

**Tobacco**  
**TOBACCO CONTROL ACT PROGRAM**

The following table displays funding and full time equivalent (FTE) staffing levels for FY 2012 through FY 2014.

**FDA Program Resources Table<sup>45</sup>**  
(Dollars in thousands)

	FY 2012 Enacted	FY 2012 Actual	FY 2013 CR	FY 014 Request	FY 2014 +/- FY 2012 Enacted
<b>Program Level</b>	<b>\$454,751</b>	<b>\$277,136</b>	<b>\$457,534</b>	<b>\$501,476</b>	<b>\$46,725</b>
Center	\$448,501	\$271,695	\$451,246	\$486,487	\$37,986
FTE	366	346	482	570	224
Field	\$6,250	\$5,441	\$6,288	\$14,989	\$8,739
FTE	26	33	41	70	37
<b>Program Level FTE</b>	<b>392</b>	<b>379</b>	<b>523</b>	<b>640</b>	<b>261</b>
<b>User Fees</b>	<b>\$454,751</b>	<b>\$277,136</b>	<b>\$457,534</b>	<b>\$501,476</b>	<b>\$46,725</b>
Center	\$448,501	\$271,695	\$451,246	\$486,487	\$37,986
FTE	366	346	482	570	224
Field	\$6,250	\$5,441	\$6,288	\$14,989	\$8,739
FTE	26	33	41	70	37
<b>User Fees FTE</b>	<b>392</b>	<b>379</b>	<b>523</b>	<b>640</b>	<b>261</b>

The FDA Tobacco Control Act Program operates under the following legal authorities:

- 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 (FACA) of 1972, as amended

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

---

<sup>45</sup> Spending authority has been adjusted pursuant to PL 112-175, Section 101(c) for the applicable user fee programs.

## **Program Description and Accomplishments**

The Food and Drug Administration's (FDA) Center for Tobacco Products (CTP) 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 subprograms that support its strategic objectives:

- Reducing initiation of tobacco product use
- Decreasing the harms of tobacco products, and
- 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 and requiring manufacturers and importers to provide a list of tobacco products they sell
- Requiring industry reporting of tobacco product ingredient and constituent data
- Inspecting tobacco product establishments, including 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 for the manufacture of tobacco products
- Strengthening health warnings for cigarettes and smokeless tobacco products
- Initiating enforcement actions for violations of the Tobacco Control Act.

FDA's Office of Regulatory Affairs (ORA) Field offices support Tobacco Control Act Program activities by:

- Collecting and analyzing samples of tobacco products to ensure compliance with the requirements of the Tobacco Control Act and other applicable regulations
- Providing training to ORA field employees and assisting in the development of training materials for employees working under FDA contracts with U.S. States and Territories to conduct tobacco retail inspections on behalf of the agency
- Conducting investigations and inspections to assess compliance with the requirements of the Tobacco Control Act and other applicable regulations.

### **Reducing Youth Initiation to Tobacco – Center Activities**

Base Amount: \$272,348,000 (All User Fees)

## Public Health Focus

In order to meet its goal of reducing initiation of tobacco use, especially by young people, FDA will focus on the following areas:

- Dramatically reducing youth access to tobacco products by deeming all tobacco products to be subject to FDA's tobacco product authorities and vigorously enforcing the law
- Using its statutory authorities to communicate broadly and effectively about tobacco product content and harms to youth, especially those most at risk of becoming addicted tobacco users
- Expanding the Tobacco Retail Inspection Program to conduct compliance check inspections of retail establishments that sell tobacco products.

As part of ongoing efforts to expand the Tobacco Retail Inspection Program, FDA recently awarded six additional tobacco retail inspection contracts to Guam, Idaho, Montana, Northern Mariana Islands, Puerto Rico, and South Carolina. FDA now contracts with 44 U.S. States, territories, and the District of Columbia to conduct inspections and expects additional awards to be made in the future.

In FY 2013, the Tobacco Retail Inspection Program will also:

- Increase the total number of inspections of tobacco retailers within U.S. 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 applicable laws and regulations
- Continue to issue Warning Letters and Civil Money Penalty actions, and other applicable enforcement actions against retailers that violate the law and applicable regulations
- When such regulations become effective, include newly-deemed tobacco products in the State Retail Enforcement Program.

