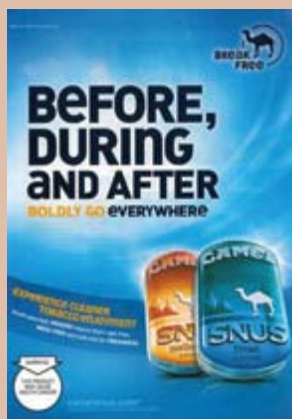




The Family Smoking Prevention and Tobacco Control Act (the “2009 FDA Law”) gives the U.S. Food and Drug Administration authority to regulate products that contain tobacco.¹ The law contains a number of restrictions on tobacco sales and marketing, sets product standards, and requires the tobacco industry to report certain information to the FDA.

Not every provision in the 2009 FDA Law, however, applies to every kind of tobacco product. This fact sheet explains which restrictions in the 2009 FDA Law apply to which tobacco products.²



The newly required warnings on tobacco advertisements are substantially larger now (bottom) than the previous warning in the small white circle (top).

This document is one in a series of FDA Law Notes addressing issues around the 2009 Family Smoking Prevention and Tobacco Control Act. All of the FDA Law Notes are available at www.changelabsolutions.org/tobacco-control.

What Tobacco Products Are Covered by the 2009 FDA Law?

Most portions of the 2009 FDA Law apply to only a few types of tobacco products: specifically, cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco.³ (The chart on the next page lists the restrictions on each of these products.) The law does contain a few restrictions on other tobacco products, like cigars and hookah tobacco—and it permits the FDA to issue regulations on such products in the future.⁴

Other Products

Some products do not fit squarely within the categories of tobacco products for which the FDA has created regulations, including little cigars, e-cigarettes, and flavored cigarette “component parts” such as rolling papers and blunt wraps.

Little Cigars vs. Cigarettes

Little cigars—products that meet the definition of a cigar but are similar in size to a cigarette—are not currently regulated by the FDA. The FDA considers them cigars, and the FDA cannot create restrictions on cigars at this time.

But the 2009 FDA Law’s definition of *cigarette* has caused some people to wonder if it includes little cigars. A cigarette is defined as any product that “because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette.”⁶ Some flavored little cigars (such as clove little cigars) look so similar to clove cigarettes that many people have wondered if these little cigars fit the 2009 FDA Law’s definition of cigarette.

The FDA has clarified that if a product is labeled as a cigar and the agency determines that the product meets the definition of cigarette, a warning letter will be issued to the firm.⁷ This guidance indicates that the FDA is not considering all little cigars to be categorically defined as cigarettes; it is determining on a case-by-case basis whether particular brands of little cigars are “offered” as cigarettes and therefore under the FDA’s jurisdiction.

Flavored Rolling Papers and Blunt Wraps

The 2009 FDA Law bans not only flavored cigarettes, but also flavored cigarette “component parts,” including the tobacco, filter, or paper.⁸ This means that flavored cigarette rolling papers may not be legally sold.⁹ However, flavored component parts of *cigars*, such as blunt wraps, are not illegal to sell because the sale of flavored cigars is not currently prohibited.

E-cigarettes

Electronic cigarettes (“e-cigarettes”) are battery-powered devices that purportedly supply doses of nicotine through an inhaled vapor solution. They are an alternative to smoked tobacco products; no smoke or combustion is involved.

Whether e-cigarettes are covered by the 2009 FDA Law is currently in dispute. The FDA has stated that it does not consider e-cigarettes to be tobacco products.¹⁰ Even e-cigarette manufacturers’ own promotional materials state that the devices do not contain tobacco.¹¹ However, a federal Court in Washington, D.C., ruled in January 2010 that because the nicotine in the cartridge of a certain brand of e-cigarettes was derived from tobacco, the e-cigarettes “contain” tobacco and therefore are regulated by the 2009 FDA Law.¹² This decision is being appealed.¹³ If the higher courts ultimately rule that e-cigarettes are tobacco products, the decision would overrule the FDA’s prior assertions to the contrary.

