

of organized and systematic violence that is intended to generate chaos and fear among the population, results in death and destruction, and is a reprehensible criminal activity”;

Whereas the Government of Argentina supports the 1998 Commitment of Mar del Plata, which calls terrorist acts “serious common crimes that erode peaceful and civilized co-existence, affect the rule of law and the exercise of democracy, and endanger the stability of democratically elected constitutional governments and their socioeconomic development of our countries”;

Whereas the Government of Argentina actively supports the development of the Three Plus One Counterterrorism Dialogue with Brazil, Paraguay, and the United States;

Whereas the Government of Argentina was successful in enacting a law on cooperation from defendants in terrorist matters, a law that will be helpful in pursuing full prosecution in the 1994 AMIA bombing and other terrorist cases; and

Whereas the Second Specialized Conference on Terrorism held in Mar del Plata, Argentina on November 23 and November 24, 1998, concluded with the adoption of the Commitment of Mar del Plata, calling for the establishment within the Organization of American States (referred to in this resolution as “OAS”) of an Inter-American Committee Against Terrorism (referred to in this resolution as “CICTE”): Now, therefore, be it

*Resolved by the Senate (the House of Representatives concurring), That Congress—*

(1) reiterates its strongest condemnation of the 1994 attack on the AMIA Jewish Community Center in Buenos Aires, Argentina, and honors the victims of this heinous act;

(2) expresses its sympathy to the relatives of the victims, who have waited 10 years without justice for the loss of their loved ones, and may have to wait even longer for justice to be served;

(3) underscores the concern of the United States regarding the continuing, decade-long delay in the proper resolution of this case;

(4) strongly urges the Government of Argentina to continue to dedicate and provide the resources necessary for its judicial system and intelligence agencies to investigate all areas of the AMIA case, including by implementing Argentine President Nestor Kirchner's Executive order mandating the opening of the archives of the SIDE of Argentina, and to prosecute with due haste those who are responsible for the bombing;

(5) calls upon the international community to cooperate fully with the investigation, including by making information, witnesses, and suspects available for review and questioning by the appropriate Argentine authorities;

(6) encourages the President to direct United States law enforcement agencies to provide support and cooperation, if requested, to the Government of Argentina, for the purposes of deepening and expanding the investigation into this bombing and suspected activities in support of terrorism in the tri-border area where the borders of Argentina, Paraguay, and Brazil meet;

(7) encourages the President to direct the United States Representative to the OAS to—

(A) seek support from OAS member countries for the creation of a special task force of the CICTE to assist, as requested by the Government of Argentina, in the investigation of all aspects of the 1994 AMIA terrorist attack; and

(B) urge OAS member countries to designate Hizballah as a terrorist organization if they have not already done so;

(8) stresses the need for international pressure on the Government of the Islamic Republic of Iran and the Government of the Syrian Arab Republic to extradite for trial individuals and government officials who are accused of planning or perpetrating the AMIA attack, and to immediately, unconditionally, and permanently cease any and all assistance to terrorists; and

(9) desires a lasting, warm relationship between the United States and Argentina that is built, in part, on mutual abhorrence of terrorism and commitments to peace, stability, and democracy in the Western Hemisphere.

## AMENDMENTS SUBMITTED AND PROPOSED

SA 3562. Mr. MCCONNELL (for Mr. GRASSLEY (for himself and Mr. BAUCUS)) proposed an amendment to the bill H.R. 4520, to amend the Internal Revenue Code of 1986 to remove impediments in such Code and make our manufacturing, service, and high-technology businesses and workers more competitive and productive both at home and abroad.

SA 3563. Mr. DEWINE (for himself, Mr. KENNEDY, Mr. MCCONNELL, Mr. HOLLINGS, Ms. COLLINS, Mrs. MURRAY, Mr. DURBIN, Mrs. FEINSTEIN, Mr. GRAHAM of Florida, Mr. JEFFORDS, Mr. REED, Mr. LAUTENBERG, and Mr. SCHUMER) proposed an amendment to amendment SA 3562 proposed by Mr. MCCONNELL (for Mr. GRASSLEY (for himself and Mr. BAUCUS)) to the bill H.R. 4520, *supra*.

SA 3564. Mr. ROBERTS (for himself and Mr. ROCKEFELLER) submitted an amendment intended to be proposed by him to the bill S. 2386, to authorize appropriations for fiscal year 2005 for intelligence and intelligence-related activities of the United States Government, the Intelligence Community Management Account, and the Central Intelligence Agency Retirement and Disability System, and for other purposes; which was ordered to lie on the table.

## TEXT OF AMENDMENTS

**SA 3562.** Mr. MCCONNELL (for Mr. GRASSLEY (for himself and Mr. BAUCUS)) proposed an amendment to the bill H.R. 4520, to amend the Internal Revenue Code of 1986 to remove impediments in such Code and make our manufacturing, service, and high-technology businesses and workers more competitive and productive both at home and abroad; as follows:

(a) **SHORT TITLE.**—This Act may be cited as the “Jumpstart Our Business Strength (JOBS) Act”.

The text of Amendment S.A. 3562 was printed in the CONGRESSIONAL RECORD on May 18, 2004, as the text of S. 1637 which was passed by the Senate on May 11, 2004.

**SA 3563.** Mr. DEWINE (for himself, Mr. KENNEDY, Mr. MCCONNELL, Mr. HOLLINGS, Ms. COLLINS, Mrs. MURRAY, Mr. DURBIN, Mrs. FEINSTEIN, Mr. GRAHAM of Florida, Mr. JEFFORDS, Mr. REED, Mr. LAUTENBERG, and Mr. SCHUMER) proposed an amendment to amendment SA 3562 proposed by Mr. MCCONNELL (for Mr. GRASSLEY (for himself and Mr. BAUCUS)) to the bill

H.R. 4520, to amend the Internal Revenue Code of 1986 to remove impediments in such Code and make our manufacturing, service, and high-technology businesses and workers more competitive and productive both at home and abroad; as follows:

At the appropriate place, insert the following:

## **TITLE —PROVISIONS RELATING TO TOBACCO**

### **Subtitle A—Family Smoking Prevention and Tobacco Control**

#### **SEC. 01. SHORT TITLE.**

This subtitle may be cited as the “Family Smoking Prevention and Tobacco Control Act”.

#### **SEC. 02. FINDINGS.**

The Congress finds the following:

(1) The use of tobacco products by the Nation's children is a pediatric disease of considerable proportions that results in new generations of tobacco-dependent children and adults.

(2) A consensus exists within the scientific and medical communities that tobacco products are inherently dangerous and cause cancer, heart disease, and other serious adverse health effects.

(3) Nicotine is an addictive drug.

(4) Virtually all new users of tobacco products are under the minimum legal age to purchase such products.

(5) Tobacco advertising and marketing contribute significantly to the use of nicotine-containing tobacco products by adolescents.

(6) Because past efforts to restrict advertising and marketing of tobacco products have failed adequately to curb tobacco use by adolescents, comprehensive restrictions on the sale, promotion, and distribution of such products are needed.

(7) Federal and State governments have lacked the legal and regulatory authority and resources they need to address comprehensively the public health and societal problems caused by the use of tobacco products.

(8) Federal and State public health officials, the public health community, and the public at large recognize that the tobacco industry should be subject to ongoing oversight.

(9) Under article I, section 8 of the Constitution, the Congress is vested with the responsibility for regulating interstate commerce and commerce with Indian tribes.

(10) The sale, distribution, marketing, advertising, and use of tobacco products are activities in and substantially affecting interstate commerce because they are sold, marketed, advertised, and distributed in interstate commerce on a nationwide basis, and have a substantial effect on the Nation's economy.

(11) The sale, distribution, marketing, advertising, and use of such products substantially affect interstate commerce through the health care and other costs attributable to the use of tobacco products.

(12) It is in the public interest for Congress to enact legislation that provides the Food and Drug Administration with the authority to regulate tobacco products and the advertising and promotion of such products. The benefits to the American people from enacting such legislation would be significant in human and economic terms.

(13) Tobacco use is the foremost preventable cause of premature death in America. It causes over 400,000 deaths in the United

States each year and approximately 8,600,000 Americans have chronic illnesses related to smoking.

(14) Reducing the use of tobacco by minors by 50 percent would prevent well over 6,500,000 of today's children from becoming regular, daily smokers, saving over 2,000,000 of them from premature death due to tobacco induced disease. Such a reduction in youth smoking would also result in approximately \$75,000,000,000 in savings attributable to reduced health care costs.

(15) Advertising, marketing, and promotion of tobacco products have been especially directed to attract young persons to use tobacco products and these efforts have resulted in increased use of such products by youth. Past efforts to oversee these activities have not been successful in adequately preventing such increased use.

(16) In 2001, the tobacco industry spent more than \$11,000,000,000 to attract new users, retain current users, increase current consumption, and generate favorable long-term attitudes toward smoking and tobacco use.

(17) Tobacco product advertising often misleadingly portrays the use of tobacco as socially acceptable and healthful to minors.

(18) Tobacco product advertising is regularly seen by persons under the age of 18, and persons under the age of 18 are regularly exposed to tobacco product promotional efforts.

(19) Through advertisements during and sponsorship of sporting events, tobacco has become strongly associated with sports and has become portrayed as an integral part of sports and the healthy lifestyle associated with rigorous sporting activity.

(20) Children are exposed to substantial and unavoidable tobacco advertising that leads to favorable beliefs about tobacco use, plays a role in leading young people to overestimate the prevalence of tobacco use, and increases the number of young people who begin to use tobacco.

(21) The use of tobacco products in motion pictures and other mass media glamorizes its use for young people and encourages them to use tobacco products.

(22) Tobacco advertising expands the size of the tobacco market by increasing consumption of tobacco products including tobacco use by young people.

(23) Children are more influenced by tobacco advertising than adults, they smoke the most advertised brands.