To encourage voluntary compliance with the Tobacco Control Act, FDA continues to educate retailers about their responsibilities to protect the Nation's young people. These efforts include outreach to small businesses and to those in minority communities. In FY 2013, FDA will hold regular compliance education webinars during which retailers will be provided an opportunity to ask questions about FDA regulatory activities. FDA also plans to 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.

FDA will continue its efforts to prevent youth from using the tobacco products it regulates, currently cigarettes, cigarette tobacco, roll-your-own, and smokeless tobacco, and encouraging youths that use tobacco products to quit. As authorized by the Tobacco

Control Act, in FY 2013, these activities will involve a full range of actions associated with planning, developing, producing, and delivering consumer-based programs, strategies, and materials for national public education campaigns. FDA will also obtain technical services for strategic planning, development, execution, and assessment of multimedia public education campaigns designed to reduce tobacco use among youth aged 12-17.

### **Public Health Outcome**

In FY 2013, FDA will continue to educate the public about tobacco products and their harms. FDA will develop and launch several public health education campaigns to educate the public about:

- Harmful and potentially harmful constituents of tobacco products
- Statutory requirement to require health warnings on cigarettes and smokeless tobacco products packages and in advertising
- Restrictions on marketing and sales of tobacco products to youth
- Use of misleading descriptors like “light,” “low,” and “mild” on tobacco products
- Other FDA regulatory authorities as they are implemented.

Examples of these public health education programs include:

- Development of comprehensive youth and young adult public health education programs designed to inform them about the harms of tobacco product use and the potential for addiction
- Support for a HHS-wide effort to provide accurate messages about tobacco products and the harms resulting from its use
- Development of a comprehensive benchmark and tracking evaluation program that will assess the effectiveness of FDA public health education programs.

On November 21, 2012 FDA awarded contracts to two small business vendors to produce public education campaigns tailored to at-risk African American, Hispanic, and Asian/Pacific Islander teens, teens who identify as Lesbian, Gay, Bisexual or Transsexual, and teens who reside in rural areas. In December 2012, FDA awarded two more contracts targeting general market youth ages 12-17 who have never tried or who are intermittent users of tobacco products. These awards will allow FDA to begin utilizing comprehensive, multi-media public education campaigns to educate at-risk, underage youth about the dangers of FDA-regulated tobacco products to prevent initiation.

### **Reducing Youth Initiation to Tobacco – Field Activities**

Base Amount: \$6,250,000 (All User Fees)

### **Public Health Focus**

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

ORA has established and continues to maintain a testing laboratory at the Southeast Regional Laboratory (SRL) with expertise and capacity to analyze tobacco products. The ORA SRL laboratory has been acquiring specific testing equipment such as mass spectrometers and smoke machines and continues to work towards developing multi-residue flavor methods to detect unpermitted compounds that impart a characterizing flavor to tobacco products. In addition, SRL, in conjunction with ORA headquarters, has been collaborating with other federal laboratory partners to leverage information, intelligence and experience. Also of note, ORA's Forensic Chemistry Center (FCC) laboratory will provide support to the Office of Criminal Investigations (OCI) to identify criminal violations in tobacco-product related cases.

In FY 2012, ORA continued to perform inspections of registered tobacco product establishments to determine their compliance with the laws and regulations enforced by FDA. During those inspections, ORA determined compliance with the provisions of the law to include registration, product and ingredient listing, packaging, labeling, and advertising requirements, and marketing authorization for new or modified risk tobacco products.

### **Public Health Outcome**

ORA carries out a multi-tiered approach towards enforcing the requirements of the Tobacco Control Act. In addition to inspecting registered tobacco establishments, ORA conducts investigations at sports and entertainment events to ensure tobacco manufacturers promote and distribute their products in accordance with the law. These inspections and investigations help to ensure that the regulated tobacco industry complies with the tobacco provisions of the Food Drug & Cosmetic Act (FD&C Act) and its implementing regulations.

