Food and Drug Administration
FY 2011 Congressional Budget Request
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TOBACCO PROGRAM

The following table displays funding and full time equivalent (FTE) staffing levels for FY 2009 through FY 2011.

FDA Program Resources Table
(Dollars in Thousands)

	FY 2009 Enacted[1]	FY 2009 Actuals	FY 2010 Appropriation	FY 2011 Pres.Bud	+/- FY 2010
Program Level	**$26,612**	**$4,908**	**$216,523**	**$421,463**	**$204,940**
Center	$26,612	$4,908	$211,823	$415,567	$203,744
FTE	13	0	174	345	171
Field	$0	$0	$4,700	$5,896	$1,196
FTE	0	0	20	25	5
Program Level FTE	**13**	**0**	**194**	**370**	**176**
Budget Authority	**$4,908**	**$4,908**	**$0**	**$0**	**$0**
Center	$4,908	$4,908	$0	$0	$0
FTE	0	0	0	0	0
Field	$0	$0	$0	$0	$0
FTE	0	0	0	0	0
User Fees	**$21,704**	**$0**	**$216,523**	**$421,463**	**$204,940**
Center	$21,704	$0	$211,823	$415,567	$203,744
FTE	13	0	174	345	171
Field	$0	$0	$4,700	$5,896	$1,196
FTE	0	0	20	25	5

[1] Amount includes an August 2009 reprogramming of $4,908,000 for Tobacco program activities.

The FDA Tobacco 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)
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

Program Description and Accomplishments

The Center for Tobacco Products (CTP) oversees the implementation of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). The Tobacco Control Act establishes a new regulatory standard for FDA. The standard for Tobacco regulation is based on whether it "will benefit the health of the population as a whole,"[1] rather than FDA's historical safe and effective standard. FDA's FY 2011 tobacco control and population-based public health and prevention goals include:

[1] Section 2 (36) of the Family Smoking Prevention and Control Act (PL 111-31).

- Preventing youth from using tobacco and helping adults who use tobacco to quit;
- Promoting public understanding of the harmful and potentially harmful constituents of tobacco products;
- Developing a science-base for tobacco regulation; and
- Beginning meaningful product regulation in order to reduce the toll of tobacco-related disease, disability, and death.

The Tobacco Control Act provides FDA with several new authorities. These include restricting the marketing of tobacco products to minors; requiring new warning labels for cigarettes and smokeless tobacco; prohibiting marketing measures that are misleading to consumers; establishing tobacco product standards; requiring Good Manufacturing Practice standards for tobacco manufacturing facilities; requiring industry reporting of tobacco product ingredient and constituent data, including a description of the nicotine content and delivery mechanisms; and developing enforcement authorities to FDA to act quickly and effectively to remove products that are in violation of the statute. In addition, the Tobacco Control Act permits FDA to assert jurisdiction over cigars and other tobacco products not specifically articulated in the statute.

The Tobacco Program budget is funded entirely by user fees that are based on the percent of a tobacco company's market share, as provided by the U.S. Department of Agriculture. The total amount of user fees to be assessed and collected annually through FY 2019 is stipulated in the Tobacco Control Act and the fees are authorized to remain available until expended. Section 919 of the statute also stipulates that these user fees may only be used for "tobacco regulation activities" and are the only FDA funds authorized for tobacco regulation. Tobacco user fees also pay for specific activities provided by other FDA Offices and Centers that assist CTP in implementing the Tobacco Control Act, including legal counsel, management and acquisitions support, regulatory compliance, and Advisory Committee management, among others.

Intra-Agency and Departmental Support for Tobacco Control and Prevention

To assist CTP in enforcing the Tobacco Control Act, the Office of Regulatory Affairs (ORA) will play a significant role. ORA already has supported enforcement of FDA's ban on flavored cigarettes by providing expert staffing assistance in internet surveillance, documentation of violations, import screening, and coordination of laboratory services, and its role will likely expand to include other tobacco control efforts. FDA anticipates that a significant level of funding will be provided to ORA in addition to the funds made available directly to the States and Territories. These partnerships will be funded through contracts and/or cooperative agreements and are essential in enforcing the Tobacco Control Act, especially with respect to enforcing the provisions of the 1996 final rule, which CTP will re-issue by March, 2010. It also is likely that some of CTP's laboratory analyses requirements may be partially met through intra-FDA collaborations (e.g., National Center for Toxicological Research, ORA, etc.).

The Office of Chief Counsel has provided significant support to CTP with respect to counseling and litigation services and that level of support is expected through FY 2011.