(24) Tobacco company documents indicate that young people are an important and often crucial segment of the tobacco market. Children, who tend to be more price-sensitive than adults, are influenced by advertising and promotion practices that result in drastically reduced cigarette prices.

(25) Comprehensive advertising restrictions will have a positive effect on the smoking rates of young people.

(26) Restrictions on advertising are necessary to prevent unrestricted tobacco advertising from undermining legislation prohibiting access to young people and providing for education about tobacco use.

(27) International experience shows that advertising regulations that are stringent and comprehensive have a greater impact on overall tobacco use and young people's use than weaker or less comprehensive ones.

(28) Text only requirements, although not as stringent as a ban, will help reduce underage use of tobacco products while preserving the informational function of advertising.

(29) It is in the public interest for Congress to adopt legislation to address the public

health crisis created by actions of the tobacco industry.

(30) The final regulations promulgated by the Secretary of Health and Human Services in the August 28, 1996, issue of the Federal Register (61 Fed. Reg. 44615-44618) for inclusion as part 897 of title 21, Code of Federal Regulations, are consistent with the First Amendment to the United States Constitution and with the standards set forth in the amendments made by this subtitle for the regulation of tobacco products by the Food and Drug Administration and the restriction on the sale and distribution, including access to and the advertising and promotion of, tobacco products contained in such regulations are substantially related to accomplishing the public health goals of this subtitle.

(31) The regulations described in paragraph (30) will directly and materially advance the Federal Government's substantial interest in reducing the number of children and adolescents who use cigarettes and smokeless tobacco and in preventing the life-threatening health consequences associated with tobacco use. An overwhelming majority of Americans who use tobacco products begin using such products while they are minors and become addicted to the nicotine in those products before reaching the age of 18. Tobacco advertising and promotion plays a crucial role in the decision of these minors to begin using tobacco products. Less restrictive and less comprehensive approaches have not and will not be effective in reducing the problems addressed by such regulations. The reasonable restrictions on the advertising and promotion of tobacco products contained in such regulations will lead to a significant decrease in the number of minors using and becoming addicted to those products.

(32) The regulations described in paragraph (30) impose no more extensive restrictions on communication by tobacco manufacturers and sellers than are necessary to reduce the number of children and adolescents who use cigarettes and smokeless tobacco and to prevent the life-threatening health consequences associated with tobacco use. Such regulations are narrowly tailored to restrict those advertising and promotional practices which are most likely to be seen or heard by youth and most likely to entice them into tobacco use, while affording tobacco manufacturers and sellers ample opportunity to convey information about their products to adult consumers.

(33) Tobacco dependence is a chronic disease, one that typically requires repeated interventions to achieve long-term or permanent abstinence.

(34) Because the only known safe alternative to smoking is cessation, interventions should target all smokers to help them quit completely.

(35) Tobacco products have been used to facilitate and finance criminal activities both domestically and internationally. Illicit trade of tobacco products has been linked to organized crime and terrorist groups.

(36) It is essential that the Food and Drug Administration review products sold or distributed for use to reduce risks or exposures associated with tobacco products and that it be empowered to review any advertising and labeling for such products. It is also essential that manufacturers, prior to marketing such products, be required to demonstrate that such products will meet a series of rigorous criteria, and will benefit the health of the population as a whole, taking into account both users of tobacco products and persons who do not currently use tobacco products.

(37) Unless tobacco products that purport to reduce the risks to the public of tobacco use actually reduce such risks, those products can cause substantial harm to the public health to the extent that the individuals, who would otherwise not consume tobacco products or would consume such products less, use tobacco products purporting to reduce risk. Those who use products sold or distributed as modified risk products that do not in fact reduce risk, rather than quitting or reducing their use of tobacco products, have a substantially increased likelihood of suffering disability and premature death. The costs to society of the widespread use of products sold or distributed as modified risk products that do not in fact reduce risk or that increase risk include thousands of unnecessary deaths and injuries and huge costs to our health care system.

(38) As the National Cancer Institute has found, many smokers mistakenly believe that "low tar" and "light" cigarettes cause fewer health problems than other cigarettes. As the National Cancer Institute has also found, mistaken beliefs about the health consequences of smoking "low tar" and "light" cigarettes can reduce the motivation to quit smoking entirely and thereby lead to disease and death.

(39) Recent studies have demonstrated that there has been no reduction in risk on a population-wide basis from "low tar" and "light" cigarettes and such products may actually increase the risk of tobacco use.

(40) The dangers of products sold or distributed as modified risk tobacco products that do not in fact reduce risk are so high that there is a compelling governmental interest in insuring that statements about modified risk tobacco products are complete, accurate, and relate to the overall disease risk of the product.

(41) As the Federal Trade Commission has found, consumers have misinterpreted advertisements in which one product is claimed to be less harmful than a comparable product, even in the presence of disclosures and advisories intended to provide clarification.

(42) Permitting manufacturers to make unsubstantiated statements concerning modified risk tobacco products, whether express or implied, even if accompanied by disclaimers would be detrimental to the public health.

(43) The only way to effectively protect the public health from the dangers of unsubstantiated modified risk tobacco products is to empower the Food and Drug Administration to require that products that tobacco manufacturers sold or distributed for risk reduction be approved in advance of marketing, and to require that the evidence relied on to support approval of these products is rigorous.

#### SEC. — 03. PURPOSE.

The purposes of this subtitle are—

(1) to provide authority to the Food and Drug Administration to regulate tobacco products under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), by recognizing it as the primary Federal regulatory authority with respect to the manufacture, marketing, and distribution of tobacco products;

(2) to ensure that the Food and Drug Administration has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco;

(3) to authorize the Food and Drug Administration to set national standards controlling the manufacture of tobacco products

and the identity, public disclosure, and amount of ingredients used in such products;

(4) to provide new and flexible enforcement authority to ensure that there is effective oversight of the tobacco industry's efforts to develop, introduce, and promote less harmful tobacco products;

(5) to vest the Food and Drug Administration with the authority to regulate the levels of tar, nicotine, and other harmful components of tobacco products;

(6) in order to ensure that consumers are better informed, to require tobacco product manufacturers to disclose research which has not previously been made available, as well as research generated in the future, relating to the health and dependency effects or safety of tobacco products;

(7) to continue to permit the sale of tobacco products to adults in conjunction with measures to ensure that they are not sold or accessible to underage purchasers;

(8) to impose appropriate regulatory controls on the tobacco industry;

(9) to promote cessation to reduce disease risk and the social costs associated with tobacco related diseases; and

(10) to strengthen legislation against illicit trade in tobacco products.

#### SEC. 4. SCOPE AND EFFECT.

(a) INTENDED EFFECT.—Nothing in this subtitle (or an amendment made by this subtitle) shall be construed to—

(1) establish a precedent with regard to any other industry, situation, circumstance, or legal action; or

(2) affect any action pending in Federal, State, or Tribal court, or any agreement, consent decree, or contract of any kind.

(b) AGRICULTURAL ACTIVITIES.—The provisions of this subtitle (or an amendment made by this subtitle) which authorize the Secretary to take certain actions with regard to tobacco and tobacco products shall not be construed to affect any authority of the Secretary of Agriculture under existing law regarding the growing, cultivation, or curing of raw tobacco.

#### SEC. 5. SEVERABILITY.

If any provision of this subtitle, the amendments made by this subtitle, or the application of any provision of this subtitle to any person or circumstance is held to be invalid, the remainder of this subtitle, the amendments made by this subtitle, and the application of the provisions of this subtitle to any other person or circumstance shall not be affected and shall continue to be enforced to the fullest extent possible.

### CHAPTER 1—AUTHORITY OF THE FOOD AND DRUG ADMINISTRATION

#### SEC. 11. AMENDMENT OF FEDERAL FOOD, DRUG, AND COSMETIC ACT.

(a) DEFINITION OF TOBACCO PRODUCTS.—Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end the following:

“(nn)(1) The term ‘tobacco product’ means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).

“(2) The term ‘tobacco product’ does not mean—

“(A) a product in the form of conventional food (including water and chewing gum), a product represented for use as or for use in a conventional food, or a product that is intended for ingestion in capsule, tablet, softgel, or liquid form; or

“(B) an article that is approved or is regulated as a drug by the Food and Drug Administration.

“(3) The products described in paragraph (2)(A) shall be subject to chapter IV or chapter V of this Act and the articles described in paragraph (2)(B) shall be subject to chapter V of this Act.

“(4) A tobacco product may not be marketed in combination with any other article or product regulated under this Act (including a drug, biologic, food, cosmetics, medical device, or a dietary supplement).”.

(b) FDA AUTHORITY OVER TOBACCO PRODUCTS.—The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) is amended—

(1) by redesignating chapter IX as chapter X;

(2) by redesignating sections 901 through 907 as sections 1001 through 1007; and

(3) by inserting after section 803 the following:

### “CHAPTER IX—TOBACCO PRODUCTS

#### “SEC. 900. DEFINITIONS.

“In this chapter:

“(1) ADDITIVE.—The term ‘additive’ means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substances intended for use as a flavoring, coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding), except that such term does not include tobacco or a pesticide chemical residue in or on raw tobacco or a pesticide chemical.

“(2) BRAND.—The term ‘brand’ means a variety of tobacco product distinguished by the tobacco used, tar content, nicotine content, flavoring used, size, filtration, or packaging, logo, registered trademark or brand name, identifiable pattern of colors, or any combination of such attributes.

“(3) CIGARETTE.—The term ‘cigarette’ has the meaning given that term by section 3(1) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1332(1)), but also includes tobacco, in any form, that is functional in the product, which, 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 or as roll-your-own tobacco.

“(4) CIGARETTE TOBACCO.—The term ‘cigarette tobacco’ means any product that consists of loose tobacco that is intended for use by consumers in a cigarette. Unless otherwise stated, the requirements for cigarettes shall also apply to cigarette tobacco.

“(5) COMMERCE.—The term ‘commerce’ has the meaning given that term by section 3(2) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1332(2)).

