Family Smoking Prevention and Tobacco Control Act
Section-by-Section

Title I—Authority of the Food and Drug Administration
Sec. 101—Amendment of Federal Food, Drug and Cosmetic Act
Chapter IX—Tobacco Products
The bill creates a new chapter within the Federal Food, Drug, and Cosmetic Act (FFDCA) to regulate tobacco products.

Sec. 900—Definitions

Sec. 901—FDA Authority over Tobacco Products
Tobacco products shall not be regulated as a drug or device unless the (tobacco) product is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, or a claim is made under section 201(g)(1)(C) or 201(h)(3) of the FFDCA. Modified risk products will not be regulated as drugs or devices. The bill limits the scope of FDA's authority to regulating manufacturers of tobacco products, making clear that FDA does not have the authority to regulate tobacco growers.

Sec. 902—Adulterated Tobacco Products
Filthy, decomposed, or otherwise contaminated substances in tobacco products, the preparation of such products, or the packaging of such products will cause them to be deemed adulterated. Tobacco products held under unsanitary conditions or manufactured, packed, or stored in violation of good manufacturing practices will likewise be deemed adulterated. A tobacco product will also be deemed adulterated if it does not meet the product standards established for the product, or if the product is required to have premarket approval or to be approved as a modified risk product and does not have an approved application.

Sec. 903—Misbranded Tobacco Products
Tobacco products will be deemed misbranded if their label is false or misleading or if they are not correctly labeled (e.g., with the percentage of domestically grown tobacco, proper warning labels, the name of the manufacturer, or in accordance with other requirements of the Secretary) or advertised. The Secretary is also specifically authorized to require prior approval of statements made on the label of a tobacco product.

Sec. 904—Submission of Health Information
Requires, within six months of passage, submission, by brand and quantity, of (1) ingredients, compounds, paper, filter, and components added to tobacco products, (2) a description of the content, delivery, and form of nicotine to the Secretary, and (3) a list of constituents, including smoke constituents identified by the Secretary as harmful or potentially harmful. This information must be provided with respect to newly-introduced tobacco products at least 90 days prior to their introduction on the market. Provides the Secretary with the authority to request documents and information relating to research activities and findings, scientific information on reduced risk products/technology, and marketing research. Within three years of passage, and annually thereafter, the Secretary must publish in an easily available and understood format a list of harmful and potentially harmful constituents in each brand. The Secretary must also conduct consumer research to ensure that publication of the list is not misleading to lay persons. After five years, the Secretary must report to Congress on the results of the consumer research, and provide a recommendation on whether or not publication of the list should continue or be modified.

Sec. 905—Annual Registration
Requires registration of every entity that owns or operates in any state any establishment engaged in the manufacture, preparation, compounding, or processing of tobacco products. The same requirement extends to foreign establishments. Allows the Secretary to create a uniform system for identification of

tobacco products. Requires a report to the Secretary 90 days prior to the introduction of a new tobacco product, demonstrating that the product is substantially equivalent to a tobacco product already on the market and therefore not subject to pre-market approval. Also requires reports on products first marketed between June 2, 2003, and 15 months after enactment. Authorizes the Secretary to issue regulations creating exemptions from premarket notification for minor modifications of existing products or where otherwise appropriate.

Sec. 906—General Provisions Respecting Control of Tobacco Products
Allows for public comment with rulemaking. Ensures limited confidentiality of certain information reported to the Secretary. Authorizes the Secretary to issue regulations restricting the sale and distribution of tobacco products, including access to, advertising and promotion of tobacco products, if the Secretary determines that the regulations would protect the public health, taking into account factors specified in the provision. Advertising and promotion restrictions are permitted to the full extent consistent with the First Amendment. Does not permit the Secretary to require that tobacco products be available only by prescription, to prohibit the face-to-face sale of any tobacco product by a specific category of retail outlets, or to establish a national minimum age of higher than 18 years to purchase tobacco products. Permits advertising on conventional matchbooks to the extent permitted in adult publications, unless the Secretary determines that such treatment of matchbooks is not appropriate for protection of the public health. Allows for regulations requiring that tobacco products conform to specified good manufacturing practices (with input from the public and interested parties, and from the Tobacco Products Scientific Advisory Committee, and provides for a three-year-delay for compliance to ensure that manufacturers with less resources have ample opportunity to comply).