FDA's tobacco prevention and control activities are part of a larger, Public Health Service-wide effort to reduce morbidity and mortality from tobacco use. The Assistant Secretary for Health is leading a HHS Tobacco Prevention and Control Working Group, comprised of senior leaders from all the Public Health Service Agencies, to help integrate and leverage Departmental assets with respect to tobacco control and public health activities. As an active member of the working group, FDA is coordinating tobacco control efforts with other Federal agencies. For example, CTP and the Centers for Disease Control and Prevention (CDC) are exploring opportunities for collaboration, including FDA use of the CDC tobacco laboratory, surveillance, epidemiology, and evaluation assets.

Major Accomplishments

The Tobacco Control Act was signed into law by the President on June 22, 2009. In July 2009, FDA announced a comment period seeking input from the public and various stakeholders on the implementation of the new statute. FDA subsequently extended the comment period from September 29, 2009 to December 28, 2009. The Assistant Secretary for Health, the FDA Commissioner, and the CDC Director hosted a conference call with over 200 State and local officials to discuss collaboration in carrying out the Act.

In August 2009, FDA officially established the Center for Tobacco Products to oversee the science-based regulation of tobacco products in the United States. During the same month, FDA created the Tobacco Product Scientific Advisory Committee (TPSAC). Subsequently, a nominations process was announced in the *Federal Register*, and a panel of HHS-wide representatives selected a group of potential committee candidates from a large pool of nominees to present to the FDA Commissioner. A simultaneous nominations process took place for three non-voting industry representatives to the Committee, who will be selected by various segments of industry. Among the issues that TPSAC will consider are:

- The impact on the public health of the use of menthol in cigarettes;
- The nature and impact of the use of dissolvable tobacco products on the public health;
- The effects of the alteration of nicotine yields from tobacco products and whether there is a threshold level below which nicotine yields do not produce dependence on the tobacco product involved; and
- Any application submitted by a manufacturer for a modified risk tobacco product.

Also in August 2009, FDA established the tobacco user fee program and began assessing and collecting those fees in the final quarter of FY 2009.

After a national search, the Commissioner announced the selection of Lawrence Deyton, M.S.P.H, M.D., as CTP Director in September 2009. Dr. Deyton is an expert on veterans' health issues, public health, and tobacco control and prevention. He also is a clinical professor of medicine and health policy at George Washington University School

of Medicine and Health Sciences. FDA also began staffing CTP, initially through recruiting detailed employees from other parts of FDA as well as through contractual support. At the same time, FDA began an aggressive recruitment and hiring program, with a goal of reaching 194 FTEs in the tobacco program in FY 2010 and 370 FTEs in FY 2011.

To date, FDA has met or exceeded the statutory requirements of the Tobacco Control Act:

- On September 22, 2009, FDA banned cigarettes with certain characterizing flavors, including fruit and spice flavors. Subsequently, CTP took several important steps to publicize and enforce the ban, including issuing warning letters to firms that have violated the ban.
- In September 2009, FDA published a draft guidance document intended to assist industry and FDA staff with respect to the scope of Section 201(rr)(4) of the Tobacco Control Act, prohibiting the marketing of a tobacco product in combination with another product regulated under the Food, Drug and Cosmetic Act.
- In October 2009, FDA published a draft guidance document intended to assist persons making tobacco product establishment registration and product listing submissions to FDA. Final guidance was issued in November 2009.
- In October 2009, FDA issued a draft guidance document describing the requirements for providing listings of all ingredients used in making cigarettes, smokeless tobacco, and certain other tobacco products. Through the public docket and a series of listening sessions, CTP received comments from both industry representatives and tobacco control advocates. Final guidance for industry on the requirements for providing tobacco product ingredients listings was issued in November 2009.
- In November 2009, FDA established a group to assist small tobacco manufacturers.
- Beginning on December 22, 2009, tobacco manufacturers or importers are required to start submitting documents developed after June 22, 2009, "that relate to health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents (including smoke constituents), ingredients, components, and additives."[2] In December 2009, FDA published a guidance document announcing enforcement discretion to extend the time for beginning these submissions and developed a guidance document that explained the requirements of and recommendations for compliance with this statutory provision.

CTP executes its regulatory and public health responsibilities in four areas: protecting the public health, scientific standard-setting and product review, compliance and regulation, and public education and outreach.

[2] Section 904(a) (1) of the Family Smoking Prevention and Control Act (PL 111-31).