Products Not Covered by the 2009 FDA Law

To be regulated by the FDA, a product must contain at least some tobacco.⁵ Products that imitate tobacco products but do not contain any tobacco—candy cigarettes, Big League Chew, chocolate cigars, bubble pipes, and other edible and novelty items, for instance—are **not restricted** in any way by the 2009 FDA Law.

Specific restrictions

This chart indicates which tobacco products are currently restricted by the FDA. There may be additional state or local laws in your area covering these topics.¹⁴ This chart does not include every provision of the 2009 FDA Law; it focuses primarily on the restrictions relating to tobacco marketing and sales. The effective date for each restriction is noted in parentheses.

Cigarettes¹⁵
 Cigars/Little Cigars¹⁶
 Hookah tobacco¹⁸

Sales	Cigarettes ¹⁵	Cigars/Little Cigars ¹⁶	Hookah tobacco ¹⁸
No sales of cigarettes or smokeless tobacco to any person under the age of 18. (6/22/2010) ¹⁹	X	X	
Tobacco retailers must verify that a purchaser is 18 years of age or older through a photo identification card including date of birth. Verification is not required for any person over the age of 26. (6/22/2010) ²⁰	X	X	
No breaking apart a package to sell or distribute in a quantity smaller than the smallest package size. (6/22/2010) ²¹	X	X	
No sales of cigarette packages that contain fewer than 20 cigarettes. (6/22/2010) ²²	X		
No vending machines or self-service displays; retailers may only sell in a direct, face-to-face exchange. (6/22/2010) ²³	X	X	
No flavors other than menthol, including in the “component parts” of the product (filter, paper, etc.). (9/22/2009) ²⁴	X		
Advertising, Marketing, and Labeling			
Only black text on a white background in print and video advertising and labeling. Audio advertising is limited to words only.* (6/22/2010) ²⁵	X	X	
No brand name sponsorship of athletic, musical, artistic, other social or cultural events, and no team in any event (corporate sponsorship is permitted).* (6/22/2010) ²⁶	X	X	
Tobacco products can not be marketed in combination with any other product regulated by the FDA.* (6/22/2010) ²⁷	X	X	
No gifts or other items may be provided in exchange for purchasing a tobacco product.* (6/22/2010) ²⁸	X	X	
Non-tobacco items may not bear the brand name, logo, symbol, motto, or recognizable color or pattern of colors identifiable with any tobacco brand.* (6/22/2010) ²⁹	X	X	
Terms such as “light,” “low tar” or “mild” may not be used on tobacco packages, labeling, or advertising. (6/22/2010) ³⁰	X	X	
Tobacco product packaging or advertising may not include any express or implied statement that would mislead consumers into believing that a tobacco product is (1) approved by the FDA, (2) endorsed by the FDA, (3) deemed safe by the FDA, or (4) less harmful due to FDA regulation.* (6/22/2009) ³¹	X	X	
Packages and advertising must bear one of nine specified health warnings, covering 50% of the front and rear panels of the package and at least 20% of the area in an advertisement. Other requirements apply.* (6/22/2011) Color graphic image warnings will be required beginning no later than 9/22/2012. ³²	X		
Packages and advertising must bear one of four specified health warnings, covering 30% each of the two principal display panels of the package and at least 20% of the area in an advertisement. Other requirements apply.* (6/22/2010) ³³		X	
Sampling			
No distribution of free tobacco products (sampling).* (6/22/2010) ³⁴	X		X
Sampling only permitted in a “qualified adult-only facility.” ³⁵ Sampling is prohibited to any sports team or entertainment group, or at any sporting or entertainment event as determined by the Secretary of the Health and Human Services.* (6/22/2010) ³⁶		X	
State and Local Authority			
State and local governments may impose specific bans on the time, place, and manner of cigarette advertising and promotion (within the bounds of the First Amendment) but may not regulate the content of advertising and promotions.* (6/22/2009) ³⁷ (This provision applies only to cigarettes, not to roll-your-own or cigarette tobacco.)	X		
State and local governments may limit tobacco product advertising and promotion, within the bounds of the First Amendment. ³⁸ (Existing provision; not in the 2009 FDA Law)		X	X
State and local governments may enact more stringent regulations on the sale, distribution, possession, use, availability, advertising, promotion, or taxation of tobacco products. State and local governments also may require reporting of information to the state or create fire safety regulations, but may not enact their own restrictions on tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified-risk tobacco products.* (6/22/2009) ³⁹	X	X	X