“(6) COUNTERFEIT TOBACCO PRODUCT.—The term ‘counterfeit tobacco product’ means a tobacco product (or the container or labeling of such a product) that, without authorization, bears the trademark, trade name, or other identifying mark, imprint or device, or any likeness thereof, of a tobacco product listed in a registration under section 905(i)(1).

“(7) DISTRIBUTOR.—The term ‘distributor’ as regards a tobacco product means any person who furthers the distribution of a tobacco product, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption. Common carriers are not considered distributors for purposes of this chapter.

“(8) ILLICIT TRADE.—The term ‘illicit trade’ means any practice or conduct prohibited by law which relates to production, shipment, receipt, possession, distribution, sale, or purchase of tobacco products including any practice or conduct intended to facilitate such activity.

“(9) INDIAN TRIBE.—The term ‘Indian tribe’ has the meaning given such term in section 4(e) of the Indian Self Determination and Education Assistance Act (25 U.S.C. 450b(e)).

“(10) LITTLE CIGAR.—The term ‘little cigar’ has the meaning given that term by section 3(7) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1332(7)).

“(11) NICOTINE.—The term ‘nicotine’ means the chemical substance named 3-(1-Methyl-2-pyrrolidinyl) pyridine or C[10]H[14]N[2], including any salt or complex of nicotine.

“(12) PACKAGE.—The term ‘package’ means a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane), in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers.

“(13) RETAILER.—The term ‘retailer’ means any person who sells tobacco products to individuals for personal consumption, or who operates a facility where self-service displays of tobacco products are permitted.

“(14) ROLL-YOUR-OWN TOBACCO.—The term ‘roll-your-own tobacco’ means any tobacco which, because of its appearance, type, packaging, or labeling, is suitable for use and likely to be offered to, or purchased by, consumers as tobacco for making cigarettes.

“(15) SMOKE CONSTITUENT.—The term ‘smoke constituent’ means any chemical or chemical compound in mainstream or sidestream tobacco smoke that either transfers from any component of the cigarette to the smoke or that is formed by the combustion or heating of tobacco, additives, or other component of the tobacco product.

“(16) SMOKELESS TOBACCO.—The term ‘smokeless tobacco’ means 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.

“(17) STATE.—The term ‘State’ means any State of the United States and, for purposes of this chapter, includes the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, Johnston Atoll, the Northern Mariana Islands, and any other trust territory or possession of the United States.

“(18) TOBACCO PRODUCT MANUFACTURER.—Term ‘tobacco product manufacturer’ means any person, including any repacker or relabeler, who—

“(A) manufactures, fabricates, assembles, processes, or labels a tobacco product; or

“(B) imports a finished cigarette or smokeless tobacco product for sale or distribution in the United States.

“(19) UNITED STATES.—The term ‘United States’ means the 50 States of the United States of America and the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, Johnston Atoll, the Northern Mariana Islands, and any other trust territory or possession of the United States.

#### “SEC. 901. FDA AUTHORITY OVER TOBACCO PRODUCTS.

“(a) IN GENERAL.—Tobacco products shall be regulated by the Secretary under this chapter and shall not be subject to the provisions of chapter V, unless—

“(1) such products are intended for use in the diagnosis, cure, mitigation, treatment,

or prevention of disease (within the meaning of section 201(g)(1)(B) or section 201(h)(2)); or

“(2) a claim is made for such products under section 201(g)(1)(C) or 201(h)(3);

other than modified risk tobacco products approved in accordance with section 911.

“(b) **APPLICABILITY.**—This chapter shall apply to all tobacco products subject to the regulations referred to in section 912 of the Family Smoking Prevention and Tobacco Control Act, and to any other tobacco products that the Secretary by regulation deems to be subject to this chapter.

“(c) **SCOPE.**—

“(1) **IN GENERAL.**—Nothing in this chapter, or any policy issued or regulation promulgated thereunder, or the Family Smoking Prevention and Tobacco Control Act, shall be construed to affect the Secretary's authority over, or the regulation of, products under this Act that are not tobacco products under chapter V or any other chapter.

“(2) **LIMITATION OF AUTHORITY.**—

“(A) **IN GENERAL.**—The provisions of this chapter shall not apply to tobacco leaf that is not in the possession of a manufacturer of tobacco products, or to the producers of tobacco leaf, including tobacco growers, tobacco warehouses, and tobacco grower cooperatives, nor shall any employee of the Food and Drug Administration have any authority to enter onto a farm owned by a producer of tobacco leaf without the written consent of such producer.

“(B) **EXCEPTION.**—Notwithstanding any other provision of this subparagraph, if a producer of tobacco leaf is also a tobacco product manufacturer or controlled by a tobacco product manufacturer, the producer shall be subject to this chapter in the producer's capacity as a manufacturer.

“(C) **RULE OF CONSTRUCTION.**—Nothing in this chapter shall be construed to grant the Secretary authority to promulgate regulations on any matter that involves the production of tobacco leaf or a producer thereof, other than activities by a manufacturer affecting production.

#### “SEC. 902. ADULTERATED TOBACCO PRODUCTS.

“A tobacco product shall be deemed to be adulterated if—

“(1) it consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise contaminated by any added poisonous or added deleterious substance that may render the product injurious to health;

“(2) it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health;

“(3) its package is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

“(4) it is, or purports to be or is represented as, a tobacco product which is subject to a tobacco product standard established under section 907 unless such tobacco product is in all respects in conformity with such standard;

“(5)(A) it is required by section 910(a) to have premarket approval and does not have an approved application in effect;

“(B) it is in violation of the order approving such an application; or

“(6) the methods used in, or the facilities or controls used for, its manufacture, packing or storage are not in conformity with applicable requirements under section 906(e)(1) or an applicable condition prescribed by an order under section 906(e)(2); or

“(7) it is in violation of section 911.

#### “SEC. 903. MISBRANDED TOBACCO PRODUCTS.

“(a) **IN GENERAL.**—A tobacco product shall be deemed to be misbranded—

“(1) if its labeling is false or misleading in any particular;

“(2) if in package form unless it bears a label containing—

“(A) the name and place of business of the tobacco product manufacturer, packer, or distributor;

“(B) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count;

“(C) an accurate statement of the percentage of the tobacco used in the product that is domestically grown tobacco and the percentage that is foreign grown tobacco; and

“(D) the statement required under section 921(a),

except that under subparagraph (B) reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary;

“(3) if any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements or designs in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

“(4) if it has an established name, unless its label bears, to the exclusion of any other nonproprietary name, its established name prominently printed in type as required by the Secretary by regulation;

“(5) if the Secretary has issued regulations requiring that its labeling bear adequate directions for use, or adequate warnings against use by children, that are necessary for the protection of users unless its labeling conforms in all respects to such regulations;

“(6) if it was manufactured, prepared, propagated, compounded, or processed in any State in an establishment not duly registered under section 905(b), 905(c), 905(d), or 905(h), if it was not included in a list required by section 905(i), if a notice or other information respecting it was not provided as required by such section or section 905(j), or if it does not bear such symbols from the uniform system for identification of tobacco products prescribed under section 905(e) as the Secretary by regulation requires;

“(7) if, in the case of any tobacco product distributed or offered for sale in any State—

“(A) its advertising is false or misleading in any particular; or

“(B) it is sold or distributed in violation of regulations prescribed under section 906(d);

“(8) unless, in the case of any tobacco product distributed or offered for sale in any State, the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that tobacco product—

“(A) a true statement of the tobacco product's established name as described in paragraph (4), printed prominently; and

“(B) a brief statement of—

“(i) the uses of the tobacco product and relevant warnings, precautions, side effects, and contraindications; and

“(ii) in the case of specific tobacco products made subject to a finding by the Secretary after notice and opportunity for comment that such action is appropriate to protect the public health, a full description of the components of such tobacco product or

the formula showing quantitatively each ingredient of such tobacco product to the extent required in regulations which shall be issued by the Secretary after an opportunity for a hearing;

“(9) if it is a tobacco product subject to a tobacco product standard established under section 907, unless it bears such labeling as may be prescribed in such tobacco product standard; or

“(10) if there was a failure or refusal—

“(A) to comply with any requirement prescribed under section 904 or 908; or

“(B) to furnish any material or information required under section 909.

“(b) **PRIOR APPROVAL OF LABEL STATEMENTS.**—The Secretary may, by regulation, require prior approval of statements made on the label of a tobacco product. No regulation issued under this subsection may require prior approval by the Secretary of the content of any advertisement, except for modified risk tobacco products as provided in section 911. No advertisement of a tobacco product published after the date of enactment of the Family Smoking Prevention and Tobacco Control Act shall, with respect to the language of label statements as prescribed under section 4 of the Cigarette Labeling and Advertising Act and section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 or the regulations issued under such sections, be subject to the provisions of sections 12 through 15 of the Federal Trade Commission Act (15 U.S.C. 52 through 55).

#### “SEC. 904. SUBMISSION OF HEALTH INFORMATION TO THE SECRETARY.

“(a) **REQUIREMENT.**—Not later than 6 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, each tobacco product manufacturer or importer, or agents thereof, shall submit to the Secretary the following information:

“(1) A listing of all ingredients, including tobacco, substances, compounds, and additives that are, as of such date, added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product by brand and by quantity in each brand and subbrand.

“(2) A description of the content, delivery, and form of nicotine in each tobacco product measured in milligrams of nicotine in accordance with regulations promulgated by the Secretary in accordance with section 4(a)(4) of the Federal Cigarette Labeling and Advertising Act.

“(3) A listing of all constituents, including smoke constituents as applicable, identified by the Secretary as harmful or potentially harmful to health in each tobacco product, and as applicable in the smoke of each tobacco product, by brand and by quantity in each brand and subbrand. Effective beginning 2 years after the date of enactment of this chapter, the manufacturer, importer, or agent shall comply with regulations promulgated under section 915 in reporting information under this paragraph, where applicable.