Protecting the Public Health from the Harmful Effects of Tobacco Use-- Center Activities
Base Amount: $38,225,000 (All UF)

The Tobacco Control Act directs FDA to regulate tobacco products based on what is appropriate for the protection of the public health. The overarching public health goal is to reduce the morbidity and mortality from use of tobacco products, and to minimize youth acquisition of tobacco products. CTP began taking action to protect the public health from the harmful effects of tobacco products by banning certain flavored cigarettes (except menthol, as stipulated in the Tobacco Control Act) in FY 2009. CTP aggressively enforced that ban in FY 2010 and will continue to do so in FY 2011.

Also in FY 2010, FDA is required to re-issue the final rule, originally promulgated in 1996, prohibiting the sale of cigarettes and smokeless tobacco to persons younger than 18 years of age and restricting the sale, distribution, and marketing of cigarettes and smokeless tobacco to help reduce the number of children and adolescents who use these products.

Other public health protection measures initiated in FY 2010 and continuing in FY 2011 include eliminating misleading descriptors, like “light,” “low,” and “mild” from tobacco products; and requiring new tobacco product labeling to better inform the public about the risks of tobacco product use.

In order to meet the requirements of the Tobacco Control Act in FY 2011, CTP will conduct research and evaluation programs to better understand how the FDA regulations and tobacco control and prevention programs protect the public from the adverse health consequences of tobacco use. Major goals for this research include achieving a better understanding of how marketing and advertising of tobacco products influence the use of tobacco products by various sectors of the public; evaluating the early impact of the tobacco regulations issued in 2009 and 2010; and developing baseline measures to better assess the impact of later provisions in the statute. This may include research efforts on the behavioral effects of industry marketing methods, the impact of governmental and other tobacco-use risk educational programs, and the impact of minors’ access to tobacco products, tobacco marketing restrictions, and smokeless warning labels. These studies may be funded through contracts, grants, interagency agreements, or cooperative agreements with other entities such as universities or private foundations.

Performance Measure

For information regarding the alignment of FDA's Strategic Action Plan goals and objectives with each subprogram area and associated annual performance goals, see the information on strategic alignment in the Performance Materials Tab of this budget document.

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

Measure	Most Recent Result	FY 2010 Target	FY 2011 Target	FY 2011 +/- FY 2010
280001: Protect the public health by developing and issuing regulations related to tobacco control and limiting access to tobacco products by youth.	N/A	Identify population-based data available to begin assessing impact of tobacco control regulations, their impact on youth and adult access to and use of tobacco products	Select initial set of data and calculate baseline for long term assessment of public health impact of tobacco regulation and associated FDA programs	N/A

Tobacco Product Scientific Standard-Setting and Tobacco Product Review -- Center Activities
Base Amount: $64,100,000 (All UF)

In order to protect the public's health, the Tobacco Control Act authorizes FDA to conduct scientific programs to inform promulgation of regulations and guidance to implement many provisions of the law, including those related to manufacturing and marketing of tobacco products. For example, the Center's scientific programs will determine appropriate science-based tobacco standards, develop criteria for establishing substantial equivalence, and develop criteria for review of applications for new tobacco products and modified-risk tobacco products. FDA is authorized to undertake research to carry out its responsibilities with respect to regulation of these products. Subsequently, the research findings obtained by FDA will be applied in confirming and refining ongoing controls for marketed products, e.g. product standards. The FDA research efforts will also provide further scientific bases for guidelines and review criteria for reports of substantial equivalence and applications for non-equivalent new products and products claimed to provide a reduced risk of harm. The research program will also provide support for regulatory decisions regarding labeling and marketing of tobacco products. The criteria for setting standards and reviewing products will be developed based on the public health impact, including effects on individual's risk of disease and population effects such as changes in tobacco initiation and cessation rates.

FDA's goals for FY 2011 in this program area include:

- Developing standards for evaluating, and guidelines for submission of Pre-Marketing Applications from manufacturers that propose to market new tobacco products and products that do not claim to be substantially equivalent to an already marketed tobacco product;
- Evaluating the report and recommendations from the Tobacco Product Scientific Advisory Committee on the impact of the use of menthol in cigarettes on public health to develop appropriate product standards;

- Further refining the scientific basis for a comprehensive list of tobacco product constituents (including smoke constituents) that are deemed harmful or potentially harmful and for which testing and reporting to FDA will be required. This will necessitate significant laboratory resources, initially under contracts or Interagency Agreements (IAGs) with other Federal agencies;
- Developing and proposing regulations setting Tobacco Product Standards; and
- Instituting a program to continually monitor products and revise standards, as appropriate, to further protect the public health.

