

# FDA Regulation: What's It All About?



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## About FDA

- America's principal scientific, regulatory, and public health agency that oversees items accounting for 25 cents of every dollar spent by consumers



## About FDA (Cont'd)

- Consists of six Centers:
  - Center for Drug Evaluation and Research (medicines to treat people)
  - Center for Biologics Evaluation and Research (vaccines, blood products)
  - Center for Devices & Radiological Health (pacemakers, Xray machines)
  - Center for Veterinary Medicine (pet food, livestock medicines)
  - Center for Food Safety and Applied Nutrition (food supply)
  - Center for Tobacco Products



## About FDA (Cont'd)

- The Federal Food, Drug and Cosmetic Act (FD&C Act) did not include tobacco products until 2009 – leaving FDA with no legal authority to combat the growing public health impact of its use



**June 22, 2009:**

The Family Smoking  
Prevention and Tobacco  
Control Act was signed  
into law



## FDA's Vision



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 Regulatory Tools

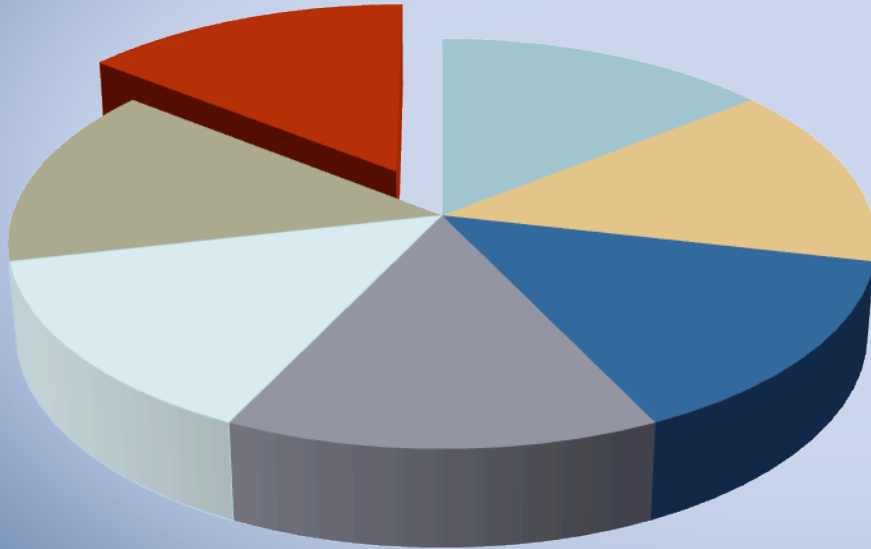
FDA does its job by issuing regulations and guidance to those industries we regulate:

- FDA regulations have the force and effect of law, and create requirements with which the regulated industry must comply
- FDA uses the best available scientific evidence in developing its regulations and guidance
- FDA guidance describes the agency's current thinking on a regulatory issue. Guidance is a generally recommended approach for meeting a legal requirement, but it is *not legally binding* on the public or FDA



# Tobacco Control Now Includes Tobacco Product Regulation

**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 are regulated as drugs)
- 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 make drug claims, etc.). FDA has announced its intent to do so



## Specific Authorities Include:

- 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 applications for new and 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



