



Tobacco Laws Affecting California

2010 Supplement

For use with the 2009 edition of TALC's
booklet *Tobacco Laws Affecting California*

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INTRODUCTION

This supplement summarizes the one tobacco-related law that was passed in 2009 following the release of the 2009 version of TALC's booklet *Tobacco Laws Affecting California*. On June 22, 2009, President Obama signed into law the Family Smoking Prevention and Tobacco Control Act (referred to as the "2009 FDA Law"), which authorizes the U.S. Food and Drug Administration (FDA) to regulate tobacco products in order to protect the public health.

The supplement should be used hand in hand with the 2009 version of *Tobacco Laws Affecting California*. It is organized according to the categories in the 2009 booklet. All of the entries in the supplement are part of the new 2009 FDA law. Some of the entries duplicate California state law; in those cases, both the 2009 FDA law and the California state law will apply.

If you have questions about the 2009 FDA Law or would like a copy of the 2009 edition of *Tobacco Laws Affecting California*, please contact us at (510) 302-3380 or www.phlpnet.org/tobaccoquestions. To access the full text of the 2009 FDA Law described in this update, please visit www.govtrack.us/congress/billtext.xpd?bill=h111-1256.

This update is provided for general information only and is not offered or intended as legal advice. Readers should seek the advice of an attorney when confronted with legal issues, and attorneys should perform an independent evaluation of the issues raised in these materials.



TOBACCO SALES

SALES TO MINORS

21 United States Code Section 333, 372, 387a-1
21 Code of Federal Regulations Section 1140.14

SCOPE: Beginning June 22, 2010, it will be unlawful for any tobacco retailer to sell cigarettes or smokeless tobacco to any person under the age of 18.

ENFORCEMENT: The U.S. Department of Health and Human Services (HHS) is authorized to enforce this provision with the help of other federal agencies and state governments.

PENALTY: Civil penalty of up to \$15,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding.

Note: The FDA reissued this rule on March 19, 2010. The rule was originally issued by the FDA in 1996. The U.S. Supreme Court invalidated the 1996 rule because, at the time, Congress had not provided the FDA with the authority to regulate tobacco products. (*FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000).)

ID CHECK REQUIREMENT

21 United States Code Section 333, 372, 387a-1
21 Code of Federal Regulations Section 1140.14

SCOPE: Beginning June 22, 2010, tobacco retailers must verify that a purchaser is 18 years of age or older through a photo identification card containing the individual's date of birth.

EXCEPTION: Verification is not required for any person over the age of 26.

ENFORCEMENT: The U.S. Department of Health and Human Services (HHS) is authorized to enforce this provision with the help of other federal agencies and state governments.

PENALTY: Civil penalty of up to \$15,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding.

Note: The FDA reissued this rule on March 19, 2010. The rule was originally issued by the FDA in 1996. The U.S. Supreme Court invalidated

the 1996 rule because, at the time, Congress had not provided the FDA with the authority to regulate tobacco products. (*FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000).)

SELF-SERVICE SALES

21 United States Code Section 333, 372, 387a-1

21 Code of Federal Regulations Section 1140.14, 1140.16

SCOPE: Beginning June 22, 2010, cigarettes and smokeless tobacco may only be sold via a direct, face-to-face exchange. The use of vending machines and self-service displays will not be permitted.

EXCEPTION: This provision does not apply to tobacco products other than cigarettes or smokeless tobacco. Mail-order sales are permitted, except for mail-order redemption of coupons. Vending machines and self-service displays are permitted in facilities where the retailer ensures that no person under the age of 18 is present or allowed to enter at any time.

ENFORCEMENT: The U.S. Department of Health and Human Services (HHS) is authorized to enforce this provision with the help of other federal agencies and state governments.

PENALTY: Civil penalty of up to \$15,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding.

Note: The FDA reissued this rule on March 19, 2010. The rule was originally issued by the FDA in 1996. The U.S. Supreme Court invalidated the 1996 rule because, at the time, Congress had not provided the FDA with the authority to regulate tobacco products. (*FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000).)

SINGLE ITEMS

21 United States Code Section 333, 372, 387a-1

21 Code of Federal Regulations Section 1140.14

SCOPE: Beginning June 22, 2010, a tobacco retailer may not sell any quantity of cigarettes or smokeless tobacco that is smaller than the smallest package distributed by the manufacturer for individual consumer use.

EXCEPTION: This provision does not apply to tobacco products other than cigarettes and smokeless tobacco.

ENFORCEMENT: The U.S. Department of Health and Human Services (HHS) is authorized to enforce this provision with the help of other federal agencies and state governments.