“(4) All documents developed after the date of enactment of the Family Smoking Prevention and Tobacco Control Act that relate to health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents (including smoke constituents), ingredients, components, and additives.

“(b) **DATA SUBMISSION.**—At the request of the Secretary, each tobacco product manufacturer or importer of tobacco products, or agents thereof, shall submit the following:

“(1) Any or all documents (including underlying scientific information) relating to

research activities, and research findings, conducted, supported, or possessed by the manufacturer (or agents thereof) on the health, toxicological, behavioral, or physiologic effects of tobacco products and their constituents (including smoke constituents), ingredients, components, and additives.

“(2) Any or all documents (including underlying scientific information) relating to research activities, and research findings, conducted, supported, or possessed by the manufacturer (or agents thereof) that relate to the issue of whether a reduction in risk to health from tobacco products can occur upon the employment of technology available or known to the manufacturer.

“(3) Any or all documents (including underlying scientific or financial information) relating to marketing research involving the use of tobacco products or marketing practices and the effectiveness of such practices used by tobacco manufacturers and distributors.

An importer of a tobacco product not manufactured in the United States shall supply the information required of a tobacco product manufacturer under this subsection.

“(c) TIME FOR SUBMISSION.—

“(1) IN GENERAL.—At least 90 days prior to the delivery for introduction into interstate commerce of a tobacco product not on the market on the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the manufacturer of such product shall provide the information required under subsection (a).

“(2) DISCLOSURE OF ADDITIVE.—If at any time a tobacco product manufacturer adds to its tobacco products a new tobacco additive or increases the quantity of an existing tobacco additive, the manufacturer shall, except as provided in paragraph (3), at least 90 days prior to such action so advise the Secretary in writing.

“(3) DISCLOSURE OF OTHER ACTIONS.—If at any time a tobacco product manufacturer eliminates or decreases an existing additive, or adds or increases an additive that has by regulation been designated by the Secretary as an additive that is not a human or animal carcinogen, or otherwise harmful to health under intended conditions of use, the manufacturer shall within 60 days of such action so advise the Secretary in writing.

“(d) DATA LIST.—

“(1) IN GENERAL.—Not later than 3 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, and annually thereafter, the Secretary shall publish in a format that is understandable and not misleading to a lay person, and place on public display (in a manner determined by the Secretary) the list established under subsection (e).

“(2) CONSUMER RESEARCH.—The Secretary shall conduct periodic consumer research to ensure that the list published under paragraph (1) is not misleading to lay persons. Not later than 5 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall submit to the appropriate committees of Congress a report on the results of such research, together with recommendations on whether such publication should be continued or modified.

“(e) DATA COLLECTION.—Not later than 12 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall establish a list of harmful and potentially harmful constituents, including smoke constituents, to health in each tobacco product by brand and by quantity in each brand and subbrand. The

Secretary shall publish a public notice requesting the submission by interested persons of scientific and other information concerning the harmful and potentially harmful constituents in tobacco products and tobacco smoke.

“SEC. 905. ANNUAL REGISTRATION.

“(a) DEFINITIONS.—In this section:

“(1) MANUFACTURE, PREPARATION, COMPOUNDING, OR PROCESSING.—The term ‘manufacture, preparation, compounding, or processing’ shall include repackaging or otherwise changing the container, wrapper, or labeling of any tobacco product package in furtherance of the distribution of the tobacco product from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user.

“(2) NAME.—The term ‘name’ shall include in the case of a partnership the name of each partner and, in the case of a corporation, the name of each corporate officer and director, and the State of incorporation.

“(b) REGISTRATION BY OWNERS AND OPERATORS.—On or before December 31 of each year every person who owns or operates any establishment in any State engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products shall register with the Secretary the name, places of business, and all such establishments of that person.

“(c) REGISTRATION OF NEW OWNERS AND OPERATORS.—Every person upon first engaging in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products in any establishment owned or operated in any State by that person shall immediately register with the Secretary that person’s name, place of business, and such establishment.

“(d) REGISTRATION OF ADDED ESTABLISHMENTS.—Every person required to register under subsection (b) or (c) shall immediately register with the Secretary any additional establishment which that person owns or operates in any State and in which that person begins the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products.

“(e) UNIFORM PRODUCT IDENTIFICATION SYSTEM.—The Secretary may by regulation prescribe a uniform system for the identification of tobacco products and may require that persons who are required to list such tobacco products under subsection (i) shall list such tobacco products in accordance with such system.

“(f) PUBLIC ACCESS TO REGISTRATION INFORMATION.—The Secretary shall make available for inspection, to any person so requesting, any registration filed under this section.

“(g) BIENNIAL INSPECTION OF REGISTERED ESTABLISHMENTS.—Every establishment in any State registered with the Secretary under this section shall be subject to inspection under section 704, and every such establishment engaged in the manufacture, compounding, or processing of a tobacco product or tobacco products shall be so inspected by 1 or more officers or employees duly designated by the Secretary at least once in the 2-year period beginning with the date of registration of such establishment under this section and at least once in every successive 2-year period thereafter.

“(h) FOREIGN ESTABLISHMENTS SHALL REGISTER.—Any establishment within any foreign country engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products, shall register under this section under regulations promulgated by the Secretary. Such regula-

tions shall require such establishment to provide the information required by subsection (i) of this section and shall include provisions for registration of any such establishment upon condition that adequate and effective means are available, by arrangement with the government of such foreign country or otherwise, to enable the Secretary to determine from time to time whether tobacco products manufactured, prepared, compounded, or processed in such establishment, if imported or offered for import into the United States, shall be refused admission on any of the grounds set forth in section 801(a).

“(i) REGISTRATION INFORMATION.—

“(1) PRODUCT LIST.—Every person who registers with the Secretary under subsection (b), (c), (d), or (h) shall, at the time of registration under any such subsection, file with the Secretary a list of all tobacco products which are being manufactured, prepared, compounded, or processed by that person for commercial distribution and which has not been included in any list of tobacco products filed by that person with the Secretary under this paragraph or paragraph (2) before such time of registration. Such list shall be prepared in such form and manner as the Secretary may prescribe and shall be accompanied by—

“(A) in the case of a tobacco product contained in the applicable list with respect to which a tobacco product standard has been established under section 907 or which is subject to section 910, a reference to the authority for the marketing of such tobacco product and a copy of all labeling for such tobacco product;

“(B) in the case of any other tobacco product contained in an applicable list, a copy of all consumer information and other labeling for such tobacco product, a representative sampling of advertisements for such tobacco product, and, upon request made by the Secretary for good cause, a copy of all advertisements for a particular tobacco product; and

“(C) if the registrant filing a list has determined that a tobacco product contained in such list is not subject to a tobacco product standard established under section 907, a brief statement of the basis upon which the registrant made such determination if the Secretary requests such a statement with respect to that particular tobacco product.

“(2) BIENNIAL REPORT OF ANY CHANGE IN PRODUCT LIST.—Each person who registers with the Secretary under this section shall report to the Secretary once during the month of June of each year and once during the month of December of each year the following:

“(A) A list of each tobacco product introduced by the registrant for commercial distribution which has not been included in any list previously filed by that person with the Secretary under this subparagraph or paragraph (1). A list under this subparagraph shall list a tobacco product by its established name and shall be accompanied by the other information required by paragraph (1).

“(B) If since the date the registrant last made a report under this paragraph that person has discontinued the manufacture, preparation, compounding, or processing for commercial distribution of a tobacco product included in a list filed under subparagraph (A) or paragraph (1), notice of such discontinuance, the date of such discontinuance, and the identity of its established name.

“(C) If since the date the registrant reported under subparagraph (B) a notice of discontinuance that person has resumed the manufacture, preparation, compounding, or

processing for commercial distribution of the tobacco product with respect to which such notice of discontinuance was reported, notice of such resumption, the date of such resumption, the identity of such tobacco product by established name, and other information required by paragraph (1), unless the registrant has previously reported such resumption to the Secretary under this subparagraph.

“(D) Any material change in any information previously submitted under this paragraph or paragraph (1).

“(j) REPORT PRECEDING INTRODUCTION OF CERTAIN SUBSTANTIALLY-EQUIVALENT PRODUCTS INTO INTERSTATE COMMERCE.—

“(1) IN GENERAL.—Each person who is required to register under this section and who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a tobacco product intended for human use that was not commercially marketed (other than for test marketing) in the United States as of June 1, 2003, shall, at least 90 days prior to making such introduction or delivery, report to the Secretary (in such form and manner as the Secretary shall prescribe)—

“(A) the basis for such person’s determination that the tobacco product is substantially equivalent, within the meaning of section 910, to a tobacco product commercially marketed (other than for test marketing) in the United States as of June 1, 2003, that is in compliance with the requirements of this Act; and

“(B) action taken by such person to comply with the requirements under section 907 that are applicable to the tobacco product.

“(2) APPLICATION TO CERTAIN POST JUNE 1, 2003 PRODUCTS.—A report under this subsection for a tobacco product that was first introduced or delivered for introduction into interstate commerce for commercial distribution in the United States after June 1, 2003, and prior to the date that is 15 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act shall be submitted to the Secretary not later than 15 months after such date of enactment.

“(3) EXEMPTIONS.—

“(A) IN GENERAL.—The Secretary may by regulation, exempt from the requirements of this subsection tobacco products that are modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive, if the Secretary determines that—

“(i) such modification would be a minor modification of a tobacco product authorized for sale under this Act;

“(ii) a report under this subsection is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for protection of the public health; and

“(iii) an exemption is otherwise appropriate.

“(B) REGULATIONS.—Not later than 9 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall issue regulations to implement this paragraph.