Furthermore, working with CTP, ORA issued two import alerts related to the restrictions on the terms "low," "mild," and "light" to describe tobacco products and for prohibited candy or fruit flavored cigarettes to identify, detain, and refuse these products being offered for import. This effort puts into place a mechanism for detention without physical examination of imported tobacco products found to be adulterated or which otherwise do not conform to the same regulatory requirements as domestically-manufactured tobacco products.

Working collaboratively with CTP, ORA continues to expand its program to train investigators to perform tobacco manufacturer inspections, thus ensuring that the investigators are well-trained in tobacco product inspection techniques.

ORA's commissioning program allows those entities to perform tobacco retail inspection on FDA's behalf and share information related to these retail inspections. As of September 30, 2012, officials have been commissioned in 37 states and the District of Columbia. FDA awarded six contracts to U.S. States and Territories in FY 2012 and they are currently going through the commissioning process.

From October 1, 2011 through September 30, 2012, tobacco-commissioned officials had conducted over 87,000 tobacco retail inspections.

On the analytical front, ORA has been working on establishing tobacco flavors methods so that the ban on characterizing flavors under the Tobacco Control Act can be enforced through special testing assignments.

During FY 2012, ORA's Office of Criminal Investigations (OCI) made 16 tobacco related arrests and secured one tobacco related conviction.

Some representative cases include:

- Foreign-based distributor of counterfeit tobacco products** – In June of 2012, a Chinese national was indicted in Providence, Rhode Island for selling and importing counterfeit tobacco products into the United States from China. The subject has been detained since his arrest in Miami on June 4, 2012, by FDA/OCI. OCI agents, acting in an undercover capacity, arranged for the shipment from China to the United States of a 20-foot cargo container containing 17 pallets of alleged counterfeit Marlboro cigarettes, worth in excess of one million dollars.
- Domestic-based distributor of counterfeit tobacco products** - In July 2012, two individuals were arrested for the distribution of counterfeit tobacco and pharmaceutical products in the Los Angeles, California area. During this multi-agency effort, OCI agents and other participating agencies and officers executed search warrants in East Los Angeles and the surrounding area resulting in the seizure of nearly \$2,000,000 in counterfeit cigarettes and \$100,000 in counterfeit Viagra pills.

### Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
280005: Total number of compliance check inspections of retail establishments in States under contract. ( <i>Outcome</i> )	FY 2012: 87,455 Target: 84,000 (Target Exceeded)	84,000	80,000	- 4,000

### **Reducing Tobacco Product Harms – Center Activities**

Base Amount: \$94,358,000 (All User Fees)

## **Public Health Focus**

FDA is dedicated to reducing tobacco harms by engaging in and supporting numerous research and scientific endeavors. The research 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 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.

## **Public Health Outcome**

FDA will continue to expand funding for biomedical research collaborations within FDA and in collaboration with the National Institutes of Health (NIH) and Centers for Disease Control and Prevention (CDC) in the areas of:

- Tobacco product addictiveness
- Tobacco product chemistry and engineering related to abuse liability thresholds
- Measurement and standards for assessment of harmful ingredients
- Biomarkers for health effects of exposure to tobacco ingredients
- Cognitive and behavioral determinants of tobacco initiation/maintenance and cessation related to marketing and health warnings
- Expanding the foundation of knowledge of the chemistry, toxicology, health and public health impact of new and emerging tobacco products and the potential public health impact of tobacco product regulations.

In April 2012, FDA published the harmful and potentially harmful tobacco product constituent (HPHC) list which established a listing of 93 tobacco product and tobacco smoke constituents FDA believes are harmful or potentially harmful to health.

Also in April 2012, FDA published the draft guidance for industry on Reporting HPHCs in Tobacco Products and Tobacco Smoke as required by section 904(a)(3) of the FD&C Act which provides assistance for reporting the quantities of HPHCs.

FDA will continue to award research contracts in addition to expanding funding for tobacco regulatory science research within FDA and in collaboration with NIH and CDC.

In FY 2013, FDA will continue to invest in broadening the cadre of regulatory science leaders needed to address tobacco product regulation today and into the future. FDA will expand the FDA Tobacco Regulatory Science Fellowship Program in conjunction with the National Academy of Sciences' Institute of Medicine and initiate a research training grant program in conjunction with NIH. These programs will help ensure that there is a diverse

pool of highly trained professionals available to address the tobacco regulatory science needs well into the future both by attracting mid-career and experienced professionals to move into tobacco product regulatory science as well as to attract young investigators into tobacco regulatory science research at different stages in their research careers.