## Tobacco Control Act – Limitations

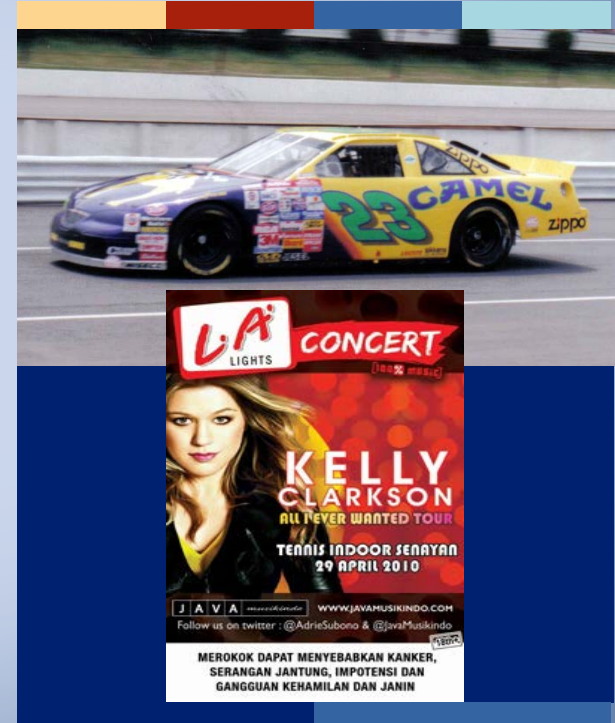
### FDA is not authorized to:

- Set nicotine levels to zero
- Ban certain classes of tobacco products
- Require prescriptions for non-therapeutic tobacco products
- Tax tobacco products
- Regulation of medications and devices to treat tobacco dependence is done by FDA's Center for Drug Evaluation and Research (not the new Center for Tobacco Products)
- Regulate clean indoor air policies
- Regulate tobacco growing

## Reducing Youth Appeal and Access to Tobacco Products



- Prohibiting sales to people younger than 18
- Prohibiting sales of cigarette packs with fewer than 20 cigarettes
- Prohibiting distribution of free samples of cigarettes and restricting free samples of smokeless tobacco products
- Prohibiting tobacco brand name sponsorship of athletic, musical, or other social events and of teams and entries in those events



- Prohibiting the sale or distribution of items, such as hats & t-shirts, that have tobacco brand names, logos, or selling messages
- Prohibiting the sale of tobacco products in vending machines, self-service displays or other impersonal modes of sale except in very limited circumstances
- Prohibiting sale of cigarettes with certain characterizing flavors such as fruit and candy





## Ensuring Compliance with FDA Regulations

- Tobacco retailer inspection now in 37 states and DC; expanding to all states & territories
  - As of July 15, 2012 over 86,000 inspections of tobacco product retailers conducted, resulting in more than 3,500 warning letters and more than 290 fines
  - Inspection to determine compliance with the regulations in effect that apply to tobacco retailers
- Unannounced Tobacco Manufacturer inspections: every 2 years – 49 completed, to date



Advertising claims that mislead consumers to think that certain products are safer





# FDA's Regulatory Response

- FDA now prohibits false claims in marketing of regulated tobacco products (no more use of 'light', 'low', 'mild' )
- FDA will allow reduced risk claims only when scientifically proven and an order is issued by FDA