PENALTY: Civil penalty of up to \$15,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding.

Note: The FDA reissued this rule on March 19, 2010. The rule was originally issued by the FDA in 1996. The U.S. Supreme Court invalidated the 1996 rule because, at the time, Congress had not provided the FDA with the authority to regulate tobacco products. (*FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000).)

MINIMUM PACK SIZE

21 United States Code Section 333, 372, 387a-1

21 Code of Federal Regulations Section 1140.16

SCOPE: Beginning June 22, 2010, cigarettes may not be manufactured, sold, or distributed in packages containing fewer than 20 cigarettes.

EXCEPTION: This provision does not apply to tobacco products other than cigarettes.

ENFORCEMENT: The U.S. Department of Health and Human Services (HHS) is authorized to enforce this provision with the help of other federal agencies and state governments.

PENALTY: Civil penalty of up to \$15,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding.

Note: The FDA reissued this rule on March 19, 2010. The rule was originally issued by the FDA in 1996. The U.S. Supreme Court invalidated the 1996 rule because, at the time, Congress had not provided the FDA with the authority to regulate tobacco products. (*FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000).)



REMOTE SALES

21 United States Code Section 333, 372, 387f

SCOPE: The U.S. Department of Health and Human Services (HHS) must issue regulations regarding the remote sale and distribution of tobacco products, such as via the Internet or mail order, by December 22, 2010. Also, the agency must issue regulations regarding the promotion and marketing of tobacco products sold or distributed remotely by June 22, 2011.

ENFORCEMENT: HHS is authorized to enforce this provision with the help of other federal agencies and state governments.

PENALTY: Civil penalty of up to \$15,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding.

TOBACCO PRODUCT STANDARDS

21 United States Code Section 333, 372, 387g

SCOPE: The U.S. Department of Health and Human Services (HHS) may establish tobacco product standards for the protection of public health. Beginning June 22, 2011, tobacco manufacturers can no longer use tobacco that contains an unsafe level of pesticide chemical residue, as determined by federal law.

ENFORCEMENT: HHS is authorized to enforce this provision with the help of other federal agencies and state governments.

PENALTY: Civil penalty for intentionally purporting to meet tobacco product standards of up to \$250,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding. If violations continue after HHS provides written notice, the violator is subject to a penalty of \$250,000 for the first 30-day period, which doubles every 30 days thereafter that the violation continues, up to \$1 million in any 30-day period or \$10 million for all such violations ruled on in a single proceeding.

PRE-MARKET REVIEW OF NEW TOBACCO PRODUCTS

21 United States Code Section 333, 372, 387j

SCOPE: Tobacco products or modified tobacco products not commercially marketed in the United States as of February 15, 2007, must be approved by the FDA prior to commercial release. Applications for new products shall be made available to the public. Approval may be withdrawn as information changes and new findings are made.

EXCEPTION: This provision does not apply to:

1. New products that are substantially equivalent to a tobacco product commercially marketed in the United States as of February 15, 2007.
2. A tobacco product first introduced into the commercial market after February 15, 2007, and before March 22, 2011, if the manufacturer has submitted a report during that period claiming that the product is substantially equivalent to a tobacco product commercially marketed as of February 15, 2007, or is a minor modification to such a product.
3. Smoking cessation products that have been approved as a drug or device by the FDA.

ENFORCEMENT: The U.S. Department of Health and Human Services (HHS) is authorized to enforce this provision with the help of other federal agencies and state governments.

PENALTY: Civil penalty of up to \$250,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding. If violations continue after the HHS provides written notice, the violator is subject to a penalty of \$250,000 for the first 30-day period, which doubles every 30 days thereafter that the violation continues, up to \$1 million in any 30-day period or \$10 million for all such violations ruled on in a single proceeding.

MISBRANDED TOBACCO PRODUCTS

21 United States Code Section 333, 372, 387c

SCOPE: A tobacco product is deemed to be misbranded if the package label does not contain any of the following:

1. The name and address of the manufacturer, packer, or distributor
2. An accurate net quantity statement
3. The percentage of tobacco that is foreign versus domestic
4. The statement “sale only allowed in the United States” (as of December 22, 2011)

A tobacco product is also misbranded if its labeling is false or misleading. The U.S. Department of Health and Human Services (HHS) may issue regulations requiring prior approval of statements made on the label of a tobacco product.

EXCEPTION: Small packages may be exempt, pending regulations issued by HHS.

ENFORCEMENT: HHS is authorized to enforce this provision with the help of other federal agencies and state governments.

PENALTY: Civil penalty of up to \$15,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding.