* Provision challenged in the federal lawsuit *Commonwealth Brands v. U.S.A.*, Case No. 1:09-CV-117-M, 2010 65013 (West. Dist. Ky. Jan. 5, 2010). For updates on the lawsuit, see the FAQs at www.changelabsolutions.org/tobacco-control/ask-question.

For more information on the FDA's actions to implement and enforce the restrictions described above, see www.fda.gov/tobaccoproducts. You can also sign up there for e-mail updates on the 2009 FDA Law. Individuals may report flavored tobacco products that may not be legal under the 2009 FDA Law online at www.accessdata.fda.gov/scripts/email/TobaccoProducts/flavoredCigarettes.cfm.

¹ Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 102, 123 Stat. 1776 (codified as amended in scattered sections of 5 U.S.C., 15 U.S.C., and 21 U.S.C.); 21 U.S.C. § 387a-1 (2009).

² For more information on the 2009 FDA Law, see the booklet, 2012 Tobacco Laws Affecting California, available at www.changelabsolutions.org/tobacco-control/products/tobaccolawsca.

³ 21 U.S.C. § 387a(b) (2010).

⁴ 21 U.S.C. § 387f(d)(1) (2010).

⁵ *Id.*

⁶ 15 U.S.C. § 1332(1)(B) (2010).

⁷ Food and Drug Administration, *Guidance to Industry and FDA Staff: General Questions and Answers on the Ban of Cigarettes that Contain Certain Characterizing Flavors (Edition 2)*, available at www.fda.gov/TobaccoProducts/ProtectingKidsfromTobacco/FlavoredTobacco/ucm183228.htm.

⁸ 21 U.S.C. § 387g(a)(1)(A) (2010).

⁹ Food and Drug Administration, *Guidance to Industry and FDA Staff: General Questions and Answers on the Ban of Cigarettes that Contain Certain Characterizing Flavors (Edition 2)*, available at www.fda.gov/TobaccoProducts/ProtectingKidsfromTobacco/FlavoredTobacco/ucm183228.htm.

¹⁰ Brief for Food and Drug Administration in Opposition to Motion for Preliminary Injunction at 18, 23-25; *Smoking Everywhere, Inc. v. FDA*, 680 F. Supp. 2d 62 (D.D.C. 2010), available at www.fda.gov/downloads/NewsEvents/PublicHealthFocus/UCM173191.pdf.

¹¹ *Id.* at 25.

¹² *Smoking Everywhere, Inc. v. FDA*, 680 F. Supp. 2d 62 (D.D.C. 2010).

¹³ At press time, the decision was binding only on Washington, D.C. The decision of the Court of Appeals would also apply only to the District. However, if the decision is appealed to the Supreme Court, any decision there would apply to the entire country.

¹⁴ For a discussion of California's laws, see "Tobacco Laws Affecting California," available at www.changelabsolutions.org/tobacco-control/products/tobaccolawsca.

¹⁵ Cigarette is defined in the 2009 FDA Law as any roll of tobacco wrapped in paper or in any substance which does not contain tobacco; the definition includes cigarette tobacco (loose tobacco that is intended for use in a cigarette) and roll-your-own tobacco. 21 U.S.C. § 387(3), (4); 15 U.S.C. 1332(1)(A).

