FDA’s Action Agenda to Reduce Tobacco Related-Cancer Incidence and Mortality

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To make tobacco-related death and disease part of America’s past, not America’s future, and, by doing so, ensure a healthier life for every family.

FDA’s Vision
Tobacco *Control* Now Includes Tobacco *Product Regulation*

- Prevention
- Treatment Access
- Surveillance
- Education
- Tax/Price Incentives
- Clean Indoor Air Laws
- Tobacco Product Regulation
FDA Authority
Under the Tobacco Control Act

- Grants authority to regulate tobacco products intended for human consumption (products marketed for use in smoking cessation regulated by another FDA Center)
- 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 (cigars, pipe tobacco, hookah, e-cigarettes that do not contain drug claims, etc.). FDA has announced its intent to do that.
Specific Authorities Include:

- Premarket applications for new and modified risk tobacco products
- Testing and reporting levels of harmful and potentially harmful constituents by brand and sub-brand
- Establishing tobacco product standards
- Health warnings on marketed products & ads
- Advertising and promotion restrictions
- Registration and listing of ingredients
- Authority to conduct research to support tobacco product regulation
<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>September 2009</td>
<td>Banned flavored cigarettes making them less appealing to kids</td>
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<tr>
<td>March 2010</td>
<td>Restricted youth access to tobacco products</td>
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<td>June 2010</td>
<td>Banned misleading advertising claims to communicate products are not safer</td>
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<td>June 2010</td>
<td>Established new smokeless tobacco warnings to communicate health risks</td>
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<tr>
<td>June 2011</td>
<td>Issued new cigarette health warnings to highlight product dangers</td>
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<tr>
<td>March 2012</td>
<td>Established list of harmful and potentially harmful constituents</td>
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<tr>
<td>March 2012</td>
<td>Issued draft guidance on submitting a Modified Risk Tobacco Product Application</td>
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Tobacco Control Act -- Limitations

FDA is not authorized to:

• Set nicotine levels to zero
• Ban some classes of tobacco products
• Require prescriptions for tobacco products
• Tax tobacco products
• Regulate medications and products marketed to treat tobacco dependence through the Center for Tobacco Products [Note: FDA already regulates cessation medications and products through CDER]
• Regulate clean indoor air policies
• Regulate tobacco growing
Four Key Elements of FDA’s Framework for Tobacco Product Regulation

1. Developing the science base for regulatory action & evaluation
2. Decreasing population harm from tobacco products
3. Ensuring industry compliance with regulations
4. Public education related to FDA authorities
Developing the Science Base for Regulatory Action & Evaluation

- Population Assessment of Tobacco and Health (PATH) study
  - National, longitudinal study of both users and those at risk of using tobacco products
- Development of more rugged methods for determining harmful and potentially harmful constituents
- Addiction research
- Research into toxicity and carcinogenicity of tobacco products
Decreasing Population Harm from Tobacco Products

• Cigarette flavor ban
  – Cigarettes cannot have characterizing flavors (except menthol).

• Deeming regulation
  – FDA has announced its intent to expand jurisdiction to include all tobacco products.

• Products standards
  – No statutory deadline
  – FDA can issue standards appropriate for the protection of public health including to make regulated products less addictive and/or less harmful.
Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents

- Prohibits sales to people younger than 18
- Prohibits sales of cigarette packs with fewer than 20 cigarettes
- Prohibits distribution of free samples of cigarettes and restricts free samples of smokeless tobacco products
- Prohibits tobacco brand name sponsorship of athletic, musical, or other social events and of teams and entries in those events
- Prohibits the sale or distribution of items, such as hats and tee shirts, that have tobacco brand names, logos, or selling messages
- Prohibits sale of tobacco products in vending machines, self-service displays or other impersonal modes of sale except in very limited circumstances
Ensuring Industry Compliance With Regulations

• Tobacco retailer inspection now in 37 states and DC; expanding to all states & territories
  – As of 5/15/12, over 63,000 inspections of tobacco product retailers conducted, resulting in more than 2,600 warning letters and more than 140 fines

• Manufacturer inspections every two years

• Tobacco Product Manufacturing Practices
  – Regulations will be developed

• Health document submission requirements
Public Education

- Public education campaigns related to statutory authorities and regulatory actions
  - Raise public awareness about FDA regulatory actions
    - Smokeless warnings
    - Graphic health warnings on cigarettes: under litigation
    - List of harmful and potentially harmful constituents
  - Educate youth and young adult audiences about the dangers of tobacco products to prevent initiation and encourage cessation
    - Paid media campaigns
    - Cooperative Agreement Program
New Graphic Health Warnings
Connecting With CTP

- Stay informed of FDA research and other activities:
  - [http://www.fda.gov/TobaccoProducts/ResourcesforYou/ucm176164.htm](http://www.fda.gov/TobaccoProducts/ResourcesforYou/ucm176164.htm)

- Potential Violations of the Act:
  - CTPCompliance@fda.hhs.gov

- Consumer Questions:
  - AskCTP@fda.hhs.gov
  - 1-877-287-1373

- Formal correspondence, and speech and meeting requests:
  - ctpexecsec@fda.hhs.gov

- CTP Ombudsman:
  - les.weinstein@fda.hhs.gov