The Family Smoking Prevention and Tobacco Control Act was signed into law June 22, 2009.
FDA Authority Under the Tobacco Control Act

- Grants authority to regulate tobacco products intended for human consumption

- Recognizes FDA as the “primary Federal regulatory authority with respect to the manufacture, marketing, and distribution of tobacco products”

- Gives FDA direct authority over cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco

- Enables FDA to assert jurisdiction over other tobacco products through rulemaking
  - FDA has announced its intent to deem other tobacco products subject to regulation
FDA/CTP Public Health Goals

- Prevent Americans—especially youth—from starting to use tobacco
- Encourage current users to quit
- Decrease the harms of tobacco product use
Specific Authorities

- Tobacco manufacturer registration with FDA
- Listing of products and ingredients
- Reporting levels of harmful and potentially harmful constituents by brand and sub-brand
- Establishing tobacco product standards
- Premarket submissions for new and potentially modified risk tobacco products to protect the public health
- Health warnings on labels and in advertising
- Advertising and promotion restrictions
- Authority to conduct public health education and research to support tobacco product regulation
In general, CTP’s regulatory authorities do not extend to:
- Setting tax rates for tobacco products
- Regulating therapeutic products, such as those marketed to treat tobacco dependence (regulated by other parts of FDA)
- Setting clean indoor air policies
- Regulating tobacco growing
- Requiring the reduction of nicotine yields to zero
- Provision of cessation services
- Banning all cigarettes, smokeless tobacco products, little cigars, other cigars, pipe tobacco, or roll-your-own tobacco products
FDA is using our regulatory authority to:

- Understand the regulated products
- Control product changes that affect public health
- Prohibit false/misleading claims that state/imply reduced risk
- Decrease harms of tobacco products
- Expand the science base for regulatory action and evaluation
- Restrict marketing and distribution to protect public health
- Ensure industry compliance with FDA regulation
- Educate the public about FDA's regulatory actions
Tobacco products cannot be regulated using FDA’s traditional “safe and effective” standard.

The Tobacco Control Act mandates tobacco product regulation using a population health standard that takes into account both users and non-users of tobacco products.
The science of tobacco products, individual risk, and population health informs FDA’s regulatory decisions

- **Product**
  - Chemistry
  - Engineering

- **Tobacco User**
  - Toxicology
  - Clinical studies
  - Behavior, use, and addiction

- **Population**
  - Epidemiology
  - Consumer Perception
  - Statistical analysis
CTP Research Priorities

- Diversity of Tobacco Products
- Reducing Addiction
- Reducing Toxicity and Carcinogenicity
- Adverse Health Consequences
- Communications
- Marketing of Tobacco Products
- Economics and Policies

More information on CTP Research Priorities and Immediate Research Needs can be found at http://prevention.nih.gov/tobacco/research.aspx
To expand the scientific foundation for FDA tobacco product regulation, CTP is funding research through various collaborations:

- NIH
- Centers for Disease Control and Prevention
  - Survey Implementation
  - Division of Laboratory Science
- FDA National Center for Toxicological Research
- Contracts
  - RTI
  - Battelle
Additional Information on Specific Research Initiatives

TRSP

PATH

CTP
http://www.fda.gov/TobaccoProducts/PublicHealthScienceResearch/default.htm

TCORS