

FDA Center for Tobacco Products Update (October 1 – December 22, 2011)

The FDA Center for Tobacco Products (CTP) provides regular updates to inform the public and Congress on its progress in implementing the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). This summary is a highlight of activities and does not include all actions undertaken by CTP during this timeframe.

December 2011

Comment Period Extended for Advance Notice of Proposed Rulemaking on Non-Face-to-Face Sale and Distribution of Tobacco Products

On December 6, 2011, FDA announced that it would be extending the comment period for the Advance Notice of Proposed Rulemaking on non-face-to-face sale and distribution of tobacco products from December 8, 2011 to January 19, 2012. The extension is in response to a request to allow interested parties additional time to comment. In the notice, FDA requested comments, data, research, or other information related to non-face-to-face sale and distribution of tobacco products; the advertising, promotion, and marketing of such products; and the advertising of tobacco products via the Internet, email, direct mail, telephone, smart phones, and other communication technologies that can be directed to specific recipients.

- [Advance Notice of Proposed Rulemaking : Non-Face-to-Face Sale and Distribution of Tobacco Products and Advertising, Promotion, and Marketing of Tobacco Products](#)

Webinar Series for Tobacco Retailers and Small Business Manufacturers

CTP continued its webinar series designed to provide tobacco retailers and small business manufacturers with information to help them comply with the Tobacco Control Act and any new FDA tobacco regulations. One-hour webinars were held in October, November, and December on a variety of topics, including the civil money penalty process, product listing requirements, warning letters for violations of the Tobacco Control Act, cigarettes and smokeless tobacco warning plan requirements, and the September 2011 draft guidance on applications for premarket review of new tobacco products. All webinars in this series are archived on the CTP website.

- [FDA Tobacco Compliance Webinars](#)
- [Archived Tobacco Compliance Training](#)

The Institute of Medicine (IOM) Report: Scientific Standards for Studies on Modified Risk Tobacco Products

On December 14, 2011, the IOM released a report on the design and conduct of studies and surveillance that IOM recommends FDA use to assess modified risk tobacco products. The Tobacco Control Act requires FDA to consult with the IOM on this subject. The report adds to comments and recommendations submitted to FDA on this topic, including information obtained from a public workshop in August 2011 and an associated open public docket. Experts within CTP will take these recommendations into consideration in developing its guidance and/or regulation on the scientific evidence required for the assessment and ongoing review of modified risk tobacco products, which will publish before April 2012.

- [FDA Statement on the Institute of Medicine Report: Scientific Standards for Studies on Modified Risk Tobacco Products](#)

November 2011

Proposed Rule Amending Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco (Brand Name Proposed Rule)

On November 17, 2011, FDA issued a proposed rule that would amend one provision of the reissued 1996 regulation restricting the sale and distribution of cigarettes and smokeless tobacco. The proposed rule would allow manufacturers of cigarettes or smokeless tobacco products with trade or brand names that are also the trade or brand names of non-tobacco products to continue to use these names if the tobacco products were sold in the United States on or before June 22, 2009.

- [Restrictions on the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents](#)

FDA Acts to Protect Children from Illegal Tobacco Sales

On November 10, 2011, FDA announced that it sent warning letters to more than 1,200 retailers as part of the agency's ongoing efforts to reduce tobacco use among kids through the State Enforcement Program. Most of the warning letters included retailers' violations related to selling tobacco products to minors.

- [FDA Acts to Protect Children from Illegal Tobacco Sales](#)
- [Tobacco Retail Warning Letters](#)

Break the Chain of Tobacco Addiction Pledge

FDA launched the Break the Chain of Tobacco Addiction campaign in 2010 to educate retailers about federal regulations designed to protect kids from the dangers of tobacco use. In November 2011, CTP launched an online, interactive Break the Chain of Tobacco Addiction Pledge and encouraged retailers and community members to take the pledge to support responsible tobacco retailing.

- [Take the Pledge to Protect Kids from Tobacco Products](#)

October 2011

Guidance for Small Business Manufacturers on Graphic Health Warnings

CTP posted a small entity compliance guide (SECG) in October 2011 for the June 22, 2011 final rule on graphic health warnings for cigarette packaging and advertisements. The SECG explains the regulation requirements in plain language to help small business manufacturers understand and comply with the regulation.

- [Guidance for Industry: Required Warnings for Cigarette Packages and on Advertisements - Small Entity Compliance Guide.](#)

Tobacco Control Act National Longitudinal Study of Tobacco Users

On October 6, 2011, FDA and the National Institutes of Health (NIH) announced a joint, large-scale, national study to monitor and assess the health and behavioral impacts of the Tobacco Control Act and help FDA determine how to best use its tobacco regulatory authorities. This initiative is the first large-scale NIH/FDA collaboration on tobacco regulatory research since the Tobacco Control Act was signed into law in 2009.

- [FDA and NIH announce joint study on tobacco use and risk perceptions](#)

CTP Infographic

In October 2011, CTP published its first monthly infographic to provide various audiences with accurate, timely content about FDA's tobacco product regulation milestones and other Center accomplishments.

- [Protecting the Public's Health: Infographic](#)