#### “SEC. 906. GENERAL PROVISIONS RESPECTING CONTROL OF TOBACCO PRODUCTS.

“(a) IN GENERAL.—Any requirement established by or under section 902, 903, 905, or 909 applicable to a tobacco product shall apply to such tobacco product until the applicability of the requirement to the tobacco product has been changed by action taken under section 907, section 910, section 911, or subsection (d) of this section, and any re-

quirement established by or under section 902, 903, 905, or 909 which is inconsistent with a requirement imposed on such tobacco product under section 907, section 910, section 911, or subsection (d) of this section shall not apply to such tobacco product.

“(b) INFORMATION ON PUBLIC ACCESS AND COMMENT.—Each notice of proposed rulemaking under section 907, 908, 909, 910, or 911 or under this section, any other notice which is published in the Federal Register with respect to any other action taken under any such section and which states the reasons for such action, and each publication of findings required to be made in connection with rulemaking under any such section shall set forth—

“(1) the manner in which interested persons may examine data and other information on which the notice or findings is based; and

“(2) the period within which interested persons may present their comments on the notice or findings (including the need therefore) orally or in writing, which period shall be at least 60 days but may not exceed 90 days unless the time is extended by the Secretary by a notice published in the Federal Register stating good cause therefore.

“(c) LIMITED CONFIDENTIALITY OF INFORMATION.—Any information reported to or otherwise obtained by the Secretary or the Secretary’s representative under section 903, 904, 907, 908, 909, 910, 911, or 704, or under subsection (e) or (f) of this section, which is exempt from disclosure under subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of that section shall be considered confidential and shall not be disclosed, except that the information may be disclosed to other officers or employees concerned with carrying out this chapter, or when relevant in any proceeding under this chapter.

“(d) RESTRICTIONS.—

“(1) IN GENERAL.—The Secretary may by regulation require restrictions on the sale and distribution of a tobacco product, including restrictions on the access to, and the advertising and promotion of, the tobacco product, if the Secretary determines that such regulation would be appropriate for the protection of the public health. The Secretary may by regulation impose restrictions on the advertising and promotion of a tobacco product consistent with and to full extent permitted by the first amendment to the Constitution. The finding as to whether such regulation would be appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the population as a whole, including users and non-users of the tobacco product, and taking into account—

“(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and

“(B) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

No such regulation may require that the sale or distribution of a tobacco product be limited to the written or oral authorization of a practitioner licensed by law to prescribe medical products.

“(2) LABEL STATEMENTS.—The label of a tobacco product shall bear such appropriate statements of the restrictions required by a regulation under subsection (a) as the Secretary may in such regulation prescribe.

“(3) LIMITATIONS.—

“(A) IN GENERAL.—No restrictions under paragraph (1) may—

“(i) prohibit the sale of any tobacco product in face-to-face transactions by a specific category of retail outlets; or

“(ii) establish a minimum age of sale of tobacco products to any person older than 18 years of age.

“(B) MATCHBOOKS.—For purposes of any regulations issued by the Secretary, matchbooks of conventional size containing not more than 20 paper matches, and which are customarily given away for free with the purchase of tobacco products shall be considered as adult written publications which shall be permitted to contain advertising. Notwithstanding the preceding sentence, if the Secretary finds that such treatment of matchbooks is not appropriate for the protection of the public health, the Secretary may determine by regulation that matchbooks shall not be considered adult written publications.

“(e) GOOD MANUFACTURING PRACTICE REQUIREMENTS.—

“(1) METHODS, FACILITIES, AND CONTROLS TO CONFORM.—

“(A) IN GENERAL.—The Secretary may, in accordance with subparagraph (B), prescribe regulations (which may differ based on the type of tobacco product involved) requiring that the methods used in, and the facilities and controls used for, the manufacture, preproduction design validation (including a process to assess the performance of a tobacco product), packing and storage of a tobacco product, conform to current good manufacturing practice, as prescribed in such regulations, to assure that the public health is protected and that the tobacco product is in compliance with this chapter. Good manufacturing practices may include the testing of raw tobacco for pesticide chemical residues regardless of whether a tolerance for such chemical residues has been established.

“(B) REQUIREMENTS.—The Secretary shall—

“(i) before promulgating any regulation under subparagraph (A), afford the Tobacco Products Scientific Advisory Committee an opportunity to submit recommendations with respect to the regulation proposed to be promulgated;

“(ii) before promulgating any regulation under subparagraph (A), afford opportunity for an oral hearing;

“(iii) provide the advisory committee a reasonable time to make its recommendation with respect to proposed regulations under subparagraph (A); and

“(iv) in establishing the effective date of a regulation promulgated under this subsection, take into account the differences in the manner in which the different types of tobacco products have historically been produced, the financial resources of the different tobacco product manufacturers, and the state of their existing manufacturing facilities, and shall provide for a reasonable period of time for such manufacturers to conform to good manufacturing practices.

“(2) EXEMPTIONS; VARIANCES.—

“(A) PETITION.—Any person subject to any requirement prescribed under paragraph (1) may petition the Secretary for a permanent or temporary exemption or variance from such requirement. Such a petition shall be submitted to the Secretary in such form and manner as the Secretary shall prescribe and shall—

“(i) in the case of a petition for an exemption from a requirement, set forth the basis for the petitioner’s determination that compliance with the requirement is not required to assure that the tobacco product will be in compliance with this chapter;

“(ii) in the case of a petition for a variance from a requirement, set forth the methods proposed to be used in, and the facilities and controls proposed to be used for, the manufacture, packing, and storage of the tobacco product in lieu of the methods, facilities, and controls prescribed by the requirement; and

“(iii) contain such other information as the Secretary shall prescribe.

“(B) REFERRAL TO THE TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE.—The Secretary may refer to the Tobacco Products Scientific Advisory Committee any petition submitted under subparagraph (A). The Tobacco Products Scientific Advisory Committee shall report its recommendations to the Secretary with respect to a petition referred to it within 60 days after the date of the petition’s referral. Within 60 days after—

“(i) the date the petition was submitted to the Secretary under subparagraph (A); or

“(ii) the day after the petition was referred to the Tobacco Products Scientific Advisory Committee,

whichever occurs later, the Secretary shall by order either deny the petition or approve it.

“(C) APPROVAL.—The Secretary may approve—

“(i) a petition for an exemption for a tobacco product from a requirement if the Secretary determines that compliance with such requirement is not required to assure that the tobacco product will be in compliance with this chapter; and

“(ii) a petition for a variance for a tobacco product from a requirement if the Secretary determines that the methods to be used in, and the facilities and controls to be used for, the manufacture, packing, and storage of the tobacco product in lieu of the methods, controls, and facilities prescribed by the requirement are sufficient to assure that the tobacco product will be in compliance with this chapter.

“(D) CONDITIONS.—An order of the Secretary approving a petition for a variance shall prescribe such conditions respecting the methods used in, and the facilities and controls used for, the manufacture, packing, and storage of the tobacco product to be granted the variance under the petition as may be necessary to assure that the tobacco product will be in compliance with this chapter.

“(E) HEARING.—After the issuance of an order under subparagraph (B) respecting a petition, the petitioner shall have an opportunity for an informal hearing on such order.

“(3) COMPLIANCE.—Compliance with requirements under this subsection shall not be required before the period ending 3 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act.

“(f) RESEARCH AND DEVELOPMENT.—The Secretary may enter into contracts for research, testing, and demonstrations respecting tobacco products and may obtain tobacco products for research, testing, and demonstration purposes without regard to section 3324(a) and (b) of title 31, United States Code, and section 5 of title 41, United States Code.

#### “SEC. 907. TOBACCO PRODUCT STANDARDS.

“(a) IN GENERAL.—

“(1) SPECIAL RULE FOR CIGARETTES.—A cigarette or any of its component parts (including the tobacco, filter, or paper) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple,

vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke. Nothing in this subparagraph shall be construed to limit the Secretary’s authority to take action under this section or other sections of this Act applicable to menthol or any artificial or natural flavor, herb, or spice not specified in this paragraph.

“(2) REVISION OF TOBACCO PRODUCT STANDARDS.—The Secretary may revise the tobacco product standards in paragraph (1) in accordance with subsection (b).

“(3) TOBACCO PRODUCT STANDARDS.—The Secretary may adopt tobacco product standards in addition to those in paragraph (1) if the Secretary finds that a tobacco product standard is appropriate for the protection of the public health. This finding shall be determined with respect to the risks and benefits to the population as a whole, including users and non-users of the tobacco product, and taking into account—

“(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and

“(B) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

“(4) CONTENT OF TOBACCO PRODUCT STANDARDS.—A tobacco product standard established under this section for a tobacco product—

“(A) shall include provisions that are appropriate for the protection of the public health, including provisions, where appropriate—

“(i) for the reduction of nicotine yields of the product;

“(ii) for the reduction or elimination of other constituents, including smoke constituents, or harmful components of the product; or

“(iii) relating to any other requirement under (B);

“(B) shall, where appropriate for the protection of the public health, include—

“(i) provisions respecting the construction, components, ingredients, additives, constituents, including smoke constituents, and properties of the tobacco product;

“(ii) provisions for the testing (on a sample basis or, if necessary, on an individual basis) of the tobacco product;

“(iii) provisions for the measurement of the tobacco product characteristics of the tobacco product;

“(iv) provisions requiring that the results of each or of certain of the tests of the tobacco product required to be made under clause (ii) show that the tobacco product is in conformity with the portions of the standard for which the test or tests were required; and

“(v) a provision requiring that the sale and distribution of the tobacco product be restricted but only to the extent that the sale and distribution of a tobacco product may be restricted under a regulation under section 906(d); and

“(C) shall, where appropriate, require the use and prescribe the form and content of labeling for the proper use of the tobacco product.

“(5) PERIODIC RE-EVALUATION OF TOBACCO PRODUCT STANDARDS.—The Secretary shall provide for periodic evaluation of tobacco product standards established under this section to determine whether such standards should be changed to reflect new medical, scientific, or other technological data. The Secretary may provide for testing under paragraph (4)(B) by any person.

