



## EFFECTIVE DATES OF NEW FDA TOBACCO LAW PROVISIONS

[Signed into Law by the President on June 22, 2009]<sup>1</sup>

<b>FDA Provision</b>	<b>In Effect</b>
No direct or indirect claims of reduced risk allowed in any advertising, marketing or labeling of any existing or new cigarettes or smokeless products without prior FDA permission (does not apply to "light," "low," "mild" and similar descriptors).	6/22/09
Federal Cigarette Labeling & Advertising Act preemption of state restrictions on the time, place, and manner of cigarette advertising eliminated.	6/22/09
Prohibition of "light," "low," "mild," and all similar descriptors in all advertising, labeling and marketing of any <u>new</u> cigarettes and smokeless tobacco products or brands.	6/22/09
FDA given authority to restrict or prohibit tobacco product advertising and marketing to promote public health.	6/22/09
FDA given authority to issue product standards to promote public health that could eliminate or reduce certain ingredients or byproducts of tobacco products.	6/22/09
FDA entitled to request industry documents related to any relevant past research, by the industry or in the industry's files relating to tobacco product ingredients, constituents, impacts; actual or potential harm reduction technologies; or marketing.	6/22/09
FDA given authority to access records of any tobacco industry participant in order to investigate and combat illicit trade, smuggling or counterfeiting of tobacco products.	6/22/09
Tobacco product manufacturers and distributors required to notify the government if they have any knowledge that a tobacco product has been distributed without payment of applicable duties or taxes or otherwise diverted into illicit trade.	6/22/09
Illegal to make any express or implied statement or representation in tobacco product labeling or advertising or through the media that would mislead the consumers to believe the tobacco product is approved or endorsed by FDA; that FDA deems the product safe for use; or that the tobacco product is safe or less harmful by virtue of being regulated by FDA or being in compliance with FDA regulatory requirements. <sup>2</sup>	6/22/09
All artificial or natural characterizing flavors other than tobacco or menthol banned from all cigarettes and their component parts.	9/22/09
Beginning of User Fee Collection From Tobacco Industry: FDA will be funded through user fees assessed on tobacco companies. First year collections will begin on or after October 1, 2009.	10/1/09
Companies provide FDA list of ingredients and additives by brand and quantity as well as all new internal documents related to health, toxicological, behavioral or physiologic effects of current or future products, their constituents, ingredients or components	12/19/09
FDA established the Tobacco Product Scientific Advisory Committee. [First meeting was held March 30-31, 2010]	3/22/10
Prohibition of "light," "low," "mild," and all similar descriptors in all advertising, labeling and marketing of <u>existing</u> cigarettes and smokeless products.	6/22/10

<sup>1</sup> While the new law applies to all tobacco products, its specific requirements and restrictions, with only minor exceptions, apply directly only to cigarettes (including RYO tobacco) and smokeless tobacco products, and will apply to other tobacco products only if and when FDA asserts its jurisdiction over them through a rule making process. Some of the new law's provisions are being challenged in court by members of the tobacco industry, which could delay or block the implementation of some of those provisions.

<sup>2</sup> A District Court in Kentucky has ruled that this provision violates the First Amendment (but could be made compliant with relatively minor modifications). FDA is appealing that ruling, but will not be enforcing this provision until the legal issues are resolved. For more about the lawsuit and FDA's suspended enforcement, see: <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm210762.htm>.