Additionally, FDA will continue review of regulatory submissions from the tobacco industry, including Substantial Equivalence Reports and requests for Substantial Equivalence Exemptions as well as New Tobacco Product applications and Modified Risk Tobacco Product applications following published FDA guidance documents intended to protect the public health.

### Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
<p><u>280002</u>: 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)</p>	<p>FY 2012: Established a list of 93 harmful and potentially harmful constituents to health, publishing it in the Federal Register on April 3, 2012. (Target Met)</p>	<p>Establish a list of harmful and potentially harmful ingredients and constituents in tobacco products and tobacco smoke. TPSAC to issue a report on dissolvable tobacco products. Issue a proposed rule or draft guidance that establishes requirements or contains recommendations regarding the scientific evidence required for assessment and ongoing review of modified risk products.</p>	<p>Develop at least one draft guidance identifying methods which should be used for measuring high priority HPHCs. Continue to review substantial equivalence reports, pre-market tobacco product applications, and modified risk tobacco product submissions</p>	<p>NA</p>

### Encouraging Cessation - Center Activities

Base Amount: \$81,795,000 (All User Fee)

### Public Health Focus

FDA is promoting the public health by leading comprehensive, science-based efforts to educate the nation about the dangers of tobacco products. Consistent with the HHS

Strategic Plan and the Secretary’s strategic initiatives, FDA seeks to prevent and reduce tobacco use through change in social norms related to tobacco use, amount other things. All aspects of FDA’s three strategic priorities (decreasing initiation of tobacco product use, decreasing the harms of tobacco products, and encouraging cessation among tobacco product users) have important public health education components with respect to implementing the Tobacco Control Act.

### Public Health Outcome

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

In addition, FDA continues to engage all stakeholders about the Tobacco Control Act and how to comply with its requirements. Specifically, FDA is providing “Break the Chain of Tobacco Addiction” educational and display materials at no charge to U.S. retailers to promote compliance with the law. The materials were developed with input from retail establishments and include posters, flyers, and syndicated content for retailer websites. FDA is creating customized tools that enable the public and other stakeholders to better access and understand the Tobacco Control Act in a plain language format. This includes plain language summaries, interactive timelines, and customized searches by audience, type of tobacco product, and topic.

### Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
<u>280004</u> : Educate stakeholders and the general public about the new tobacco products regulations and the health effects of tobacco use. (Output)	FY 2012 Target: Implemented and refined education program directed to retailers and the general public, especially youth. (Target Met)	Continue to implement and improve programs designed to educate the public and industry.	Continue to implement and improve programs designed to educate the public and industry. Expand consumer health education in support of FDA’s regulatory authorities.	NA

**Information Technology Investments –Tobacco Program Activities (Base Amount displayed as a non-add item: \$21,965,994)**

CTP’s Information Technology (IT) investment portfolio represents a management analytic for IT capital assets through their life-cycle, assuring that IT plans support Center business planning and mission objectives in support of the Family Smoking Prevention and Tobacco Control Act. The Electronic Submissions and Business Automation investment provides development, modernization, and enhancement, as well as operations and maintenance activities, associated with critical core business processes including: internal workflow management, product review and approval, and compliance oversight business requirements.

The Electronic Submissions and Business Automation investment is comprised of four major projects. The first is Business Process Automation (BPA) which automates current business processes being performed manually in order to improve efficiency and ensure compliance with large workloads. The second is Electronic Submissions (CTP eSub) which handles the receipt, review, and response process for tobacco industry electronic and non-electronic submissions. The third is the Tobacco Inspection Management System (TIMS), an iPhone-based mobile application that provides the capability for state inspectors to efficiently and effectively conduct compliance check inspections of retail establishments. The fourth is the Stakeholder Relationship Management System (SRMS) which will enable CTP to manage and leverage new and existing relationships between the offices, as well as with their respective stakeholder communities, to enhance collaboration and information sharing to address stakeholders with consistency and a unified voice.

**Funding History Table with FTE Totals**

The following table displays funding and full time equivalent (FTE) program levels from FY 2010 through FY 2013, plus FY 2014 request.