Note: At the time of this publication, a number of tobacco companies had challenged this provision in federal court in Western Kentucky. (*Commonwealth Brands v. United States*, No. 1:09-CV-117-M, 2010 WL 65013 (W.D.Ky. Jan. 5, 2010).)

MODIFIED RISK TOBACCO PRODUCTS

21 United States Code Section 333, 372, 387k

SCOPE: No person may introduce a “modified risk” tobacco product into interstate commerce or commercially market such a product without approval from the U.S. Department of Health and Human Services (HHS). Approval is limited to a five-year term but may be renewed. The agency shall approve modified risk products only after determining that the product, as it is actually used by consumers, (1) significantly reduces harm and the risk of tobacco-related disease to individual tobacco users, and (2) benefits the health of the population as a whole.

Approval is conditioned on the applicant’s agreement to conduct postmarket surveillance and studies and to submit the results to HHS annually so that the agency may determine the impact of such marketing on consumer perception, behavior, and health. HHS may also impose additional marketing and label restrictions. Approval may be withdrawn if requirements are not met.

Descriptors similar to and including “light,” “low,” and “mild” are prohibited in all advertising, labeling, and marketing of new cigarettes and smokeless tobacco products, which will also apply to existing cigarettes and smokeless tobacco products beginning June 22, 2010.



EXCEPTION: In some cases a modified risk tobacco product can be introduced into interstate commerce and yet may not be commercially marketed.

ENFORCEMENT: HHS is authorized to enforce this provision with the help of other federal agencies and state governments.

PENALTY: Civil penalty for intentionally purporting to meet tobacco product standards of up to \$250,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding. If violations continue after the agency provides written notice, the violator is subject to a penalty of \$250,000 for the first 30-day period, which doubles every 30 days thereafter that the violation continues, up to \$1 million in any 30-day period or \$10 million for all such violations ruled on in a single proceeding.

Note: At the time of this publication, a number of tobacco companies had challenged this provision in federal court in Western Kentucky. (*Commonwealth Brands v. United States*, No. 1:09-CV-117-M, 2010 WL 65013 (W.D.Ky. Jan. 5, 2010).)

BAN ON FLAVORED CIGARETTES OR CIGARETTE COMPONENTS

21 United States Code Section 333, 372, 387g

SCOPE: As of September 22, 2009, cigarettes and their component parts (including the tobacco, filter, or paper) must not contain any flavoring.

EXCEPTION: Tobacco flavor and menthol are excluded from this provision.

ENFORCEMENT: The U.S. Department of Health and Human Services (HHS) is authorized to enforce this provision with the help of other federal agencies and state governments.

PENALTY: Civil penalty of up to \$15,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding.

ORIGIN LABELING

21 United States Code Section 333, 372, 387t

SCOPE: Tobacco products manufactured on or later than June 22, 2010, must bear the statement “sale only allowed in the United States” on all labels, packaging, and shipping containers. All products, regardless of manufacture date, must comply with this requirement by July 22, 2010.



Cigarette manufacturers must comply with this requirement beginning 15 months after the U.S. Department of Health and Human Services (HHS) issues regulations about cigarette labels and advertising.

ENFORCEMENT: HHS is authorized to enforce this provision with the help of other federal agencies and state governments.

PENALTY: Civil penalty of up to \$15,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding.

Note: At the time of this publication a number of tobacco companies had challenged this provision in federal court in Western Kentucky. (*Commonwealth Brands v. United States*, No. 1:09-CV-117-M, 2010 WL 65013 (W.D.Ky. Jan. 5, 2010).)

TAXATION, LICENSING, AND REPORTING

RECORDKEEPING

21 United States Code Section 333, 372, 387t

SCOPE: The U.S. Department of Health and Human Services (HHS) must issue regulations regarding how any person who manufactures, processes, transports, distributes, receives, packages, holds, exports, or imports tobacco products should establish and maintain records. Some records must be furnished for inspection upon request by the government to aid an investigation about illicit trade, smuggling, or a counterfeit product.

EXCEPTION: Retailers do not have to maintain records for individual purchasers who purchase tobacco products for personal consumption. HHS must have the express written consent of an Indian tribe before inspecting records located on Indian country.

ENFORCEMENT: HHS is authorized to enforce this provision with the help of other federal agencies and state governments. The HHS Secretary may also consult with the U.S. Attorney General and the Secretary of the Treasury. Manufacturers and distributors of a tobacco product must notify the Attorney General and the Secretary of the Treasury if they have knowledge of illegal transactions.

PENALTY: Civil penalty of up to \$15,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding.