¹⁶ Smokeless tobacco is defined in the 2009 FDA Law as any tobacco product that consists of cut, ground, powdered or leaf tobacco and that is intended to be placed in the oral or nasal cavity. 21 U.S.C. § 387(18). This definition includes snuff, chew, snus, and dissolvables.

¹⁷ Cigar is defined as "any roll of tobacco wrapped in leaf tobacco or in any substance containing tobacco (other than any roll of tobacco that is a cigarette)." 27 C.F.R. 40.11 (2010).

¹⁸ Hookahs—sometimes called water pipes, shisha, or nargile—are used to smoke specially-made, often flavored tobacco through a tall metal pipe. See Centers for Disease Control and Prevention, *Smoking and Tobacco Use—Hookahs*, available at www.cdc.gov/tobacco/data_statistics/fact_sheets/tobacco_industry/hookahs/.

¹⁹ 21 C.F.R. § 1140.14(a) (2010).

²⁰ 21 C.F.R. § 1140.14(b) (2010).

²¹ 21 C.F.R. § 1140.14(d) (2010).

²² *Id.*

²³ 21 C.F.R. §§ 1140.14(c), 1140.16(c) (2010).

²⁴ 21 U.S.C. § 387g(a)(1)(A) (2010).

²⁵ 21 C.F.R. § 1140.32 (2010). On May 4, 2010, the FDA stated that it would voluntarily suspend enforcement actions related to this provision in light of the court's decision in the lawsuit challenging the 2009 FDA Law. Guidance for Industry and FDA Staff: Enforcement Policy Concerning Certain Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco, available at www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm210762.htm.

²⁶ 21 C.F.R. § 1140.34(c) (2010).

²⁷ 21 U.S.C. § 321(rr)(4) (2010).

²⁸ 21 C.F.R. § 1140.34(b) (2010).

²⁹ 21 C.F.R. § 1140.34(a) (2010).

³⁰ 21 U.S.C. § 387k (2010). The law bans the manufacture of packages with the prohibited descriptors, but it does not ban the sale of packages manufactured before June 22, 2010.

³¹ 21 U.S.C. § 331(tt) (2010).

³² 15 U.S.C. §§ 1333, 1336 (2010).

³³ 15 U.S.C. §§ 4402, 4404 (2010).

³⁴ 21 U.S.C. § 387a-1(d)(1) (2010); 21 C.F.R. § 1140.16(d)(1) (2010).

³⁵ 21 C.F.R. § 1140.16(d)(2)(iii) (2010). A qualified adult-only facility (QAF) must (1) have a law enforcement officer present to check photo ID and ensure that access is limited only to adults; (2) not sell, serve, or distribute alcohol; (3) not be located adjacent to or immediately across from an area used primarily for youth-oriented marketing, promotional, or other activities; (4) be a temporary structure created for the purpose of distributing free samples of smokeless tobacco; (5) be enclosed by a barrier that prevents people from outside the facility from seeing inside the facility unless they make an unreasonable effort to do so; and (6) not have exterior advertising other than brand names in conjunction with a word to identify the AOF. QAFs are not permitted at any football, basketball, baseball, soccer, or hockey event.

³⁶ 21 C.F.R. § 1140.16(d)(3) (2010).

³⁷ 15 U.S.C. §§ 1334, 1336 (2010).

³⁸ This was not part of the FDA Law, but is included in this chart to make clear that there are no existing restrictions on limiting advertising for tobacco products other than cigarettes.

³⁹ 21 U.S.C. § 387p (2010).

ChangeLab Solutions formerly existed under the name Public Health Law & Policy (PHLP), which included the Technical Assistance Legal Center (TALC). Any references to PHLP or TALC in this publication should now be understood to refer to ChangeLab Solutions.

ChangeLab Solutions is a nonprofit organization that provides legal information on matters relating to public health. The legal information provided in this document does not constitute legal advice or legal representation. For legal advice, readers should consult a lawyer in their state. This material was made possible with funds received from the California Department of Public Health under contract #09-11182.