“(6) INVOLVEMENT OF OTHER AGENCIES; INFORMED PERSONS.—In carrying out duties

under this section, the Secretary shall endeavor to—

“(A) use personnel, facilities, and other technical support available in other Federal agencies;

“(B) consult with other Federal agencies concerned with standard-setting and other nationally or internationally recognized standard-setting entities; and

“(C) invite appropriate participation, through joint or other conferences, workshops, or other means, by informed persons representative of scientific, professional, industry, agricultural, or consumer organizations who in the Secretary’s judgment can make a significant contribution.

“(b) ESTABLISHMENT OF STANDARDS.—

“(1) NOTICE.—

“(A) IN GENERAL.—The Secretary shall publish in the Federal Register a notice of proposed rulemaking for the establishment, amendment, or revocation of any tobacco product standard.

“(B) REQUIREMENTS OF NOTICE.—A notice of proposed rulemaking for the establishment or amendment of a tobacco product standard for a tobacco product shall—

“(i) set forth a finding with supporting justification that the tobacco product standard is appropriate for the protection of the public health;

“(ii) set forth proposed findings with respect to the risk of illness or injury that the tobacco product standard is intended to reduce or eliminate; and

“(iii) invite interested persons to submit an existing tobacco product standard for the tobacco product, including a draft or proposed tobacco product standard, for consideration by the Secretary.

“(C) STANDARD.—Upon a determination by the Secretary that an additive, constituent (including smoke constituent), or other component of the product that is the subject of the proposed tobacco product standard is harmful, it shall be the burden of any party challenging the proposed standard to prove that the proposed standard will not reduce or eliminate the risk of illness or injury.

“(D) FINDING.—A notice of proposed rulemaking for the revocation of a tobacco product standard shall set forth a finding with supporting justification that the tobacco product standard is no longer appropriate for the protection of the public health.

“(E) CONSIDERATION BY SECRETARY.—The Secretary shall consider all information submitted in connection with a proposed standard, including information concerning the countervailing effects of the tobacco product standard on the health of adolescent tobacco users, adult tobacco users, or non-tobacco users, such as the creation of a significant demand for contraband or other tobacco products that do not meet the requirements of this chapter and the significance of such demand, and shall issue the standard if the Secretary determines that the standard would be appropriate for the protection of the public health.

“(F) COMMENT.—The Secretary shall provide for a comment period of not less than 60 days.

“(2) PROMULGATION.—

“(A) IN GENERAL.—After the expiration of the period for comment on a notice of proposed rulemaking published under paragraph (1) respecting a tobacco product standard and after consideration of such comments and any report from the Tobacco Products Scientific Advisory Committee, the Secretary shall—

“(i) promulgate a regulation establishing a tobacco product standard and publish in the



Federal Register findings on the matters referred to in paragraph (1); or

“(ii) publish a notice terminating the proceeding for the development of the standard together with the reasons for such termination.

“(B) EFFECTIVE DATE.—A regulation establishing a tobacco product standard shall set forth the date or dates upon which the standard shall take effect, but no such regulation may take effect before 1 year after the date of its publication unless the Secretary determines that an earlier effective date is necessary for the protection of the public health. Such date or dates shall be established so as to minimize, consistent with the public health, economic loss to, and disruption or dislocation of, domestic and international trade.

“(3) POWER RESERVED TO CONGRESS.—Because of the importance of a decision of the Secretary to issue a regulation establishing a tobacco product standard—

“(A) banning 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

“(B) requiring the reduction of nicotine yields of a tobacco product to zero, Congress expressly reserves to itself such power.

“(4) AMENDMENT; REVOCATION.—

“(A) AUTHORITY.—The Secretary, upon the Secretary's own initiative or upon petition of an interested person may by a regulation, promulgated in accordance with the requirements of paragraphs (1) and (2)(B), amend or revoke a tobacco product standard.

“(B) EFFECTIVE DATE.—The Secretary may declare a proposed amendment of a tobacco product standard to be effective on and after its publication in the Federal Register and until the effective date of any final action taken on such amendment if the Secretary determines that making it so effective is in the public interest.

“(5) REFERENCE TO ADVISORY COMMITTEE.—The Secretary may—

“(A) on the Secretary's own initiative, refer a proposed regulation for the establishment, amendment, or revocation of a tobacco product standard; or

“(B) upon the request of an interested person which demonstrates good cause for referral and which is made before the expiration of the period for submission of comments on such proposed regulation,

refer such proposed regulation to the Tobacco Products Scientific Advisory Committee, for a report and recommendation with respect to any matter involved in the proposed regulation which requires the exercise of scientific judgment. If a proposed regulation is referred under this paragraph to the Tobacco Products Scientific Advisory Committee, the Secretary shall provide the advisory committee with the data and information on which such proposed regulation is based. The Tobacco Products Scientific Advisory Committee shall, within 60 days after the referral of a proposed regulation and after independent study of the data and information furnished to it by the Secretary and other data and information before it, submit to the Secretary a report and recommendation respecting such regulation, together with all underlying data and information and a statement of the reason or basis for the recommendation. A copy of such report and recommendation shall be made public by the Secretary.

#### “SEC. 908. NOTIFICATION AND OTHER REMEDIES.

“(a) NOTIFICATION.—If the Secretary determines that—

“(1) a tobacco product which is introduced or delivered for introduction into interstate commerce for commercial distribution presents an unreasonable risk of substantial harm to the public health; and

“(2) notification under this subsection is necessary to eliminate the unreasonable risk of such harm and no more practicable means is available under the provisions of this chapter (other than this section) to eliminate such risk,

the Secretary may issue such order as may be necessary to assure that adequate notification is provided in an appropriate form, by the persons and means best suited under the circumstances involved, to all persons who should properly receive such notification in order to eliminate such risk. The Secretary may order notification by any appropriate means, including public service announcements. Before issuing an order under this subsection, the Secretary shall consult with the persons who are to give notice under the order.

“(b) NO EXEMPTION FROM OTHER LIABILITY.—Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided under such order shall be taken into account.

“(c) RECALL AUTHORITY.—

“(1) IN GENERAL.—If the Secretary finds that there is a reasonable probability that a tobacco product contains a manufacturing or other defect not ordinarily contained in tobacco products on the market that would cause serious, adverse health consequences or death, the Secretary shall issue an order requiring the appropriate person (including the manufacturers, importers, distributors, or retailers of the tobacco product) to immediately cease distribution of such tobacco product. The order shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than 10 days after the date of the issuance of the order, on the actions required by the order and on whether the order should be amended to require a recall of such tobacco product. If, after providing an opportunity for such a hearing, the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

“(2) AMENDMENT OF ORDER TO REQUIRE RECALL.—

“(A) IN GENERAL.—If, after providing an opportunity for an informal hearing under paragraph (1), the Secretary determines that the order should be amended to include a recall of the tobacco product with respect to which the order was issued, the Secretary shall, except as provided in subparagraph (B), amend the order to require a recall. The Secretary shall specify a timetable in which the tobacco product recall will occur and shall require periodic reports to the Secretary describing the progress of the recall.

“(B) NOTICE.—An amended order under subparagraph (A)—

“(i) shall not include recall of a tobacco product from individuals; and

“(ii) shall provide for notice to persons subject to the risks associated with the use of such tobacco product.

In providing the notice required by clause (ii), the Secretary may use the assistance of retailers and other persons who distributed such tobacco product. If a significant number of such persons cannot be identified, the Secretary shall notify such persons under section 705(b).

“(3) REMEDY NOT EXCLUSIVE.—The remedy provided by this subsection shall be in addition to remedies provided by subsection (a) of this section.

#### “SEC. 909. RECORDS AND REPORTS ON TOBACCO PRODUCTS.

“(a) IN GENERAL.—Every person who is a tobacco product manufacturer or importer of a tobacco product shall establish and maintain such records, make such reports, and provide such information, as the Secretary may by regulation reasonably require to assure that such tobacco product is not adulterated or misbranded and to otherwise protect public health. Regulations prescribed under the preceding sentence—

“(1) may require a tobacco product manufacturer or importer to report to the Secretary whenever the manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed tobacco products may have caused or contributed to a serious unexpected adverse experience associated with the use of the product or any significant increase in the frequency of a serious, expected adverse product experience;

“(2) shall require reporting of other significant adverse tobacco product experiences as determined by the Secretary to be necessary to be reported;

“(3) shall not impose requirements unduly burdensome to a tobacco product manufacturer or importer, taking into account the cost of complying with such requirements and the need for the protection of the public health and the implementation of this chapter;

“(4) when prescribing the procedure for making requests for reports or information, shall require that each request made under such regulations for submission of a report or information to the Secretary state the reason or purpose for such request and identify to the fullest extent practicable such report or information;

“(5) when requiring submission of a report or information to the Secretary, shall state the reason or purpose for the submission of such report or information and identify to the fullest extent practicable such report or information; and

“(6) may not require that the identity of any patient or user be disclosed in records, reports, or information required under this subsection unless required for the medical welfare of an individual, to determine risks to public health of a tobacco product, or to verify a record, report, or information submitted under this chapter.

In prescribing regulations under this subsection, the Secretary shall have due regard for the professional ethics of the medical profession and the interests of patients. The prohibitions of paragraph (6) continue to apply to records, reports, and information concerning any individual who has been a patient, irrespective of whether or when he ceases to be a patient.

“(b) REPORTS OF REMOVALS AND CORRECTIONS.—

“(1) IN GENERAL.—Except as provided in paragraph (2), the Secretary shall by regulation require a tobacco product manufacturer or importer of a tobacco product to report promptly to the Secretary any corrective action taken or removal from the market of a tobacco product undertaken by such manufacturer or importer if the removal or correction was undertaken—

“(A) to reduce a risk to health posed by the tobacco product; or

“(B) to remedy a violation of this chapter caused by the tobacco product which may present a risk to health.



A tobacco product manufacturer or importer of a tobacco product who undertakes a corrective action or removal from the market of a tobacco product which is not required to be reported under this subsection shall keep a record of such correction or removal.

