

FDA Regulation of Tobacco Products – Effective Dates
(Updated June 24, 2009)

<u>FDA Provision</u>	<u>When In Effect</u>
No direct or indirect claims of reduced risk allowed in any advertising, marketing or labeling of any <u>existing</u> or <u>new</u> cigarettes or smokeless products without prior FDA permission (does not apply to “light,” “low,” “mild” and similar descriptors).	Upon Enactment
Federal Cigarette Labeling Act preemption of state restrictions on the time, place, and manner of cigarette advertising eliminated.	Upon Enactment
Prohibition of “light,” “low,” “mild,” and all similar descriptors in all advertising, labeling and marketing of any <u>new</u> cigarettes and smokeless tobacco.	30 Days after Enactment
All artificial or natural characterizing flavors other than tobacco or menthol banned from all cigarettes and their component parts.	3 Months after Enactment
Prohibition of “light,” “low,” “mild,” and all similar descriptors in all advertising, labeling and marketing of <u>existing</u> cigarettes and smokeless products.	12 Months after Enactment
Larger, stronger warning labels required on all smokeless tobacco packages and in advertisements	12 Months
Larger, graphic cigarette warning labels required that cover top half of front and back of all cigarette packages and in advertisements (FDA must issue regulation no later than two years after enactment, with implementation 15 months later).	No later than 39 Months after Enactment
Publication of FDA Rule on marketing and sales to youth: New restrictions on tobacco marketing to children and federal prohibition on sales to persons younger than 18 with enhanced enforcement	9 Months
FDA Rule implemented: No vending machine sales or self-service displays of cigarettes or smokeless tobacco except in adult-only facilities	12 Months
FDA Rule: No branded product tie-ins, such as T-shirts, with purchases	12 Months
FDA Rule: No free samples of cigarettes; no free samples of smokeless, except in certain restricted situations.	12 Months
FDA Rule: No outdoor advertising within 1000 feet of schools, parks or playgrounds	12 Months
FDA Rule: No sponsorships of athletic or cultural events by tobacco product manufacturers, distributors or retailers	12 Months
FDA Rule: All advertising (including electronic and video) in magazines and at point of sale must be black text on white background only – and all audio advertising must be only spoken words with no sound effects or music – except in adult-only facilities and in magazines with only small youth readerships	12 Months
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 given authority to restrict or prohibit tobacco product marketing to promote public health.	Upon Enactment
FDA given authority to issue product standards to promote public health that could eliminate or reduce certain ingredients or byproducts of tobacco products.	Upon Enactment
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	6 months
Companies provide FDA listing of all constituents identified by FDA as harmful or potentially harmful by brand and quantity	3 years after Enactment
FDA shall establish a list of harmful and potentially harmful constituents, including smoke constituents	30 months after Enactment

<u>FDA Provision</u>	<u>When In Effect</u>
FDA entitled to request industry documents related to any relevant past research by the industry or in the industry's files	Upon Enactment
FDA must issue regulations to prevent the sale of tobacco products to youth via Internet, mail-order or other non-face-to-face sales.	18 months
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 in order to protect youth.	24 months
FDA shall establish and require new testing and reporting of tobacco products constituents, ingredients and additives, including smoke constituents	42 months after Enactment
FUNDING: FDA will be funded through user fees assessed on tobacco companies in the amounts provided for in the law and provided for in annual appropriations acts. In the first year this means collections will begin on or after October 1, 2009. FDA is able to borrow start-up costs prior to that date.	User fees collections begin on or after Oct 1, 2009

THE IMPACT OF THE FDA TOBACCO LEGISLATION ON STATE TOBACCO CONTROL EFFORTS

The FDA tobacco legislation signed into law preserves the rights of states to raise tobacco tax rates, implement and enforce comprehensive smoke-free laws, adequately fund strong state tobacco prevention programs, enhance access to smoking cessation, and take any actions to restrict the sale and distribution of tobacco products. It also expands what states can do to prohibit or restrict tobacco product marketing.

Consistent with the way the FDA regulates other products under its jurisdiction, the passage of the legislation will block states from taking action specifically to regulate the structure of any tobacco product that is subject to FDA regulation – except that states are left free to pass any fire-safe cigarette laws.