Performance Measure

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

Measure	Most Recent Result	FY 2010 Target	FY 2011 Target	FY 2011 +/- FY 2010
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)*	N/A	Identify potential set of harmful ingredients; establish criteria for evaluating testing methods	Select initial set of harmful ingredients and establish adequate testing methods	N/A

Compliance and Regulatory Activities – Center Activities
Base Amount: $64,118,000 (All UF)

The Tobacco Control Act requires the issuance of regulations pursuant to certain timetables. For example, in FY 2011, statutorily required activities will include issuance of regulations that require color graphics depicting the negative health consequences of smoking to accompany the required warning on cigarette packaging and advertising. In FY 2011, FDA also will devote significant resources to meeting its statutory obligations to publish proposed and final regulations regarding cigarette warning labels, smokeless tobacco warning labels, exemptions for products substantially equivalent to statutorily defined predicate products, cigarette and smokeless tobacco products with modified risk claims, and the sale and distribution of cigarettes and smokeless tobacco by other than direct, face-to-face transaction. At the same time, FDA will devote significant resources to providing regulated industry with guidance on these new requirements and to developing compliance programs to ensure that the new requirements are followed.

Compliance and Regulatory Activities – Field Activities
Base Amount: $4,700,000 (All UF)

With respect to enforcement of the regulations pertaining to the reissued 1996 rule, the Tobacco Control Act requires that a program to implement and enforce the restrictions be in place by December 2010. In accordance with the statute, FDA will contract with the

States and Territories to conduct compliance checks on behalf of FDA to assure that retailers are not selling tobacco products to anyone under the age of 18. Therefore a major FDA goal in FY 2011 is to implement an effective program to support enforcement of the 1996 rule by contracting with at least 75 percent of the States and Territories to conduct compliance training and enforcement to support the public health goals of the Tobacco Control Act.

In addition, FDA will develop other enforcement programs under the authority of the Tobacco Control Act to enable prompt and effective action by ORA and/or States and Territories to remove noncompliant tobacco products from the market.

Performance Measure

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

Measure	Most Recent Result	FY 2010 Target	FY 2011 Target	FY 2011 +/- FY 2010
280003: Increase compliance with tobacco product regulation by increasing the percentage of States and Territories with which FDA has developed a contract program to support the enforcement and public health goals of the 1996 rule to assure that retailers refuse sales of cigarettes and smokeless tobacco products to adolescents under the age of 18. *(Outcome)*	FY 2009: 0% (Historical Actual)	25%	75%	+50%

Tobacco Product Public Education and External Communications - Center Activities
Base Amount: $45,380,000 (All UF)

In addition to regulatory and enforcement programs, the Tobacco Control Act requires FDA to be engaged in public education and outreach activities to communicate the adverse risks associated with tobacco products use.

During FY 2011, FDA plans to implement a comprehensive educational program regarding the 1996 rule in particular, and about the hazards of tobacco product use more generally. Large and small retailers will be among the audiences targeted to enhance enforcement efforts.

Informed by social/behavioral science, FDA also will develop and disseminate public education campaigns to decrease tobacco product initiation and increase cessation. Further, FDA will create and launch a health literacy program focused on tobacco product use and targeted at various populations, with a special emphasis on educating youth and adolescents across racial, ethnic, cultural, and social demographics.

Also in FY 2011, FDA will continue its Stakeholder Discussion Series that began in FY 2010 to fully explore ideas and options for overarching principles for the implementation of the Tobacco Control Act and the establishment of effective communications mechanisms between and among FDA and various stakeholder groups.

Performance Measure

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

Measure	Most Recent Result	FY 2010 Target	FY 2011 Target	FY 2011 +/- FY 2010
280004: Educate stakeholders and the general public about the new tobacco products regulations and the health effects of tobacco use. *(Output)*	N/A	Develop education program directed to retailers and the general public, especially youth.	Implement and refine education program directed to retailers and the general public, especially youth.	N/A

Information Technology Investments –Tobacco Program Activities
Base Amount displayed as a non-add item: $2,363,000

The ongoing modernization and enhancement of the FDA information technology (IT) infrastructure and systems is creating a robust foundation to enable interoperability of regulatory data sharing across the FDA program areas. This allows the FDA to transform nearly every aspect of its operations and regulatory duties. FDA has agency-wide costs associated with the operation and maintenance of shared information technology infrastructure which includes data centers, security, telecommunication networks, and help desk functions. In addition, each center and office has program specific information technology systems and FDA also has a number of enterprise systems ranging from improving the pre-market review process for all regulated products to post-market surveillance, including adverse event detection and future scientific computing capabilities.