“(2) EXCEPTION.—No report of the corrective action or removal of a tobacco product may be required under paragraph (1) if a report of the corrective action or removal is required and has been submitted under subsection (a).

**“SEC. 910. APPLICATION FOR REVIEW OF CERTAIN TOBACCO PRODUCTS.**

“(a) IN GENERAL.—

“(1) NEW TOBACCO PRODUCT DEFINED.—For purposes of this section the term ‘new tobacco product’ means—

“(A) any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of June 1, 2003; or

“(B) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after June 1, 2003.

“(2) PREMARKET APPROVAL REQUIRED.—

“(A) NEW PRODUCTS.—Approval under this section of an application for premarket approval for any new tobacco product is required unless—

“(i) the manufacturer has submitted a report under section 905(j); and

“(ii) the Secretary has issued an order that the tobacco product—

“(I) is substantially equivalent to a tobacco product commercially marketed (other than for test marketing) in the United States as of June 1, 2003; and

“(II)(aa) is in compliance with the requirements of this Act; or

“(bb) is exempt from the requirements of section 905(j) pursuant to a regulation issued under section 905(j)(3).

“(B) APPLICATION TO CERTAIN POST JUNE 1, 2003 PRODUCTS.—Subparagraph (A) shall not apply to a tobacco product—

“(i) that was first introduced or delivered for introduction into interstate commerce for commercial distribution in the United States after June 1, 2003, and prior to the date that is 15 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act; and

“(ii) for which a report was submitted under section 905(j) within such 15-month period, until the Secretary issues an order that the tobacco product is not substantially equivalent.

“(3) SUBSTANTIALLY EQUIVALENT DEFINED.—

“(A) IN GENERAL.—In this section and section 905(j), the terms ‘substantially equivalent’ or ‘substantial equivalence’ mean, with respect to the tobacco product being compared to the predicate tobacco product, that the Secretary by order has found that the tobacco product—

“(i) has the same characteristics as the predicate tobacco product; or

“(ii) has different characteristics and the information submitted contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that it is not appropriate to regulate the product under this section because the product does not raise different questions of public health.

“(B) CHARACTERISTICS.—In subparagraph (A), the term ‘characteristics’ means the materials, ingredients, design, composition, heating source, or other features of a tobacco product.

“(C) LIMITATION.—A tobacco product may not be found to be substantially equivalent to a predicate tobacco product that has been removed from the market at the initiative of the Secretary or that has been determined by a judicial order to be misbranded or adulterated.

“(4) HEALTH INFORMATION.—

“(A) SUMMARY.—As part of a submission under section 905(j) respecting a tobacco product, the person required to file a premarket notification under such section shall provide an adequate summary of any health information related to the tobacco product or state that such information will be made available upon request by any person.

“(B) REQUIRED INFORMATION.—Any summary under subparagraph (A) respecting a tobacco product shall contain detailed information regarding data concerning adverse health effects and shall be made available to the public by the Secretary within 30 days of the issuance of a determination that such tobacco product is substantially equivalent to another tobacco product.

“(b) APPLICATION.—

“(1) CONTENTS.—An application for premarket approval shall contain—

“(A) full reports of all information, published or known to, or which should reasonably be known to, the applicant, concerning investigations which have been made to show the health risks of such tobacco product and whether such tobacco product presents less risk than other tobacco products;

“(B) a full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation, of such tobacco product;

“(C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such tobacco product;

“(D) an identifying reference to any tobacco product standard under section 907 which would be applicable to any aspect of such tobacco product, and either adequate information to show that such aspect of such tobacco product fully meets such tobacco product standard or adequate information to justify any deviation from such standard;

“(E) such samples of such tobacco product and of components thereof as the Secretary may reasonably require;

“(F) specimens of the labeling proposed to be used for such tobacco product; and

“(G) such other information relevant to the subject matter of the application as the Secretary may require.

“(2) REFERENCE TO TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE.—Upon receipt of an application meeting the requirements set forth in paragraph (1), the Secretary—

“(A) may, on the Secretary’s own initiative; or

“(B) may, upon the request of an applicant, refer such application to the Tobacco Products Scientific Advisory Committee for reference and for submission (within such period as the Secretary may establish) of a report and recommendation respecting approval of the application, together with all underlying data and the reasons or basis for the recommendation.

“(c) ACTION ON APPLICATION.—

“(1) DEADLINE.—

“(A) IN GENERAL.—As promptly as possible, but in no event later than 180 days after the receipt of an application under subsection (b), the Secretary, after considering the report and recommendation submitted under paragraph (2) of such subsection, shall—

“(i) issue an order approving the application if the Secretary finds that none of the grounds for denying approval specified in paragraph (2) of this subsection applies; or

“(ii) deny approval of the application if the Secretary finds (and sets forth the basis for such finding as part of or accompanying such denial) that 1 or more grounds for denial specified in paragraph (2) of this subsection apply.

“(B) RESTRICTIONS ON SALE AND DISTRIBUTION.—An order approving an application for a tobacco product may require as a condition to such approval that the sale and distribution of the tobacco product be restricted but only to the extent that the sale and distribution of a tobacco product may be restricted under a regulation under section 906(d).

“(2) DENIAL OF APPROVAL.—The Secretary shall deny approval of an application for a tobacco product if, upon the basis of the information submitted to the Secretary as part of the application and any other information before the Secretary with respect to such tobacco product, the Secretary finds that—

“(A) there is a lack of a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health;

“(B) the methods used in, or the facilities or controls used for, the manufacture, processing, or packing of such tobacco product do not conform to the requirements of section 906(e);

“(C) based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular; or

“(D) such tobacco product is not shown to conform in all respects to a tobacco product standard in effect under section 907, compliance with which is a condition to approval of the application, and there is a lack of adequate information to justify the deviation from such standard.

“(3) DENIAL INFORMATION.—Any denial of an application shall, insofar as the Secretary determines to be practicable, be accompanied by a statement informing the applicant of the measures required to place such application in approvable form (which measures may include further research by the applicant in accordance with 1 or more protocols prescribed by the Secretary).

“(4) BASIS FOR FINDING.—For purposes of this section, the finding as to whether approval of a tobacco product is appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account—

“(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and

“(B) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

“(5) BASIS FOR ACTION.—

“(A) INVESTIGATIONS.—For purposes of paragraph (2)(A), whether permitting a tobacco product to be marketed would be appropriate for the protection of the public health shall, when appropriate, be determined on the basis of well-controlled investigations, which may include 1 or more clinical investigations by experts qualified by training and experience to evaluate the tobacco product.

“(B) OTHER EVIDENCE.—If the Secretary determines that there exists valid scientific evidence (other than evidence derived from investigations described in subparagraph (A)) which is sufficient to evaluate the tobacco product the Secretary may authorize

that the determination for purposes of paragraph (2)(A) be made on the basis of such evidence.

“(d) WITHDRAWAL AND TEMPORARY SUSPENSION.—

“(1) IN GENERAL.—The Secretary shall, upon obtaining, where appropriate, advice on scientific matters from an advisory committee, and after due notice and opportunity for informal hearing to the holder of an approved application for a tobacco product, issue an order withdrawing approval of the application if the Secretary finds—

“(A) that the continued marketing of such tobacco product no longer is appropriate for the protection of the public health;

“(B) that the application contained or was accompanied by an untrue statement of a material fact;

“(C) that the applicant—

“(i) has failed to establish a system for maintaining records, or has repeatedly or deliberately failed to maintain records or to make reports, required by an applicable regulation under section 909;

“(ii) has refused to permit access to, or copying or verification of, such records as required by section 704; or

“(iii) has not complied with the requirements of section 905;

“(D) on the basis of new information before the Secretary with respect to such tobacco product, evaluated together with the evidence before the Secretary when the application was approved, that the methods used in, or the facilities and controls used for, the manufacture, processing, packing, or installation of such tobacco product do not conform with the requirements of section 906(e) and were not brought into conformity with such requirements within a reasonable time after receipt of written notice from the Secretary of nonconformity;

“(E) on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when the application was approved, that the labeling of such tobacco product, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary of such fact; or

“(F) on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when the application was approved, that such tobacco product is not shown to conform in all respects to a tobacco product standard which is in effect under section 907, compliance with which was a condition to approval of the application, and that there is a lack of adequate information to justify the deviation from such standard.

“(2) APPEAL.—The holder of an application subject to an order issued under paragraph (1) withdrawing approval of the application may, by petition filed on or before the 30th day after the date upon which such holder receives notice of such withdrawal, obtain review thereof in accordance with subsection (e).

“(3) TEMPORARY SUSPENSION.—If, after providing an opportunity for an informal hearing, the Secretary determines there is reasonable probability that the continuation of distribution of a tobacco product under an approved application would cause serious, adverse health consequences or death, that is greater than ordinarily caused by tobacco products on the market, the Secretary shall by order temporarily suspend the approval of the application approved under this section. If the Secretary issues such an order, the

Secretary shall proceed expeditiously under paragraph (1) to withdraw such application.

“(e) SERVICE OF ORDER.—An order issued by the Secretary under this section shall be served—

“(1) in person by any officer or employee of the department designated by the Secretary; or

“(2) by mailing the order by registered mail or certified mail addressed to the applicant at the applicant's last known address in the records of the Secretary.

“(f) RECORDS.—

“(1) ADDITIONAL INFORMATION.—In the case of any tobacco product for which an approval of an application filed under subsection (b) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, as the Secretary may by regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination of, whether there is or may be grounds for withdrawing or temporarily suspending such approval.

“(2) ACCESS TO RECORDS.—Each person required under this section to maintain records, and each person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

“(g) INVESTIGATIONAL TOBACCO PRODUCT EXEMPTION FOR INVESTIGATIONAL USE.—The Secretary may exempt tobacco products intended for investigational use from the provisions of this chapter under such conditions as the Secretary may by regulation prescribe.