Sec. 907—Product Standards
Allows the Secretary to adopt, through notice and comment rulemaking, performance standards for tobacco products if appropriate for protection of public health. Standard(s) could include provisions to reduce nicotine yields, or to reduce or eliminate other constituents or harmful components, or respecting other aspects of the construction, constituents, including smoke constituents, properties, and labeling of the tobacco product. The Secretary shall periodically review the performance standards, taking into consideration new medical, scientific or other technological data. The bill prohibits the use in cigarettes of flavors, herbs, and spices, such as strawberry, grape, orange, clove, and cinnamon, that are used as a "characterizing flavor" of the tobacco product or tobacco smoke. The "characterizing flavor" ban does not include tobacco or menthol, but the Secretary retains the authority to take action against menthol and other flavors not mentioned in this provision, under this section or other sections of the Act. Congress reserves the power to ban all cigarettes, all smokeless tobacco products, all little cigars, all cigars other than little cigars, all pipe tobacco, or all "roll your own" tobacco products, or to reduce nicotine yields of any tobacco product to zero.

Sec. 908—Notification and Other Remedies
Provides authority for the Secretary to give "notice" (e.g., through PSAs) if a tobacco product presents an "unreasonable risk of substantial harm," and notification is necessary and the most practicable means available to eliminate the unreasonable risk. Also authorizes the Secretary to recall a tobacco product, after an opportunity for an informal hearing, if the product contains a manufacturing or other defect that would cause serious adverse health consequences or death and is not ordinarily contained in tobacco products on the market.

Sec. 909—Records and Reports on Tobacco Products
Tobacco manufacturers and importers must establish and maintain records and submit them to the Secretary, if required by the Secretary by regulation, to ensure that tobacco products are not adulterated or misbranded. The Secretary may also require manufacturers and importers to report serious unexpected adverse reactions caused by the use of a tobacco product. Such regulations shall also require the reporting of other significant adverse reactions, if necessary, and of actions taken to correct or remove products from the market when undertaken to reduce a health risk. Reports required under this

section shall not be unduly burdensome, nor require the disclosure of the identity of patients or users unless required for reasons specified in the provision.

Sec. 910—Application for Review of Certain Tobacco Products

Requires pre-market approval for all new tobacco products entering the market, unless the Secretary determines that the product is substantially equivalent to an existing product. Defines substantial equivalence to mean that the product has the same characteristics as a marketed product, or has different characteristics, but does not raise different public health questions. Specifies information that must be provided under section 905(j) to establish substantial equivalence, including detailed information on adverse health effects, and provides that such information be made public within 30 days of a determination of substantial equivalence. An application for premarket approval must contain all information published, known, or which should reasonably be known, to the applicant concerning studies on the health risks of the product. The application must also contain a listing of components, ingredients and composition of products; how the product is operated or used; a description of the methods used to manufacture or produce the product; and samples of the product and the product's proposed labeling. The Secretary may refer the application to the Tobacco Products Advisory Committee (and must do so if the applicant requests). The Secretary shall, within 180 days, deny the application if the Secretary finds that the applicant has not shown that permitting marketing of the product would be appropriate for the public health, or if the Secretary finds that the making and handling of the product do not conform to good manufacturing practices, the labeling is false or misleading, or the product fails to conform to an applicable product standard promulgated under section 907 without justification. Provides the Secretary authority to withdraw or suspend an approved application for a number of reasons, including that continued marketing is no longer appropriate for the protection of public health; the application contained a materially false statement; the applicant has failed to maintain records or make reports; the labeling becomes false or misleading; or the product does not conform to a tobacco standard without appropriate justification. Authorizes the Secretary to require the maintenance of records and the making of reports as necessary to permit the Secretary to determine whether to withdraw or suspend the approval.

Sec. 911—Modified Risk Tobacco Products

A person may not sell or distribute a modified risk tobacco product without having obtained approval from FDA. The bill specifically defines the sale or distribution of these products to include labeling or advertising that states or implies that there is reduced risk of harm or of tobacco-related disease, or that there is reduced exposure to a substance, or that uses the words "light," "mild," or "low," or similar descriptors. This definition also includes any action taken by the manufacturer after passage of the legislation directed to consumers through the media or otherwise, other than by means of the tobacco product's label, labeling or advertising, that would be reasonably expected to result in consumers believing that the tobacco product or its smoke may present a lower risk of disease, lower exposure to a substance, or is less harmful. Products intended for use in the treatment of tobacco dependence are not modified risk tobacco products and are subject to Chapter V of the FFDCA. This section also outlines the specific requirements that tobacco manufacturers must meet before selling or distributing modified risk tobacco products. An application must include a description of the product; the conditions for using the product with respect to the claim; formulation of the product; sample labels; sample product and each component of the product; all documents relating to research regarding the product (effect on tobacco-related diseases and other health-related conditions); data on how consumers actually use the product; and any other information required by the Secretary. The Secretary must make the application and all of its contents (except trade secrets and confidential commercial information) public and seek public comment. The application must be referred to the Tobacco Products Advisory Committee for its recommendations. The Secretary will make the decision to approve such an application based on scientific data about whether the product will reduce harm and the risk of tobacco-related disease to individual users and benefit the population as a whole, and whether approval of the application is appropriate to protect the public health. The Secretary must issue regulations within two years establishing minimum standards for the scientific studies needed to show a substantial reduction in