The following are enterprise wide systems which benefit all FDA centers and offices:

Regulated Product Submission (RPS) will provide a standard framework for receiving regulatory information using predefined parameters for the more efficient identification and cataloging of submitted information.

Janus will establish a FDA-wide data architecture and standards that will ultimately convert and store scientific data from external and internal sources into a structured format that can be used throughout FDA.

The Common Electronic Document Room (cEDR) will establish a single, FDA-wide repository for all FDA-regulated documents and provide an end-to-end electronic environment from the receipt of product pre-market application information through its

review, approval, and post-market surveillance to achieve a more efficient review and surveillance process.

Harmonized Inventory (HI) will provide a complete and reliable inventory of firms, facilities, products, and components/ingredients, as well as their relationships and points of contact for all FDA regulated products.

MedWatch Plus will provide an integrated system for receiving, processing, storing and analyzing adverse event reports and other safety information for all FDA regulated products.

FDA Advisory Committee Tracking and Reporting System (FACTRS) will provide a fully electronic system to support advisory committee meetings and management of meeting information, people, and reporting capabilities.

Automated Employee Process (AEP) will streamline the process of getting staff (employees and contractors) on board and operational in a timely fashion.

The Tobacco Control Act granted FDA the authority to regulate tobacco products and impacted more than the infrastructure and enterprise investments described above. It also resulted in a need to leverage existing IT systems supporting FDA Foods and Medical Device programs to provide an electronic solution to regulate the marketing, sale, and content of tobacco products. Two specific examples include the creation of the Tobacco module in the FDA Unified Registration and Listing System (FURLS) that will allow tobacco facilities to register themselves and their products with the FDA and the e-Submitter/e-Loader which will create a customized form for collecting, processing and loading the data into an internal FDA document management system. With such information management technologies, the FDA will be able to regulate the tobacco products with transparency, collaboration, knowledge management, agility and improved efficiency.

Five Year Funding Table with FTE Totals

The following table displays funding and full time equivalent (FTE) staffing levels from FY 2007 through FY 2011.

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
FY 2007 Actual	NA	NA	NA	NA
FY 2008 Actual	NA	NA	NA	NA
FY 2009 Actual	$4,908,000	$4,908,000	$0	0
FY 2010 Appropriation	$216,523,000	$0	$216,523,000	194
FY 2011 President's Budget Request	$421,463,000	$0	$421,463,000	370

Budget Request

The FY 2011 budget request for the Tobacco Program is $421,463,000. This amount is an increase of $204,940,000 above the FY 2010 enacted user fee amount. The Center for Tobacco Products amount in this request is $415,567,000, supporting 345 FTE. The Field Tobacco Products amount is $5,896,000, supporting 25 FTE.

The base funding for the Tobacco Program is $216,523,000, which includes $211,823,000 for the Tobacco Program Center activities and $4,700,000 for the Tobacco Program Field activities.

The increase provides the additional resources needed to support the implementation of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act).

During FY 2011, in order to succeed in meeting regulatory milestones and other specific requirements of the Tobacco Control Act, a major goal of the program will be to continue to build the scientific foundation for public health-focused tobacco product regulation. This will require the Tobacco Program to continue to hire the necessary staff, growing from a level of 194 FTEs in FY 2010 to a level of 370 FTES in FY 2011. This will allow FDA to further develop research and evaluation programs, health promotion campaigns, and compliance activities to enforce the provisions of the Tobacco Control Act.

Major initiatives for FY 2011 include:

- Conducting research and evaluation programs to better understand how the FDA regulations and tobacco control and prevention programs protect the public from the adverse health consequences of tobacco use.
- Implementing a comprehensive framework for a tobacco product research and testing program to support tobacco product standards development, review of tobacco ingredients, identification of potentially harmful constituents, and tobacco product review activities.
- Developing comprehensive education and communications programs designed to reach the public, with special attention paid to as many racial, ethnic, cultural, and social elements of the population as possible. A specific goal to be accomplished during FY 2011 is implementing an outreach program directed toward tobacco product retailers and the general public, especially youth, to assure compliance with the 1996 rule, as reissued during FY 2010, to prevent tobacco sales of cigarettes and smokeless tobacco to children and adolescents younger than 18 years of age.
- Contracting with at least 75 percent of States and Territories to conduct inspections to enforce restricting youth access to cigarettes and smokeless tobacco and to meet the public health goals mandated by the Tobacco Control Act, and collaborating with other law enforcement agencies and tobacco control programs at the federal, state, tribal, and local levels of government.