REGISTRATION OF TOBACCO ESTABLISHMENTS

21 United States Code Section 333, 372, 387e

SCOPE: Owners and operators engaged in the manufacture, preparation, compounding, or processing of a tobacco product sold or distributed must register their establishments, both foreign and domestic, with the U.S. Department of Health and Human Services (HHS). Registration information shall be made available to the public.

ENFORCEMENT: HHS is authorized to enforce this provision with the help of other federal agencies and state governments.

PENALTY: Civil penalty of up to \$15,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding.



USER FEES

21 United States Code Section 333, 372, 387s

SCOPE: Tobacco manufacturers and importers must pay a quarterly fee that will be earmarked for tobacco regulation activities.

ENFORCEMENT: The U.S. Department of Health and Human Services (HHS) is authorized to enforce this provision with the help of other federal agencies and state governments.

PENALTY: Civil penalty of up to \$15,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding.

ADVERTISING

BAN ON MISLEADING CONSUMERS ABOUT FDA ENDORSEMENTS

21 United States Code Section 331, 333, 372

SCOPE: It is illegal to make any express or implied statement to consumers in tobacco product labeling or through the media or advertising 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
4. Less harmful due to FDA regulation

ENFORCEMENT: The U.S. Department of Health and Human Services (HHS) is authorized to enforce this provision with the help of other federal agencies and state governments.

PENALTY: Civil penalty of up to \$15,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding.

Note: At the time of this publication, a number of tobacco companies had challenged this provision in federal court in Western Kentucky. (*Commonwealth Brands v. United States*, No. 1:09-CV-117-M, 2010 WL 65013 (W.D.Ky. Jan. 5, 2010).)

CONTENT DISCLOSURES TO THE PUBLIC

21 United States Code Section 387d, 387n

15 United States Code Section 1333, 1336, 1338, 1339

SCOPE: The U.S. Department of Health and Human Services (HHS) will determine whether tar and nicotine yields of cigarette and tobacco products must be disclosed on all product packages and advertisements. If the HHS decides that the levels of any other cigarette or tobacco constituents should be disclosed to benefit the public health, the disclosure must be prescribed through a product package or advertisement insert, or by another approved means. HHS will establish a list of harmful and potentially harmful tobacco product constituents by June 22, 2011, which will be shared with the public by June 22, 2012 and maintained by HHS. This list will be republished annually thereafter.

EXCEPTION: Mandatory disclosures of yields of cigarette or tobacco constituents, other than tar or nicotine, cannot appear directly on the face of any cigarette package or advertisement.

ENFORCEMENT: The U.S. Attorney General is authorized to enforce this provision, acting through several U.S. attorneys. A violation is also considered an unfair or deceptive act or practice and subject to enforcement under the Federal Trade Commission Act.

PENALTY: A violation is considered a misdemeanor, and a conviction will subject the violator to a fine of \$10,000 or less.

PERMISSIBLE FORMS OF LABELING AND ADVERTISING

21 United States Code Section 333, 372, 387a-1

21 Code of Federal Regulations Section 1140.30

SCOPE: Beginning June 22, 2010, a manufacturer, distributor, or retailer must notify the FDA 30 days in advance if it seeks to advertise cigarettes or smokeless tobacco in a medium other than in periodicals or other publications; on billboards, posters, and placards; or in promotional material (e.g., direct mail or point-of-sale material, including audio or video presented at the point of sale). The notice to the FDA must discuss the extent to which the advertising or labeling may be seen by people under the age of 18.

EXCEPTION: This provision does not apply to tobacco products other than cigarettes or smokeless tobacco products.

ENFORCEMENT: The U.S. Department of Health and Human Services (HHS) is authorized to enforce this provision with the help of other federal agencies and state governments. A violation is also considered an unfair or deceptive act or practice and subject to enforcement under the Federal Trade Commission Act.

PENALTY: Civil penalty of up to \$15,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding.

Note: The FDA reissued this rule on March 19, 2010. The rule was originally issued by the FDA in 1996. The U.S. Supreme Court invalidated the 1996 rule because, at the time, Congress had not provided the FDA with the authority to regulate tobacco products. (*FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000).)

OUTDOOR ADVERTISING

21 United States Code Section 333, 372, 387a-1

21 Code of Federal Regulations Section 1140

SCOPE: By June 22, 2010, the FDA must issue a rule regulating outdoor advertising for cigarettes or smokeless tobacco. The FDA should consider any necessary modifications to its proposed 1996 rule prohibiting advertising (i.e., billboards, posters, placards) within 1,000 feet of any public playground or playground areas on public property (e.g., swings, seesaws, baseball diamonds, basketball courts, public schools).