morbidity or mortality among individual tobacco users, and describing the types of evidence that would be adequate to meet those standards. The bill creates a special rule for certain products, if the Secretary determines, among other things, that (1) the product's label, labeling, or advertising explicitly or implicitly claims only that the product contains a reduced level of a substance, or presents a reduced exposure to a substance; (2) scientific evidence of reduced harm is not, or cannot be made, available, using the best available scientific methods, i.e., those described in the regulations that the Secretary is required to issue, except by conducting long-term epidemiological studies; and (3) such data as currently exists predicts substantially reduced morbidity or mortality among individual tobacco users. Approvals of these products terminate after five years but may be renewed. The Secretary must also limit the approval of modified tobacco products under the general rule to a specified period of time. The Secretary may require a manufacturer of a product to comply with requirements relating to labeling, advertising, and promotion of the tobacco product, and the Secretary must require postmarket surveillance. The Secretary has discretion to require that a modified risk tobacco product making a comparative claim compare the tobacco product to a commercially marketed tobacco product which is representative of that type of tobacco product on the market (e.g. average value of the top three brands). The Secretary may also require quantitative comparisons of the amount of the substance reduced. This information must be prominently placed near the most prominent claim. The Secretary may withdraw approval of a modified risk product if: he or she can no
longer make the findings on which approval was based; the application contained a material false statement; product representations about reduced risk or exposure are no longer valid; the applicant failed to conduct required postmarket studies and surveillance; or the applicant failed to meet any other condition of approval.

Sec. 912—Judicial Review
Any person adversely affected by an FDA regulation(s) relating to performance standards or premarket approval may within 30 days file a petition for judicial review of such regulation with a United States Court of Appeals. The remedies provided shall be in addition to, not in lieu of, any other remedies provided by law. Judgment by the appellate court shall be final, subject to review by the Supreme Court.

Sec. 913—Equal Treatment of Retail Outlets
In order to ensure a level playing field among all retailers, the Secretary shall issue regulations requiring that retail establishments whose predominant business is the sale of tobacco products comply with any advertising restriction applicable to retail establishments accessible to individuals under the age of 18.

Sec. 914—Jurisdiction of and Coordination with the Federal Trade Commission
Clarifies that the Federal Trade Commission's authority regarding the advertising, sale, or distribution of tobacco products is not limited or diminished by the Act, and that violations of this Act will also be considered unfair or deceptive practices under the Federal Trade Commission Act. The Secretary and the Chairman of the FTC are to coordinate enforcement of section 4 of the Federal Cigarette Labeling and Advertising Act and section 3 of the Comprehensive Smokeless Tobacco Health Education Act.

Sec. 915—Congressional Review Provisions
In accordance with existing law, Congress may review any rule promulgated under this law.

Sec. 916—Regulation Requirement
Within 24 months of passage, the Secretary is required to issue regulations that require the testing, reporting, and disclosure of tobacco product smoke constituents, ingredients and additives that the Secretary determines should be tested in order to protect public health. Such constituents may include tar, nicotine, carbon monoxide and other smoke constituents or ingredients as determined by the Secretary. Regulations may require disclosure of the test results relating to tar and nicotine in labeling or advertising, and disclosure regarding other constituents and ingredients if such disclosures would protect the public health and not mislead consumers.

Sec. 917—Preservation of State and Local Authority
States' authority is preserved, with no federal preemption, in regard to enacting, adopting, promulgating, and enforcing any law, rule, or regulation in critical areas with respect to tobacco products that is in addition to or more stringent than required under this Act, including measures relating to prohibiting the sale, distribution, possession, exposure to, access to, advertising and promotion of, or use of tobacco products by individuals of any age, information reporting to the state, or measures relating to fire safety standards for cigarettes. States are generally preempted from establishing or continuing any requirement that is different from or in addition to any FDA requirement relating to specified and limited areas, including tobacco product standards, pre-market approval, adulteration, misbranding, labeling, registration, reporting, good manufacturing standards, and modified risk tobacco products. Product liability actions under state law are not modified or otherwise affected by this bill.

Sec. 918—Tobacco Products Scientific Advisory Committee
Establishes an 11-member advisory committee representing the public, tobacco growers, the health community, and tobacco manufacturing and tobacco growing industry interests. Representatives of the tobacco industry will be non-voting. The committee will provide advice and guidance to the Secretary on effects of the alteration of the nicotine yields from tobacco products; the threshold level at which nicotine becomes addictive; and other issues as needed by the Secretary.

