufacture, marketing, and distribution of tobacco products under its jurisdiction. FDA will expand research on modified-risk tobacco products that may be authorized to be sold or distributed for use to reduce harm or the risk of tobacco-related disease. Section 911 of the Federal Food, Drug, and Cosmetic (FD&C) Act may be valuable tools to promote public health by reducing the morbidity and mortality associated with tobacco use, particularly if companies substantially reduce or even eliminate altogether, either the toxicity or addictiveness of tobacco products, or both. FDA must consider the risks and benefits to the population as a whole when evaluating a modified-risk tobacco product application.

Consequently, FDA needs to evaluate these products not only in terms of the relative health risks to individuals, but at the population level. FDA must evaluate the increased or decreased likelihood that nonusers will start using the product, whether tobacco users who would otherwise stop using tobacco products will switch to the product, whether tobacco users will use the product in combination with one or more other tobacco products, and if former users will begin using the product.

FDA’s major ongoing research for FY 2015 includes studies and surveys including the Population Assessment of Tobacco and Health Study, the National Youth Tobacco Survey and the Tobacco Centers of Regulatory Science Program (TCORS).

The Population Assessment of Tobacco and Health Study – an ongoing national, longitudinal, cohort study of users and non-users will provide data to increase understanding of what makes people susceptible to tobacco use, evaluate patterns of tobacco product use, and evaluate the effects of regulatory
changes on risk perceptions and other tobacco-related attitudes and behaviors. This longitudinal study will also provide a valuable platform for additional scientific investigations to assess and focus FDA regulatory action.

The National Youth Tobacco Survey is a nationally representative cross-sectional survey assessing adolescents in grades 6 to 12 regarding tobacco-related beliefs, attitudes, behaviors, and exposure to pro- and anti- tobacco influences. This survey’s yearly data collection will provide national estimates of tobacco use prevalence among youth, including the use of tobacco products newly introduced onto the market. Because it is an on-going survey, data collected allows FDA to monitor changes in use, knowledge, and attitudes over time.

The Tobacco Centers of Regulatory Science is a nation-wide program to aid in the development and evaluation of tobacco product regulations is comprised of scientists with expertise in fields including epidemiology, behavior, biology, medicine, economics, chemistry, toxicology, addictions, public health, communications, and marketing. This cohort is the centerpiece of FDA’s collaboration with NIH to foster research relevant to tobacco regulatory science. New research from TCORS will help inform and assess the impact of FDA’s prior, ongoing and potential future tobacco regulatory activities.

Section 905 of the FD&C Act provides FDA with tools to better understand tobacco products since it requires tobacco product manufacturers to submit scientific data and information to FDA whenever they make a change to an existing product to support that the changes do not raise questions of public health. For new tobacco products that do not qualify for review under the substantial equivalence provision, Section 910 of the FD&C Act provides premarket review authority to evaluate whether the marketing of new tobacco products would be appropriate for the protection of public health. In order to inform the evaluation and review of tobacco product submissions, FDA will carry out research in a number of areas, including but not limited to chemistry, engineering, toxicology, and behavioral and social science.

Section 907 of FD&C Act also gives FDA authority to establish tobacco product standards that are appropriate for the protection of public health. These authorities include reducing or eliminating constituents – including smoke constituents – and provisions related to the construction, components, ingredients, additives, and properties of the tobacco product. Product standards could have a meaningful impact on reducing the harm caused by tobacco products. FDA will continue to investigate potential product standards in the areas of addiction, toxicity, and tobacco appeal.

FDA’s Forensic Chemistry Center laboratory will provide support to Office of Criminal Investigations by identifying criminal violations in tobacco-related cases. FDA is expanding the capabilities of the SRL laboratory to better analyze tobacco products and regulatory samples to support enforcement actions. To this end, FDA works with internal and external stakeholders to share data, databases, and analytical expertise.
**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.

<table>
<thead>
<tr>
<th>Measure</th>
<th>Year and Most Recent Result / Target for Recent Result (Summary of Result)</th>
<th>FY 2014 Target</th>
<th>FY 2015 Target</th>
<th>FY 2015 +/- FY 2014</th>
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<tbody>
<tr>
<td>280005: Total number of compliance check inspections of retail establishments in States under contract. (Outcome)</td>
<td>FY 2013:109,908 Target: 75,000 (Target Exceeded)</td>
<td>100,000</td>
<td>105,000</td>
<td>+5,000</td>
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<td>280002: Develop a scientific base to understand and reduce harm from tobacco products by initiating a testing program to support tobacco product standards development, which will include a review of tobacco product ingredients. (Output)</td>
<td>Develop regulation requiring testing and reporting of tobacco product constituents, ingredients and additives Continue to review substantial equivalence reports, pre-market tobacco product applications, and modified risk tobacco product applications</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
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The following selected items highlight notable results and trends detailed in the performance table.

**Compliance Check Inspections**

A key element in enforcing the Tobacco Control Act involves contracts with U.S. States and Territories to conduct compliance checks. In FY 2013, under these state contracts, FDA conducted 109,908 compliance check inspections of retail establishments. Although this number was much higher than expected, it reflects the high level of variability inherent in this goal that requires estimating the number of compliance checks that each State will be able to conduct. In addition, some of the state contracts are expiring, and will need to be renewed in the next year to continue these efforts. Although most States are expected to renew their contracts, there are always outside factors that may prohibit them from doing so.
The FY 2014 and FY 2015 targets consider these challenges, but have still been increased.

**PROGRAM ACTIVITY DATA**

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<th>Tobacco Products Performance Activity Data (PAD)</th>
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<tr>
<td>CTP Workload and Outputs</td>
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<tr>
<td>Administrative/Management Support</td>
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<tr>
<td>Workload</td>
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<tr>
<td>Number of Advisory Committee Meetings</td>
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<tr>
<td>Percentage of Tobacco User Fees Collected</td>
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<td>Number of Tobacco Manufacture Inspections</td>
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