Protecting the Public Health from the Harmful Effects of Tobacco Use

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Center Activities (Base Amount: $38,225,000)

FY 2011 increase for current law user fees: +$43,700,000; 18 FTE

A major goal in this program area for FY 2011 is to conduct research and evaluation programs to better understand how the FDA regulations and tobacco control and prevention programs protect the public from the adverse health consequences of tobacco use. Major goals for this program include achieving a better understanding of how marketing and advertising of tobacco products influence tobacco use by various sectors of the public; evaluating the early impact of the tobacco regulations issued in 2009 and 2010; and, developing baseline measures to better assess the impact of later provisions in the statute. This may include research on the behavioral effects of industry marketing methods, the impact of governmental and other tobacco-use risk educational programs, and the impact of minors' access to tobacco products, tobacco marketing restrictions, and smokeless warning labels.

Tobacco Product Scientific Standard-Setting and Tobacco Product Review

Center Activities (Base Amount: $64,100,000)

FY 2011 increase for current law user fees: +$81,613,000; 106 FTE

FDA's goals for FY 2011 in this program area include:

- Develop standards for evaluating, and guidelines for submission of, "Pre-Marketing Applications" from manufacturers that propose to market new tobacco products and products that do not claim to be substantially equivalent to an already marketed tobacco product;
- Evaluate the report and recommendations from the Tobacco Product Scientific Advisory Committee on the impact of the use of menthol in cigarettes on public health to develop appropriate product standards;
- Further refine the scientific basis for an initial list of tobacco product constituents (including smoke constituents) that are deemed harmful or potentially harmful and for which testing and reporting to FDA will be required;
- Develop and proposing regulations to set Tobacco Product Standards; and,
- Institute a program to continually monitor products and revise standards, as appropriate, to further protect the public health.

Compliance and Regulatory Activities

Center Activities (Base Amount: $64,118,000)

FY 2011 increase for current law user fees: +$26,405,000; 20 FTE

The Tobacco Control Act requires the issuance of regulations pursuant to certain timetables. In FY 2011, the mandated activities include the issuance of regulations that require color graphics depicting the negative health consequences of smoking to accompany the required warning statements on cigarette packaging.

Field Activities (Base Amount: $4,700,000)

FY 2011 increase for current law user fees: +$1,196,000; 5 FTE

In accordance with the Tobacco Control Act, FDA will contract with the States and Territories to conduct inspections on behalf of FDA to ensure that retailers are complying with requirements of the rule, including provisions requiring that retailers examine photographic identification of persons younger than 27 and refuse sales of cigarettes and smokeless tobacco to persons younger than 18 years of age, as well as other public health provisions to support these goals. Therefore a major FDA goal in FY 2011 is to implement an effective State contracts program to support enforcement of the 1996 rule

by contracting with at least 75 percent of the States and Territories to conduct inspections of retailers.

In addition, FDA will develop other enforcement programs under the authority of the Tobacco Control Act to enable prompt and effective action by ORA and/or States and Territories to remove noncompliant tobacco products from the market and to prevent imported tobacco products in violation of the Act from entering the country. FDA will develop a strategic enforcement plan under the authority of the Tobacco Control Act to enforce the several provisions of the Tobacco Control Act and implement any new regulations as they become effective in order to obtain compliance by regulated industry.

Tobacco Product Public Education and External Communications

Center Activities (Base Amount: $45,380,000)

FY 2011 increase for current law user fees: +$52,026,000; 27 FTE

During FY 2011, FDA will implement a comprehensive educational program regarding the 1996 rule in particular and the hazards of tobacco use more generally. Large and small tobacco product retailers will be among the audiences targeted to enhance enforcement efforts.

Informed by social and behavioral science, FDA also will develop and disseminate public education campaigns to decrease initiation of tobacco product use and increase to cessation in FY 2011. Further, FDA will create and launch a tobacco health literacy program in FY 2011 targeted at various populations, with a special emphasis on educating youth and adolescents across racial, ethnic, cultural, and social demographics.

Also in FY 2011, FDA will continue its Stakeholder Discussion Series that began in FY 2010 to fully explore ideas and options for overarching principles for the implementation of the Tobacco Control Act and the establishment of effective communications mechanisms between and among FDA and various stakeholder groups.