EXCEPTION: This provision does not apply to tobacco products other than cigarettes or smokeless tobacco products.

ENFORCEMENT: The U.S. Department of Health and Human Services (HHS) is authorized to enforce this provision with the help of other federal agencies and state governments. A violation is also considered an unfair or deceptive act or practice and subject to enforcement under the Federal Trade Commission Act.

PENALTY: Civil penalty of up to \$15,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding.

Note: On March 19, 2010, the FDA issued an advance notice of proposed rulemaking seeking comments from the public on how the original 1996 rule should be modified in light of the U.S. Supreme Court decision in *Lorillard Tobacco Co. v. Reilly* (533 U.S. 525 (2001)). The 1996 FDA rule was invalidated by the U.S. Supreme Court because, at the time, Congress had not provided the FDA with the authority to regulate tobacco products. (*FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000).)

At the time of this publication, a number of tobacco companies had challenged this provision in federal court in Western Kentucky. (*Commonwealth Brands v. United States*, No. 1:09-CV-117-M, 2010 WL 65013 (W.D.Ky. Jan. 5, 2010).)



TOMBSTONE ADVERTISING

21 United States Code Section 333, 372, 387a-1

21 Code of Federal Regulations Section 1140.32

SCOPE: Beginning June 22, 2010, all cigarette or smokeless tobacco labeling and advertising, including video formats, must use only black text on a white background. Audio formats, including audio combined with video, must only contain words. Music or sound effects are not permitted.

EXCEPTION: This provision does not apply to advertising in facilities where persons under the age of 18 are not permitted to enter as long as the advertising is affixed to a wall or fixture and not visible from outside the facility. This provision also does not apply to advertising in a newspaper, magazine, periodical or other publication proven to be an adult publication (i.e., 15 percent or less of the total readership is under the age of 18, and fewer than 2 million people under the age of 18 read the publication).

ENFORCEMENT: The U.S. Department of Health and Human Services (HHS) is authorized to enforce this provision with the help of other federal agencies and state governments. A violation is also considered an unfair or deceptive act or practice and subject to enforcement under the Federal Trade Commission Act.

PENALTY: Civil penalty of up to \$15,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding.

Note: The FDA reissued this rule on March 19, 2010. The rule was originally issued by the FDA in 1996. The U.S. Supreme Court invalidated the 1996 rule because, at the time, Congress had not provided the FDA with the authority to regulate tobacco products. (*FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000).)

At the time of this publication, a number of tobacco companies had challenged this provision in federal court in Western Kentucky. (*Commonwealth Brands v. United States*, No. 1:09-CV-117-M, 2010 WL 65013 (W.D.Ky. Jan. 5, 2010).)

STATE AND LOCAL REGULATION OF CIGARETTE ADVERTISING AND PROMOTION

15 United States Code Section 1334, 1336, 1338, 1339

SCOPE: State and local governments may impose specific bans on the time, place, and manner of cigarette advertising and promotion, even if such bans are based on smoking and health.

EXCEPTION: State and local governments may not regulate the content of advertising and promotions.

ENFORCEMENT: The U.S. Attorney General is authorized to enforce this provision, acting through several U.S. attorneys.

PENALTY: A violation is considered a misdemeanor, and a conviction will subject the violator to a fine of \$10,000 or less.

Note: At the time of this publication, a number of tobacco companies had challenged this provision in federal court in Western Kentucky. (*Commonwealth Brands v. United States*, No. 1:09-CV-117-M, 2010 WL 65013 (W.D.Ky. Jan. 5, 2010).)

EQUAL TREATMENT OF RETAIL OUTLETS

21 United States Code Section 333, 372, 387m

SCOPE: The U.S. Department of Health and Human Services (HHS) will issue rules requiring retail establishments whose primary business is the sale of tobacco products to comply with all advertising restrictions that apply to retail establishments accessible to people under 18 years of age.

ENFORCEMENT: HHS is authorized to enforce this provision with the help of other federal agencies and state governments.

PENALTY: Civil penalty of up to \$15,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding.



SPONSORSHIP, BRANDING, AND PRODUCT PLACEMENT

SPONSORSHIP

21 United States Code Section 333, 372, 387a-1

21 Code of Federal Regulations Section 1140.34

SCOPE: Beginning June 22, 2010, manufacturers, distributors, or retailers may not directly or indirectly sponsor any athletic, social, or cultural event, or any entry or team in any event, in the brand name or anything identifiable with any brand of cigarettes or smokeless tobacco.