The FDA tobacco legislation, once fully implemented, will establish a range of new marketing restrictions and other measures that will apply nationwide to complement state tobacco prevention efforts and will provide assistance to states to implement their laws restricting sales to youth.

Expanded State Authority to Restrict Cigarette Advertising and Promotion. For many years, the Federal Cigarette Labeling and Advertising Act (FCLAA) has preempted states from taking any action, for health purposes, to restrict cigarette advertising or promotion. The passage of the FDA bill changes that by newly allowing states to restrict or regulate the time, place and manner (but not the content) of any cigarette advertising or promotions.

Among other things, states may now for the first time, *to the extent permitted under the First Amendment*, take action to do such things as:

- Supplement the new FDA requirement that all retail ads for cigarettes and smokeless consist only of black text on white background by applying the same restrictions to cigar and other tobacco product ads;
- Restrict or eliminate “power walls” of cigarettes being offered for sale at retail outlets (which will be the only remaining presentation of cigarette brand logos, labels and colors in retail outlets after the FDA black-text-on-white-background restriction goes into effect);
- Limit the number or size of tobacco product ads at retail outlets; or

- Require that all tobacco products or tobacco product ads be kept away from cash registers in order to reduce impulse purchases by smokers trying to quit.

As noted above, the states will still have to comply with First Amendment protections for commercial speech. This requires creating a strong legislative history and a substantial evidentiary record that shows that the restrictions address a form of marketing that is of legitimate government concern and that the regulation will directly advance the substantial government interest of preventing youth tobacco use, reducing adult tobacco use or otherwise protecting and promoting public health. It is also necessary to show that the regulations will leave tobacco companies still reasonably able to communicate truthful information to their legal adult customers; and are reasonably related to the government interests they seek to address.*

No Impact on the Forms of State Tobacco Control Activity that States have Traditionally Exercised. With the passage of the FDA tobacco legislation, state and local governments remain free to pursue those key policies – such as smoke-free laws, restrictions on sales to youth and other sales restrictions, tobacco tax increases, increased tobacco prevention program funding, and enhanced access to tobacco cessation services – that states have used to prevent and reduce tobacco use. More broadly, the FDA legislation also does nothing to restrict states from adopting and enforcing measures to restrict youth or adult access to tobacco products or to do anything else to regulate or restrict the sale, distribution, and possession of tobacco products. The legislation leaves the states free to prohibit the sale of cigarettes or any other tobacco products, either totally, to persons of any age, to change the age of sale or to restrict sales to just at certain specified locations (e.g., by prohibiting sales at pharmacies or other health facilities, or at college campuses or any other locations frequented by youth).

Limits on State Regulation of the Tobacco Products Themselves. As with the laws giving FDA authority to regulate other products, the passage of the FDA tobacco legislation will provide FDA with exclusive authority in such areas as establishing tobacco product standards, prohibiting adulterated or misbranded tobacco products, establishing labeling requirements, implementing and enforcing manufacturing standards, and regulating modified risk tobacco products. These provisions remove state authority in these areas for products for which FDA jurisdiction has been asserted under the Act – in order to provide for consistent national standards. But the bill does expressly allow states to continue to pass and enforce state “fire-safe” cigarette laws; and the states are left free to impose additional reporting requirements (including ingredient disclosures) on tobacco product manufacturers if there is any information FDA was not getting or not sharing that the states consider useful to have.

The authority of the FDA to regulate the product itself is one of the most important provisions of the bill because it gives the agency the authority to do such things as require changes to existing or new products to make them less harmful or less addictive. Because such product regulation is complex and requires considerable oversight and testing expertise and capacity, the states have not regulated the content of tobacco products (beyond “fire-safe” cigarette laws and bans on flavored cigarettes).

* For more information on First Amendment constraints and how they can be overcome, see the Campaign factsheet, *Permissible State Restrictions on Tobacco Product Marketing*, available at <http://tobaccofreekids.org/research/factsheets/pdf/0280.pdf>. That factsheet has not yet been updated to reflect the FDA legislation’s sharp reduction to the scope of FCLA preemption, but its information relating to the First Amendment is up to date. That factsheet will be updated soon, and additional materials will soon be available regarding how states can most effectively use the new authority they now have to regulate and restrict cigarette advertising and promotions.