<b>Fiscal Year</b>	<b>Program Level</b>	<b>Budget Authority</b>	<b>User Fees</b>	<b>Program Level FTE</b>
2010 Actual	\$64,418,000	\$0	\$64,418,000	90
2011 Actual	\$135,708,000	\$0	\$135,708,000	236
2012 Actual	\$277,136,000	\$0	\$277,136,000	379
2013 CR	\$457,534,000	\$0	\$457,534,000	523
2014 Request	\$501,476,000	\$0	\$501,476,000	640

## Summary of the Budget Request

The FY 2014 budget request for the Tobacco Control Act Program is \$501,476,000. This amount is an increase of \$46,725,000 above the FY 2012 Enacted level. The CTP amount is \$486,487,000 which supports 570 FTE. The Field amount is \$14,989,000 which supports 70 FTE. The source of funding for the request is tobacco user fees. The Tobacco Control Act requires that these user fees may only be used for FDA tobacco regulatory activities. Conversely, the law prohibits the use of non-tobacco funds for FDA tobacco regulatory activities.

The FY 2014 budget allows the Tobacco Control Act 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.

### Reducing Youth Initiation to Tobacco

**Center Activities** (FY 2012 Enacted Amount: \$272,348,000)  
FY 2014 increase above the base: +\$9,282,000; 137 FTE

In FY 2014, FDA will continue its implementation of the Tobacco Retail Inspection Program. This work includes re-awarding contracts to U.S. 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 contracts with U.S. States and Territories to cover more retailer inspections, where feasible.

Additionally, FDA will continue to update and enhance its mobile device inspection tool using customized software known as the Tobacco Inspection Management Systems (TIMS) Mobile Application. The tool can help reduce the amount of equipment inspectors need, reduce or eliminate the need to mail, fax, or scan paper forms to and from field inspectors, and reduce data entry, thereby decreasing the time for conducting and reviewing inspections and gathering evidence.

In FY 2014, FDA will continue the expansion of its tobacco-related Promotion, Advertising, and Labeling Enforcement programmatic activities. FDA will enforce the warning label requirements, which includes the review of warning plans for smokeless tobacco products. FDA expects these reviews to increase once the cigarette warnings take effect and when "other tobacco products" are deemed to be subject to Chapter IX of the FD&C Act. FDA will review additional regulatory submissions and applications that contain packaging, labeling or advertising materials.

FDA will continue to conduct monitoring activities, which include reviews of websites, magazines and other publications that promote and sell regulated tobacco products in the U.S. FDA will collaborate with other agencies to ensure that enforcement efforts are coordinated. This effort will require FDA to invest in more advanced information

technologies, including software programs and/or contract for services, to broaden its monitoring and surveillance programs. Consistent with the HHS Strategic Plan and the Secretary's strategic initiatives, FDA will seek to prevent and reduce tobacco use while leveraging systems and resources.

In FY 2014, FDA will continue expansion of its Enforcement and Manufacturing activities by monitoring compliance with registration and listing requirements. FDA will continue to coordinate the activities surrounding the development of Tobacco Product Manufacturing Practice (TPMP) requirements for regulated tobacco manufacturers. As part of the ongoing oversight of these establishments, FDA will continue to develop new mobile technologies to assist in streamlining the efficiency of these inspections.

FDA will continue to provide training, educational webinars and other web-based training for small tobacco product businesses. FDA will also continue to provide information to industry and retailers to ensure a better understanding of the Tobacco Control Act and regulations through the Compliance and Enforcement webpage, compliance training webinars, and by responding to inquiries. FDA will also provide compliance training and outreach to other federal, state and local stakeholders involved in tobacco control.

In FY 2014, FDA will continue to educate the public about tobacco products and their harms. FDA intends to develop public health education campaigns and key messages, support effective design, development, implementation and evaluation of its public health education efforts, and increase the impact of FDA's health education program with FDA's stakeholders and audiences on priority issues and key messages related to FDA tobacco product regulations.

In FY 2014, FDA plans to engage in several major research activities regarding decreasing youth tobacco use initiation. This research will expand the scientific evidence needed to support several authorities in the Tobacco Control Act, and also help assess the impact of regulatory actions on preventing the initiation of tobacco use.