EXCEPTION: This provision does not apply to tobacco products other than cigarettes or smokeless tobacco. Also, manufacturers, distributors, or retailers are allowed to sponsor events in the name of the corporation that manufactures the tobacco product. However, both the corporate name and the corporation must have been registered and in use in the United States prior to January 1, 1995, and must not include anything identifiable with any brand of cigarettes or smokeless tobacco.

ENFORCEMENT: The U.S. Department of Health and Human Services (HHS) is authorized to enforce this provision with the help of other federal agencies and state governments.

PENALTY: Civil penalty of up to \$15,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding.

Note: The FDA reissued this rule on March 19, 2010. The rule was originally issued by the FDA in 1996. The U.S. Supreme Court invalidated the 1996 rule because, at the time, Congress had not provided the FDA with the authority to regulate tobacco products. (*FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000).)

At the time of this publication, a number of tobacco companies had challenged this provision in federal court in Western Kentucky. (*Commonwealth Brands v. United States*, No. 1:09-CV-117-M, 2010 WL 65013 (W.D.Ky. Jan. 5, 2010).)

BRAND NAME LIMITATIONS

21 United States Code Section 333, 372, 387a-1

21 Code of Federal Regulations Section 1140.16

SCOPE: Beginning June 22, 2010, brands of cigarettes or smokeless tobacco may not include a trade or brand name of a non-tobacco product.

EXCEPTION: This provision does not apply to a tobacco product whose trade or brand name was both a tobacco product and a non-tobacco product that were sold in the United States on January 1, 1995.

ENFORCEMENT: The U.S. Department of Health and Human Services (HHS) is authorized to enforce this provision with the help of other federal agencies and state governments.

PENALTY: Civil penalty of up to \$15,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding.

Note: The FDA reissued this rule on March 19, 2010. The rule was originally issued by the FDA in 1996. The U.S. Supreme Court invalidated the 1996 rule because, at the time, Congress had not provided the FDA with the authority to regulate tobacco products. (*FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000).)

SAMPLES, COUPONS, AND PROMOTIONAL OFFERS

21 United States Code Section 333, 372, 387a-1

21 Code of Federal Regulations Section 1140.16

SCOPE: Beginning June 22, 2010, manufacturers, distributors, and retailers may not distribute (or cause to be distributed) free samples of cigarettes, smokeless tobacco, or other tobacco products.

EXCEPTION: This prohibition does not apply to the distribution of free samples of smokeless tobacco in a qualified adult-only facility (QAF), but an adult consumer may only leave with one package (15 grams) of smokeless tobacco. A 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
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.

ENFORCEMENT: The U.S. Department of Health and Human Services (HHS) is authorized to enforce this provision with the help of other federal agencies and state governments.

PENALTY: Civil penalty of up to \$15,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding.

Note: This provision does not affect the authority of a state or local government to prohibit or otherwise restrict the distribution of free samples of smokeless tobacco.

The FDA reissued this rule on March 19, 2010. The rule was originally issued by the FDA in 1996. The U.S. Supreme Court invalidated the 1996 rule because, at the time, Congress had not provided the FDA with the authority to regulate tobacco products. (*FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000).)

At the time of this publication, a number of tobacco companies had challenged this provision in federal court in Western Kentucky. (*Commonwealth Brands v. United States*, No. 1:09-CV-117-M, 2010 WL 65013 (W.D.Ky. Jan. 5, 2010).)

PROOF-OF-PURCHASE GIFTS

21 United States Code Section 333, 372, 387a-1

21 Code of Federal Regulations Section 1140.34

SCOPE: Beginning June 22, 2010, manufacturers, distributors, or retailers may not directly or indirectly offer gifts or items in exchange for the purchase of a tobacco product, including coupons or other proofs of purchase.

EXCEPTION: This provision does not prohibit cigarettes or smokeless tobacco offered in exchange for the purchase of cigarettes or smokeless tobacco.

ENFORCEMENT: The U.S. Department of Health and Human Services (HHS) is authorized to enforce this provision with the help of other federal agencies and state governments.

PENALTY: Civil penalty of up to \$15,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding.

Note: The FDA reissued this rule on March 19, 2010. The rule was originally issued by the FDA in 1996. The U.S. Supreme Court invalidated the 1996 rule because, at the time, Congress had not provided the FDA with the authority to regulate tobacco products. (*FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000).)

At the time of this publication, a number of tobacco companies had challenged this provision in federal court in Western Kentucky. (*Commonwealth Brands v. United States*, No. 1:09-CV-117-M, 2010 WL 65013 (W.D.Ky. Jan. 5, 2010).)