<b>FDA Provision</b>	<b>In Effect</b>
Larger, stronger warning labels required on all smokeless tobacco packages and in ads	6/22/10
Final Rule implemented: Sales to persons under 18 made a federal violation for the first time, with FDA financed compliance checks and enforcement.	6/22/10
Final Rule: No vending machine sales or self-service displays of cigarettes or smokeless tobacco except in adult-only facilities	6/22/10
Final Rule: No branded product tie-ins (e.g., T-shirts) with purchases of cigarettes or smokeless tobacco products	6/22/10
Final Rule: No sales of cigarettes in packages of fewer than 20 cigarettes.	6/22/10
Final Rule: No branded sponsorships of athletic or cultural events by cigarette or smokeless manufacturers, distributors or retailers	6/22/10
Final Rule: No free samples of tobacco products, except free samples of smokeless allowed in adult-only facilities in certain restricted situations	6/22/10
Final Rule: All cigarette and smokeless advertising must be black text on white background only – with all audio ads only spoken words with no sound effects or music – except in adult-only facilities and in magazines with less than 15% or fewer than 2 million youth readers <sup>3</sup>	6/22/10
Final Rule: No cigarettes or smokeless brands with same names as brands of other non-tobacco products (unless in effect prior to 1995) <sup>4</sup>	6/22/10
Comments due to FDA pursuant to its Advance Notice of Proposed Rulemaking re the possible development of new restrictions on outdoor cigarette or smokeless tobacco product advertising to replace the provision banning all such ads within 1,000 feet of schools or playgrounds which FDA deleted from the Final Rule that goes into effect June 22, 2010. <sup>5</sup>	7/19/10
FDA shall publish an action plan to enforce restrictions on promotion and advertising of menthol and other cigarettes to youth	By 10/1/10
New Product Review: Any new products introduced or modified after February 15, 2007, are subject to review as either a “new product” or as “substantially equivalent” to existing products. Current products must submit documentation within 30 months. Beginning 30 months after the date of enactment, all such products must first be submitted to FDA for review prior to being placed on the market.	Covers new products introduced after Feb. 15, 2007
FDA Tobacco Product Scientific Advisory Committee must issue report on menthol cigarettes impact on public health, especially among youth, African Americans, Hispanics, and other racial and ethnic minorities (within 12 months after Committee established)	By 3/23/11
FDA must publish regulations requiring larger, graphic warning labels for cigarette ads and that cover top half of front and back of all cigarette packages (effective 15 months later).	By 6/22/11
FDA must issue regulations to prevent the sale of tobacco products to youth via Internet, mail-order or other non-face-to-face sales.	By 10/1/11
FDA Tobacco Product Scientific Advisory Committee must issue report on dissolvable	By 3/23/12

<sup>3</sup> A District Court in Kentucky has ruled that this provision violates the First Amendment (but could be made compliant with relatively minor modifications). FDA is appealing that ruling, but will not be enforcing this provision until the legal issues are resolved. For more information, see the FDA website at: <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm210762.htm>.

<sup>4</sup> FDA has said it will postpone enforcing this provision until related concerns are resolved about its scope. See: <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm210762.htm>.

<sup>5</sup> Section 897.30(b) of the initial Final Rule called for a total ban on any outdoor cigarette or smokeless ads within 1000 feet of schools or playgrounds. But the new law directed FDA to make changes to this provision prior to the publication of the Final Rule if FDA determined that any modifications were appropriate in light of governing case law regarding the First Amendment and permissible restrictions on commercial speech. On March 19, 2010, FDA published the Final Rule without any provision relating to outdoor ads near schools or playgrounds, at all, but issued a related notice and request for comments on that same topic. See <http://www.fda.gov/TobaccoProducts/ProtectingKidsfromTobacco/RegsRestrictingSale/default.htm>.

<b>FDA Provision</b>	<b>In Effect</b>
tobacco products on public health, especially among youth (within 24 months after Committee established)	
To protect youth, FDA must issue regulations to address the promotion and marketing of tobacco products sold over the Internet, by mail-order or other non-face-to-face sales.	By 4/1/12
FDA shall establish a list of harmful and potentially harmful constituents, including smoke constituents – and shall publish the list in a non-misleading format one year later.	By 4/1/12
Companies provide FDA a listing of all constituents identified by FDA as harmful or potentially harmful by brand and quantity	By 4/1/13
FDA must issue report (and every two years thereafter) on progress and impediments encountered in implementing the FDA tobacco legislation, number of new product and modified risk product applications received and their status, and on the number of full-time employees engaged in implementing the legislation.	By 4/1/13
FDA shall establish and require new testing and reporting of tobacco products constituents, ingredients and additives, including smoke constituents	By 10/1/13
FDA shall issue report on public health implications of raising minimum age to purchase tobacco products	By 4/1/15
FDA shall issue regulations regarding recordkeeping and labeling codes or other tobacco product designs or devices to promote the tracking and tracing of tobacco products through the distribution system and to assist in combating illicit trade, smuggling or counterfeiting of tobacco products.	No specified date
FDA must issue regulations requiring adult-only retail establishments that primarily sell tobacco products to comply with any advertising restrictions that apply to retail establishments accessible to youth.	No specified date