Sec. 919—Drug Products Used to Treat Tobacco Dependence
Requires the Secretary to consider designating nicotine replacement products as fast track research and approval products. Requires the Commissioner of FDA to consider approving the extended use of over-the-counter nicotine replacement products and to consider other issues relating to the approval of nicotine replacement therapies.

Sec. 920—User Fees
Requires the Secretary to assess a quarterly fee from tobacco product manufacturers and importers to cover the costs of the activities of the Food and Drug Administration related to the regulation of tobacco products under the Act. Specifies the allocation of fees by class of tobacco products and the amount to be paid by each manufacturer or importer, by determination of company market share.

Sec. 102—Codification of FDA Rules on Advertising and Access
Within 30 days of bill passage, the Secretary shall publish a final rule on the advertising of, and access to, tobacco products, which shall become effective one year after passage of the bill. The interim final rule is deemed to be in compliance with the Administrative Procedures Act. The interim final rule shall be identical in its provisions to the advertising and access regulations promulgated by the FDA in 1996. Prior to making any amendments to the published interim rule, the Secretary would be required to promulgate a proposed rule.

Sec. 103—Conforming and Other Amendments
These provisions include export provisions and retailer/licensing provisions. Contains retailer procedural protections and requires FDA, to the extent possible, to contract with the states for retailer enforcement.

Title II—Tobacco Product Warnings and Smoke Constituent Disclosure
Sec. 201---Cigarette Label and Advertising Warnings
This section specifies nine new required warning labels that must appear on cigarette packages and advertisements. The warnings must comprise at least the top 30% of the front and rear panels of the package, and at least 20% of the related advertisements. It is unlawful for a manufacturer, importer, distributor, or retailer to advertise any cigarette unless its advertising bears one of the required warning labels; however, retailers will not be held responsible for packages and advertisements that they do not create. The bill requires that all warnings be displayed on all brands and be randomly distributed in all

areas of the U.S. where the product is distributed and requires that a plan be submitted to the Secretary to ensure that the statements in product advertising are equally distributed and rotated quarterly and that all required label statements be displayed at the same time.

Sec. 202—Authority to Revise Cigarette Warning Label Statements
Provides the Secretary with authority, by rulemaking, to adjust format, type size, and text of any label requirements, as well as to increase the required label area from 30 percent up to 50 percent of the front and rear panels.

Sec. 203—State Regulation of Cigarette Advertising and Promotion
A state or locality may enact statutes and promulgate regulations based on smoking and health imposing specific bans or restrictions on the time, place, and manner. States or localities may not restrict the content of advertisements or promotions of any cigarettes.

Sec. 204—Smokeless Tobacco Labels and Advertising Warnings
This section specifies the required warning labels that must appear on smokeless tobacco product labels and advertisements, and imposes minimum size and text requirements. The section requires that all warnings be displayed on all brands and be randomly distributed in all areas of the US where the product is distributed and requires that a plan be submitted to the Secretary to ensure that the statements in product advertising are equally distributed and rotated quarterly, and that all required label statements are displayed at the same time.

Sec. 205—Authority to Revise Smokeless Tobacco Warning Label Statements
Provides the Secretary with authority, by rulemaking, to adjust format, type size, and text of any label requirements, as well as to increase the required label area from 30 percent up to 50 percent of the front and rear panels.

Sec. 206—Tar, Nicotine, and Other Smoke Constituent Disclosure to the Public
Requires the Secretary to determine, using his or her sole discretion, whether cigarette and other tobacco product manufacturers should be required to include in each advertisement, package, label, or both, the tar and nicotine yields of a tobacco product, and whether the yields of other constituents will be required to be disclosed by appropriate means.

Title III—Prevention of Illicit Trade in Tobacco Products
Sec. 301—Labeling, Record Keeping, Records Inspection
Requires the label, packaging, and shipping containers of tobacco products to bear a statement "sale only allowed in the United States." Not later than nine months after enactment of the Act, the Secretary shall issue regulations regarding the establishment and maintenance of records by any person who manufacturers, processes, transports, distributes, receives, packages, holds, exports, or imports tobacco products. These records will be used to track and assist in the investigation of illicit trade, smuggling, or counterfeiting of tobacco products. Retailers will not be required to maintain records of sales made to consumers. The Secretary is authorized to inspect and copy all records,
including financial records, of each person who manufacturers, processes, transports, distributes, receives, holds, packages, exports, or imports a tobacco product that the Secretary has a reasonable belief is part of an illicit trade, or smuggling, or is counterfeit. Requires manufacturers and distributors to report to the Attorney General any knowledge that a tobacco product it manufactures or distributes has been imported, exported, distributed, or offered for sale (1) without payment of duties or taxes, or (2) for possible illicit marketing.

Sec. 302—Study and Report
No later than 18 months after enactment, the Comptroller General shall conduct a study of cross-border trade in tobacco products and submit a report to Congress.