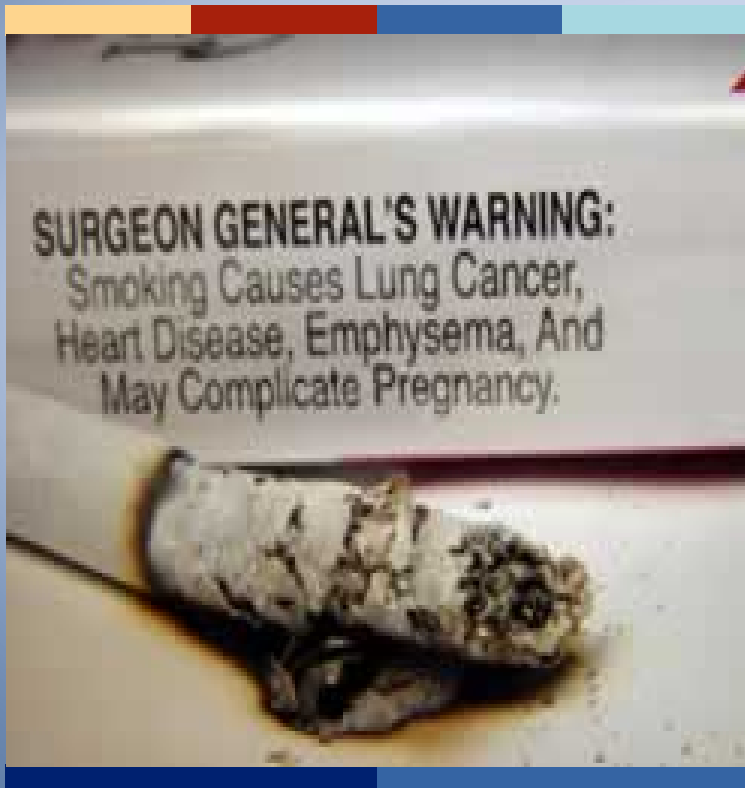


Lack of Awareness of the  
Health Risks of  
Smokeless Tobacco Use

- New requirement that smokeless tobacco packages and advertisements have larger and more visible warnings

Warning must be located on the two principal sides of the package and cover at least 30 percent of each side





Effectively  
Communicating the  
Dangers of Cigarettes

- Nine new graphic health warnings (new text paired with an image) required on all cigarette packages and ads
- Warnings to occupy 50% of front and back panels on packs and at least 20% of ads
- Currently under litigation



FDA will implement broad-based and sustained public education initiatives - including paid media campaigns, that support:

- Support FDA regulation of tobacco products
- Inform the public about FDA regulatory actions
- Expand awareness of the dangers of tobacco use



## Lack of Awareness of Harmful and Potentially Harmful Constituents





## FDA's Regulatory Response

- Established list of 93 harmful and potentially harmful constituents (HPHCs)
- Manufacturers are required to report HPHCs by brand and sub-brand for all regulated tobacco products (initially 20)
- FDA will provide the public with consumer-friendly information about HPHCs in products by brand and sub-brand



# Our Goals for the Future

- Consider product standards:
  - Reduce harms
  - Reduce/eliminate addictiveness
- Continue marketing controls:
  - Limit youth tobacco access
  - Mandate truthful marketing
- Protection of public health:
  - Significant, sustained reduction in youth tobacco use
  - Significant reduction in burden of disease, disability and death from tobacco use





# Expanding Youth Involvement

Youth engagement in tobacco control has always played a fundamental role in the decline of youth tobacco use

Now, youth can make an important contribution to the success of the Tobacco Control Act

- Young people and youth organizations are submitting comments/data and provide input into the regulatory process
- Young people are able to report suspected violations of the law
- Young people are informing FDA of what's happening in their communities related to new products or marketing



# Speaking Out and Being Heard



Judy Hou, a volunteer with the Virginia Foundation for Healthy Youth: the first teen to testify before the FDA's Tobacco Products Scientific Advisory Committee, Rockville, Md.



Youth with U.S. Surgeon General at Youth and Tobacco Town Hall Meeting, Seattle.



CTP meets with Bold Teens, Dorchester, Mass.



## How You Can Help!

- Know the Tobacco Control Act
- Submit potential violations:
  - 1.877.CTP.1373 (option #3)
  - Email: [CTPCompliance@fda.hhs.gov](mailto:CTPCompliance@fda.hhs.gov)
  - Mail correspondence to CTP
  - Electronic tobacco violations reporting web form and mobile apps in development
- Be active in FDA rulemaking by providing comments and data supporting your views



## How You Can Help! (Cont'd)

- Understand and support FDA compliance efforts
- Amplify FDA public education campaigns
- Stay informed and connected by signing up for e-mail updates:  
<http://www.fda.gov/TobaccoProducts/ResourcesforYou/ucm176164.htm> for weekly FDA updates



# Stay Informed and Connected

- Consumer Questions:
  - [AskCTP@fda.hhs.gov](mailto:AskCTP@fda.hhs.gov)
  - 1-877-CTP-1373
- Formal correspondence, and speech and meeting requests:
  - [ctpexecsec@fda.hhs.gov](mailto:ctpexecsec@fda.hhs.gov)
- CTP Ombudsman:
  - [les.weinstein@fda.hhs.gov](mailto:les.weinstein@fda.hhs.gov)



# Center for Tobacco Products

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