Some of the major research activities planned for FY 2014 includes:

- The Population Assessment of Tobacco and Health (PATH) study, which will support an on-going, national, longitudinal, cohort study of almost 59,000 users and non-users of tobacco products and those at risk for tobacco use ages 12 and older. Research topics in the PATH study related to reducing youth tobacco initiation include understanding what makes people susceptible to tobacco use, evaluating patterns of tobacco product use, and evaluating the effects of regulatory changes on risk perceptions and other tobacco-related attitudes and behaviors.
- The National Youth Tobacco Survey is a nationally-representative cross-sectional survey of middle and high school youth examining tobacco-related beliefs, attitudes, and behaviors, as well as measuring exposure to pro- and anti-tobacco influences. The target sample size is over 24,000 students and the survey will explore a broad range of topics such as use of cigarettes, smokeless tobacco, cigars, pipes, bidis, and

kreteks, as well as newer tobacco products, media and advertising; access to tobacco products and enforcement of restrictions on product access in youth. Because the NYTS is an on-going study, data collected allows FDA to monitor changes in use, knowledge and attitudes over time which provides the agency with an indicator of its effectiveness.

- FDA will work with the National Institutes of Health (NIH) to stimulate investigator-initiated research and release targeted Funding Opportunity Announcements to examine the impact of marketing, communications, use behavior, perceptions, knowledge, attitudes, and beliefs regarding tobacco products and use.
- FDA will target research needs regarding youth tobacco initiation. Examples include Poison Control Center data to understand childhood accidental poisonings from using tobacco products, collection of qualitative and quantitative data to understand how youth and adolescents perceive various tobacco products and understand communications from FDA, and statistical analyses of data sets that will provide information related to youth tobacco use.

**Field Activities** (FY 2012 Enacted Amount: \$6,250,000)

FY 2014 increase above the base: +\$8,739,000; 37 FTE

ORA will continue to conduct surveillance, investigations, inspections, sample collections, and other regulatory actions to ensure compliance by manufacturers, distributors, and importers of tobacco products with the requirements of the FD&C Act. By the end of FY 2014, ORA expects to continue conducting biennial tobacco inspections of all registered tobacco manufacturing facilities as required under Section 905(g) of the FD&C Act. ORA in conjunction with CTP will continue efforts to develop and present training to ORA staff.

ORA will continue establishing its testing laboratory at SRL with expertise and capacity to analyze tobacco products. After successful completion and validation of multi-residue flavors methods, ORA will focus on establishing methods to perform product qualification. In addition to analyzing the tobacco product itself, ORA also plans to perform testing on tobacco smoke.

ORA's FCC laboratory continues to provide support to OCI related to identifying criminal violations in tobacco-related cases, as OCI conducts investigations of potential criminal activity. These cases could include counterfeit identification and country of origin determinations. As both SRL and FCC may be using similar analytical tools to address different needs, both labs will be communicating and collaborating on development and use of new methods.

Lastly, ORA will collaborate with CTP regarding the use and enhancement of database and software systems managed by ORA for inspection data, recalls, imported product, enforcement actions, and training purposes. In addition, CTP plans to provide ORA inspectors with new mobile technology to use for their inspections of tobacco product manufacturers.

## Reducing Tobacco Product Harms

**Center Activities** (FY 2012 Enacted Amount: \$94,358,000)

FY 2014 increase above the base: \$11,230,000; 51 FTE

Even as FDA is trying to educate youth about the dangers of tobacco use, it recognizes that millions of adults currently use tobacco products. FDA is dedicated to helping all tobacco users by working to decrease the harms and addiction caused by use of tobacco products.

In FY 2014, FDA intends to:

- Support scientific research including identifying substances other than nicotine that contribute to tobacco product addiction as well as threshold levels of substances, including nicotine, that generate and sustain addiction
- Identify population measures of addiction
- Consider fast-track of new product and/or modified risk application reviews for significantly less harmful / less addictive tobacco products if this can be scientifically proven by criteria established in the Tobacco Control Act and articulated in published FDA guidance
- Draft guidance to industry and regulation to provide requirements appropriate for each type of premarket submission and review program
- Continue proactive communication processes with industry and the public about the FDA tobacco premarket review process and status of submissions, and
- Conduct and support research to continue to enhance the evidence base for reviewing and making decisions on tobacco industry submissions and to inform regulatory options.