SALE AND DISTRIBUTION OF NON-TOBACCO ITEMS OR SERVICES

21 United States Code Section 333, 372, 387a-1

21 Code of Federal Regulations Section 1140.34

SCOPE: Beginning June 22, 2010, manufacturers and distributors of imported cigarettes or smokeless tobacco may not directly or indirectly market, license, distribute, or sell any item or service bearing anything identifiable with any brand of cigarettes or smokeless tobacco, such as the brand name, logo, symbol, motto, or recognizable color or pattern of colors.

EXCEPTION: This provision does not apply to manufacturers of domestic cigarettes or tobacco products other than cigarettes or smokeless tobacco.

ENFORCEMENT: The U.S. Department of Health and Human Services (HHS) is authorized to enforce this provision with the help of other federal agencies and state governments.

PENALTY: Civil penalty of up to \$15,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding.

Note: The FDA reissued this rule on March 19, 2010. The rule was originally issued by the FDA in 1996. The U.S. Supreme Court invalidated the 1996 rule because, at the time, Congress had not provided the FDA with the authority to regulate tobacco products. (*FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000).)



At the time of this publication, a number of tobacco companies had challenged this provision in federal court in Western Kentucky: *Commonwealth Brands v. United States*, No. 1:09-CV-117-M, 2010 WL 65013 (W.D.Ky. Jan. 5, 2010).)

JOINT MARKETING

21 United States Code Section 321, 333, 372

SCOPE: A tobacco product may not be marketed with any other product regulated by the FDA, including a drug, food, cosmetic, medical device, or dietary supplement.

ENFORCEMENT: The U.S. Department of Health and Human Services (HHS) is authorized to enforce this provision with the help of other federal agencies and state governments.

PENALTY: Civil penalty of up to \$15,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding.

Note: At the time of this publication, a number of tobacco companies had challenged this provision in federal court in Western Kentucky. (*Commonwealth Brands v. United States*, No. 1:09-CV-117-M, 2010 WL 65013 (W.D.Ky. Jan. 5, 2010).)

WARNING LABELS

CIGARETTE LABEL AND ADVERTISING WARNINGS

21 United States Code Section 387n

15 United States Code Section 1333, 1336, 1338, 1339

SCOPE: All cigarette packages made, sold, or distributed within the United States, and all related advertising and marketing, must bear one of nine specified warnings regarding associated health risks. No later than June 22, 2011, the U.S. Department of Health and Human Services (HHS) must issue regulations (effective 15 months later) requiring color graphics depicting the negative consequences of smoking. The warning labels must adhere to placement and typography restrictions. (For example, the warnings must cover 50 percent of the top front and rear panels of cigarette packages, and must cover at least 20 percent of a newspaper, magazine, or poster ad and be in the predominant language of the publication.) The HHS can make changes to the warning label requirements upon a finding that such a change would promote greater public understanding of the risks associated with the use of smokeless tobacco products.

EXCEPTION: This provision does not apply to tobacco products other than cigarettes or to foreign distribution of cigarettes.

ENFORCEMENT: The U.S. Attorney General is authorized to enforce this provision, acting through several U.S. attorneys. A violation is also considered an unfair or deceptive act or practice and subject to enforcement under the Federal Trade Commission Act.

PENALTY: A violation is considered a misdemeanor, and a conviction will subject the violator to a fine of \$10,000 or less.

Note: At the time of this publication, a number of tobacco companies had challenged this provision in federal court in Western Kentucky. (*Commonwealth Brands v. United States*, No. 1:09-CV-117-M, 2010 WL 65013 (W.D.Ky. Jan. 5, 2010).)

SMOKELESS TOBACCO LABEL AND ADVERTISING WARNINGS

21 United States Code Section 387n

15 United States Code Section 4402, 4404, 4405

SCOPE: Beginning June 22, 2010, all smokeless tobacco product packages made, sold, or distributed within the United States must bear one of four specified warnings regarding associated health risks. The warning labels must adhere to placement and typography restrictions. (For example, the warning labels must cover 30 percent of each of the two principal display panels of the product. For press and poster ads, the warning labels must cover at least 20 percent of the ad. Warning labels in a newspaper, magazine or poster ad must be in the predominant language of the publication.) The U.S. Department of Health and Human Services (HHS) can make changes to the warning label requirements upon a finding that such a change would promote greater public understanding of the risks associated with the use of smokeless tobacco products.

EXCEPTION: This provision does not apply to tobacco products other than smokeless tobacco or to foreign distribution of smokeless tobacco.

ENFORCEMENT: The U.S. Attorney General is authorized to enforce this provision, acting through several U.S. attorneys. A violation is also considered an unfair or deceptive act or practice and subject to enforcement under the Federal Trade Commission Act.

PENALTY: A violation is considered a misdemeanor, and a conviction will subject the violator to a fine of \$10,000 or less.

Note: At the time of this publication, a number of tobacco companies had challenged this provision in federal court in Western Kentucky. (*Commonwealth Brands v. United States*, No. 1:09-CV-117-M, 2010 WL 65013 (W.D.Ky. Jan. 5, 2010).)

MISCELLANEOUS

REQUIRED DISCLOSURES TO THE FDA

21 United States Code Section 333, 372, 387d, 387i, 387o
15 United States Code Section 1333

SCOPE: Tobacco manufacturers and importers or their agents must provide the FDA with:

1. A list of the ingredients used in each product (by April 30, 2010)
2. A description of content, delivery, and form of nicotine
3. A list of smoke constituents that are harmful or potentially harmful to health and reports of required testing (the U.S. Department of Health and Human Services (HHS) must issue regulations by June 22, 2012 regarding testing and reporting of tobacco product constituents, ingredients, and additives)
4. All documents related to health, toxicological, behavioral, or physiological effects (by April 30, 2010)

At the request of HHS, tobacco manufacturers and importers must furnish any or all documents relating to particular research activities. In addition, tobacco product manufacturers or importers of tobacco products must establish and maintain records and provide reports and information to HHS upon request to assure that a tobacco product is not adulterated or misbranded, and to otherwise protect public health.

EXCEPTION: Small tobacco product manufacturers shall be exempt from testing and reporting requirements regarding tobacco product constituents, ingredients, and additives either two years after final regulations are issued or when a compliance date is set by HHS for all other tobacco product manufacturers, whichever is later.

ENFORCEMENT: HHS is authorized to enforce this provision with the help of other federal agencies and state governments.

PENALTY: Civil penalty of up to \$15,000 for each violation and up to \$1 million for multiple violations ruled on in a single proceeding.



PRESERVATION OF STATE AND LOCAL AUTHORITY

21 United States Code Section 372, 387p

SCOPE: State and local governments are not preempted from enacting more stringent restrictions related to the sale, distribution, possession, use, availability, or advertising and promotion of tobacco products. State and local governments also may regulate the reporting of information to the state, measures relating to fire safety standards of tobacco products, and taxation of tobacco products.

EXCEPTION: State and local governments cannot enact restrictions that differ in any way from the provisions in the 2009 FDA Law regarding tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products.

ENFORCEMENT: Not applicable

PENALTY: Not applicable

Note: At the time of this publication, a number of tobacco companies had challenged this provision in federal court in Western Kentucky. (*Commonwealth Brands v. United States*, No. 1:09-CV-117-M, 2010 WL 65013 (W.D.Ky. Jan. 5, 2010).)

ADDITIONAL REGULATIONS

21 United States Code Section 372, 387f

SCOPE: The U.S. Department of Health and Human Services (HHS) may issue additional regulations restricting the sale and distribution of tobacco products, including restrictions on advertising and promotion. Regulations must be appropriate for the protection of the public health, which should be determined with respect to the risks and benefits to the population as a whole, taking into account whether individuals will likely either stop or start using tobacco products.

EXCEPTION: Restrictions on the advertising and promotion of a tobacco product must be consistent with the First Amendment to the U.S. Constitution. Regulations may not limit the sale or distribution of a tobacco product to prescription by licensed medical professionals; prohibit the sale of a tobacco product in face-to-face transactions by a specific category of retail outlets; or raise the minimum age for the sale of tobacco products above the age of 18.

ENFORCEMENT: HHS is authorized to enforce this provision with the help of other federal agencies and state governments.

PENALTY: Not applicable.

Note: At the time of this publication, a number of tobacco companies had challenged this provision in federal court in Western Kentucky. (*Commonwealth Brands v. United States*, No. 1:09-CV-117-M, 2010 WL 65013 (W.D.Ky. Jan. 5, 2010).)

ADVISORY COMMITTEE

21 United States Code Section 387q

SCOPE: The U.S. Department of Health and Human Services (HHS) shall appoint 12 people to a Tobacco Products Scientific Advisory Committee to provide advice, information, and recommendations. The members will include seven individuals from the medical, dental, scientific, and health care industries; one government employee; one member of the general public; and three nonvoting members representing the tobacco manufacturing industry, the small business tobacco manufacturing industry, and tobacco growers.

EXCEPTION: Full-time employees of the FDA or any agency responsible for enforcing 2009 FDA Law may not be appointed to this Advisory Committee.

ENFORCEMENT: Not applicable.

PENALTY: Not applicable.



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