Additional research projects proposed to be funded during FY 2014 will identify the impact of nicotine reduction in tobacco products. These projects are designed to:

- Identify the nicotine concentration below which tobacco products will not be addictive
- Assess the effects of prolonged use of very low nicotine content cigarettes with a particular interest on identifying the differences between abrupt reduction of nicotine versus a gradual reduction
- Examine the acceptability of reduced nicotine products in smokers with schizophrenia, a population with extremely high rates of smoking, and
- Assess the reinforcing effects of nicotine within the context of other components of cigarette smoke.

FDA will also support additional research assessing the toxicity of complex mixtures of tobacco and smoke to further understand the toxicity of individual tobacco constituents. This research will be used to assess toxicity levels of tobacco smoke condensates and to develop genetic toxicological assays.

The foundation of science upon which tobacco product regulation is being built will continue to expand in FY 2014. Data from the PATH study will be used to support FDA's goal to reduce tobacco harms. This longitudinal study will also provide a valuable platform for additional scientific investigations to assess and focus FDA regulatory action.

Scientific review of new tobacco products and substantially equivalent (SE) tobacco products is critical to the fulfillment of the FDA objectives to reduce tobacco product harms and protecting the public health. By reviewing new tobacco product and SE submissions, FDA can prevent marketing of new, potentially more harmful tobacco products or products that raise new issues of public health. To accomplish these evaluations, FDA has developed the regulatory framework for scientific and public health review as required by law and as appropriate for each type of premarket submission. For example, FDA issued final guidance to industry on the submission of SE reports on January 6, 2011, a final regulation on exemptions from SE requirements on July 5, 2011, and draft guidance on premarket tobacco application on September 28, 2011. FDA has not yet received any new tobacco product applications and is reviewing SE reports submitted by industry. Additionally, FDA oversight of investigational studies of tobacco products will help ensure that the proposed studies are designed to minimize risk to human subjects. By monitoring adverse events and industry reports, FDA can detect signals of increased tobacco product harms which may need to be addressed by agency action.

As FDA continues to implement the Tobacco Control Act, it is important to convey to regulated industry and other interested parties FDA's expectations and to clarify aspects of regulatory authority. Development of regulation and guidance documents is an important tool to assist in relaying this message.

In 2014 FDA may develop regulations and guidance in three major areas:

- Product Review and Evaluation Policies -- FDA reviews industry reports and applications for new tobacco products and for products with claims of modified risk. As part of the ongoing development, implementation, and improvement of this review program, regulations may be proposed to standardize the format and content of new tobacco product applications and of reports demonstrating substantial equivalence.
- Tobacco Product Monitoring Policies -- Manufacturers are required by statute to submit information to FDA regarding their research activities and the ingredients and constituents in marketed tobacco products. This information is useful for monitoring changes in grandfathered and new products and identifying emerging areas of research and product development. To improve the quality and usefulness of this information, regulations may be published to specify criteria for measurement and reporting the information.
- Tobacco Product Standards -- The statute authorizes FDA to issue standards that are appropriate for the protection of public health. Examples of rulemaking that FDA may begin working on include standards related to the toxicity and/or addictiveness of tobacco products.

## Encouraging Cessation

**Center Activities** (FY 2012 Enacted Amount: \$81,795,000)

FY 2014 increase above the base: +\$17,475,000; 36 FTE

The Tobacco Control Act and the FD&C Act contain provisions that are intended to prevent false and misleading advertising of tobacco products, namely by addressing the impact that labeling and advertising can have on consumers. Providing consumers with truthful, accurate and non-misleading information, including information on the negative health consequences of tobacco use in product labeling and advertising may encourage users to quit.

Based on its statutory authorities, one of FDA's major goals is to expand science-based public education efforts to encourage cessation among current users of tobacco products. This will be bolstered by increased efforts to prevent false and misleading advertising, which serves to reinforce incorrect assumptions about the safety of tobacco products, and by the expansion of compliance and enforcement efforts.

During FY 2014, FDA will continue to provide education to the public and stakeholders on tobacco products. FDA will also design and evaluate public education campaigns to encourage current tobacco product users to quit. Collectively, the campaign activities will be rigorously evaluated to determine their effectiveness in increasing tobacco use cessation and creating changes in knowledge, beliefs, and attitudes about tobacco products and use.

In FY 2014, FDA will assist grantees in establishing or expanding public health education programs at the community level, in support of current and future FDA tobacco regulations. Community-based programs will educate the public so as to amplify FDA's messages about FDA's tobacco product regulations.

FDA will continue to evaluate false and misleading claims made in the labeling and advertising of regulated tobacco products. This is an important step in ensuring that current tobacco product users do not receive deceptive information from tobacco manufactures and are equipped with candid information to assist them to quit. U.S State and Territorial contractors will conduct compliance check inspections of retailers, and FDA will conduct inspections of tobacco product manufacturers, thus ensuring that claims on cigarette and smokeless tobacco products' labeling and advertising are truthful and not misleading. In addition, FDA will conduct surveillance of the marketing and promotion of regulated tobacco products on the internet, in magazines, and other publications to ensure regulated industry's compliance with the laws.

FDA will continue to ensure that regulated entities comply with the Tobacco Control Act and is implementing regulations through a multi-pronged approach. This includes assuring industry's compliance with the risk provisions of the law through inspections of tobacco product manufacturers, inspections of tobacco product retailers, review of

tobacco product marketing and promotion on the internet, in magazines and other publications, review of labeling and consumer information, review of regulatory submissions, and evaluation of complaints. Periodic compliance training webinars will be held during FY 2014 to assist small tobacco product manufacturers on how to comply with the labeling and advertising provisions of the law as new provisions become effective.

As new products emerge, including those making modified risk claims, FDA is required to evaluate them based on a population health standard that analyzes the impact of that product on both tobacco product users and non-users, including their effect on initiation and cessation of tobacco use.

FDA will expand its research base in order to study issues relevant to scientific standards for evaluation of tobacco products proposed to be marketed with a modified risk claim. Marketing of modified risk tobacco products is authorized under the Tobacco Control Act if FDA determines that such products have the potential to reduce the burden of tobacco-related disease, death, and disability in the United States. Information regarding modified risk claims will be made public so that current tobacco users are aware of new products and product harms.

During FY 2014, FDA will engage in and support numerous research and scientific endeavors not only to expand the scientific evidence needed for several authorities in the Tobacco Control Act, but to also help assess the impact of regulatory actions on tobacco cessation. The major research activities planned for FY 2014 include:

- Research topics in the PATH study related to encouraging tobacco cessation include examining quit attempts, success in quitting and motivations to quit. Data from this study will be used to strengthen FDA's efforts to encourage tobacco product cessation.
- National Adult Tobacco Survey (NATS) – NATS is a nationally representative cross-sectional survey assessing adult tobacco use and quitting, as well as an individual's knowledge, attitudes and beliefs regarding tobacco. This survey plans for yearly data collection and will provide national estimates of tobacco use prevalence among adults, including the use of tobacco products newly introduced onto the market. Because it is an on-going study, data collected allows FDA to monitor changes in use, knowledge and attitudes over time.
- FDA collaboration with NIH to stimulate investigator-initiated research and release targeted Funding Opportunity Announcements to examine the impact of marketing, communications, use behavior, perceptions, and knowledge, attitudes, and beliefs regarding tobacco products and use on tobacco cessation.
- Initiation of a contract to support both quantitative and qualitative research and data collection on tobacco cessation in order to understand how communications consistent with FDA's regulatory authorities influence quit attempts and quitting.

### CTP Performance Activity Data (PAD)

The following table lists the CTP Program Activity Data (PAD) over a four year fiscal period.

CTP Workload and Outputs	FY 2012 Actual	FY 2013 Estimate	FY 2014 Budget
<b>Administrative/Management Support</b>			
<i>Workload</i>			
Number of Advisory Committee Meetings	2	4	6
Number of Warning Letters and Civil Money Penalty Actions (CMPs) Issued	4,524	3,500	3,500
Percentage of Tobacco User Fees Collected	99%	99%	99%