#### “SEC. 911. MODIFIED RISK TOBACCO PRODUCTS.

“(a) IN GENERAL.—No person may introduce or deliver for introduction into interstate commerce any modified risk tobacco product unless approval of an application filed pursuant to subsection (d) is effective with respect to such product.

“(b) DEFINITIONS.—In this section:

“(1) MODIFIED RISK TOBACCO PRODUCT.—The term ‘modified risk tobacco product’ means any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products.

“(2) SOLD OR DISTRIBUTED.—

“(A) IN GENERAL.—With respect to a tobacco product, the term ‘sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products’ means a tobacco product—

“(A) the label, labeling, or advertising of which represents explicitly or implicitly that—

“(I) the tobacco product presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products;

“(II) the tobacco product or its smoke contains a reduced level of a substance or presents a reduced exposure to a substance; or

“(III) the tobacco product or its smoke does not contain or is free of a substance;

“(ii) the label, labeling, or advertising of which uses the descriptors ‘light’, ‘mild’, or ‘low’ or similar descriptors; or

“(iii) the tobacco product manufacturer of which has taken any action directed to consumers through the media or otherwise, other than by means of the tobacco product's label, labeling or advertising, after the date of enactment of the Family Smoking Pre-

vention and Tobacco Control Act, respecting the product that would be reasonably expected to result in consumers believing that the tobacco product or its smoke may present a lower risk of disease or is less harmful than one or more commercially marketed tobacco products, or presents a reduced exposure to, or does not contain or is free of, a substance or substances.

“(B) LIMITATION.—No tobacco product shall be considered to be ‘sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products’, except as described in subparagraph (A).

“(c) TOBACCO DEPENDENCE PRODUCTS.—A product that is intended to be used for the treatment of tobacco dependence, including smoking cessation, is not a modified risk tobacco product under this section and is subject to the requirements of chapter V.

“(d) FILING.—Any person may file with the Secretary an application for a modified risk tobacco product. Such application shall include—

“(1) a description of the proposed product and any proposed advertising and labeling;

“(2) the conditions for using the product;

“(3) the formulation of the product;

“(4) sample product labels and labeling;

“(5) all documents (including underlying scientific information) relating to research findings conducted, supported, or possessed by the tobacco product manufacturer relating to the effect of the product on tobacco related diseases and health-related conditions, including information both favorable and unfavorable to the ability of the product to reduce risk or exposure and relating to human health;

“(6) data and information on how consumers actually use the tobacco product; and

“(7) such other information as the Secretary may require.

“(e) PUBLIC AVAILABILITY.—The Secretary shall make the application described in subsection (d) publicly available (except matters in the application which are trade secrets or otherwise confidential, commercial information) and shall request comments by interested persons on the information contained in the application and on the label, labeling, and advertising accompanying such application.

“(f) ADVISORY COMMITTEE.—

“(1) IN GENERAL.—The Secretary shall refer to an advisory committee any application submitted under this subsection.

“(2) RECOMMENDATIONS.—Not later than 60 days after the date an application is referred to an advisory committee under paragraph (1), the advisory committee shall report its recommendations on the application to the Secretary.

“(g) APPROVAL.—

“(1) MODIFIED RISK PRODUCTS.—Except as provided in paragraph (2), the Secretary shall approve an application for a modified risk tobacco product filed under this section only if the Secretary determines that the applicant has demonstrated that such product, as it is actually used by consumers, will—

“(A) significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and

“(B) benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.

“(2) SPECIAL RULE FOR CERTAIN PRODUCTS.—

“(A) IN GENERAL.—The Secretary may approve an application for a tobacco product that has not been approved as a modified risk tobacco product pursuant to paragraph

(1) if the Secretary makes the findings required under this paragraph and determines that the applicant has demonstrated that—

“(i) the approval of the application would be appropriate to promote the public health;

“(ii) any aspect of the label, labeling, and advertising for such product that would cause the tobacco product to be a modified risk tobacco product under subsection (b)(2) is limited to an explicit or implicit representation that such tobacco product or its smoke contains or is free of a substance or contains a reduced level of a substance, or presents a reduced exposure to a substance in tobacco smoke.

“(iii) scientific evidence is not available and, using the best available scientific methods, cannot be made available without conducting long-term epidemiological studies for an application to meet the standards set forth in paragraph (1); and

“(iv) the scientific evidence that is available without conducting long-term epidemiological studies demonstrates that a measurable and substantial reduction in morbidity or mortality among individual tobacco users is anticipated in subsequent studies.

“(B) ADDITIONAL FINDINGS REQUIRED.—In order to approve an application under subparagraph (A) the Secretary must also find that the applicant has demonstrated that—

“(i) the magnitude of the overall reductions in exposure to the substance or substances which are the subject of the application is substantial, such substance or substances are harmful, and the product as actually used exposes consumers to the specified reduced level of the substance or substances;

“(ii) the product as actually used by consumers will not expose them to higher levels of other harmful substances compared to the similar types of tobacco products then on the market unless such increases are minimal and the anticipated overall impact of use of the product remains a substantial and measurable reduction in overall morbidity and mortality among individual tobacco users;

“(iii) testing of actual consumer perception shows that, as the applicant proposes to label and market the product, consumers will not be misled into believing that the product—

“(I) is or has been demonstrated to be less harmful; or

“(II) presents or has been demonstrated to present less of a risk of disease than 1 or more other commercially marketed tobacco products; and

“(iv) approval of the application is expected to benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.

“(C) CONDITIONS OF APPROVAL.—

“(i) IN GENERAL.—Applications approved under this paragraph shall be limited to a term of not more than 5 years, but may be renewed upon a finding by the Secretary that the requirements of this paragraph continue to be satisfied based on the filing of a new application.

“(ii) AGREEMENTS BY APPLICANT.—Applications approved under this paragraph shall be conditioned on the applicant's agreement to conduct post-market surveillance and studies and to submit to the Secretary the results of such surveillance and studies to determine the impact of the application approval on consumer perception, behavior, and health and to enable the Secretary to review the accuracy of the determinations upon which the approval was based in ac-

cordance with a protocol approved by the Secretary.

“(iii) ANNUAL SUBMISSION.—The results of such post-market surveillance and studies described in clause (ii) shall be submitted annually.

“(3) BASIS.—The determinations under paragraphs (1) and (2) shall be based on—

“(A) the scientific evidence submitted by the applicant; and

“(B) scientific evidence and other information that is available to the Secretary.

“(4) BENEFIT TO HEALTH OF INDIVIDUALS AND OF POPULATION AS A WHOLE.—In making the determinations under paragraphs (1) and (2), the Secretary shall take into account—

“(A) the relative health risks to individuals of the tobacco product that is the subject of the application;

“(B) the increased or decreased likelihood that existing users of tobacco products who would otherwise stop using such products will switch to the tobacco product that is the subject of the application;

“(C) the increased or decreased likelihood that persons who do not use tobacco products will start using the tobacco product that is the subject of the application;

“(D) the risks and benefits to persons from the use of the tobacco product that is the subject of the application as compared to the use of products for smoking cessation approved under chapter V to treat nicotine dependence; and

“(E) comments, data, and information submitted by interested persons.

“(h) ADDITIONAL CONDITIONS FOR APPROVAL.—

“(1) MODIFIED RISK PRODUCTS.—The Secretary shall require for the approval of an application under this section that any advertising or labeling concerning modified risk products enable the public to comprehend the information concerning modified risk and to understand the relative significance of such information in the context of total health and in relation to all of the diseases and health-related conditions associated with the use of tobacco products.

“(2) COMPARATIVE CLAIMS.—

“(A) IN GENERAL.—The Secretary may require for the approval of an application under this subsection that a claim comparing a tobacco product to 1 or more other commercially marketed tobacco products shall compare the tobacco product to a commercially marketed tobacco product that is representative of that type of tobacco product on the market (for example the average value of the top 3 brands of an established regular tobacco product).

“(B) QUANTITATIVE COMPARISONS.—The Secretary may also require, for purposes of subparagraph (A), that the percent (or fraction) of change and identity of the reference tobacco product and a quantitative comparison of the amount of the substance claimed to be reduced shall be stated in immediate proximity to the most prominent claim.

“(3) LABEL DISCLOSURE.—

“(A) IN GENERAL.—The Secretary may require the disclosure on the label of other substances in the tobacco product, or substances that may be produced by the consumption of that tobacco product, that may affect a disease or health-related condition or may increase the risk of other diseases or health-related conditions associated with the use of tobacco products.

“(B) CONDITIONS OF USE.—If the conditions of use of the tobacco product may affect the risk of the product to human health, the Secretary may require the labeling of conditions of use.

“(4) TIME.—The Secretary shall limit an approval under subsection (g)(1) for a specified period of time.

“(5) ADVERTISING.—The Secretary may require that an applicant, whose application has been approved under this subsection, comply with requirements relating to advertising and promotion of the tobacco product.

“(i) POSTMARKET SURVEILLANCE AND STUDIES.—

“(1) IN GENERAL.—The Secretary shall require that an applicant under subsection (g)(1) conduct post market surveillance and studies for a tobacco product for which an application has been approved to determine the impact of the application approval on consumer perception, behavior, and health, to enable the Secretary to review the accuracy of the determinations upon which the approval was based, and to provide information that the Secretary determines is otherwise necessary regarding the use or health risks involving the tobacco product. The results of post-market surveillance and studies shall be submitted to the Secretary on an annual basis.

“(2) SURVEILLANCE PROTOCOL.—Each applicant required to conduct a surveillance of a tobacco product under paragraph (1) shall, within 30 days after receiving notice that the applicant is required to conduct such surveillance, submit, for the approval of the Secretary, a protocol for the required surveillance. The Secretary, within 60 days of the receipt of such protocol, shall determine if the principal investigator proposed to be used in the surveillance has sufficient qualifications and experience to conduct such surveillance and if such protocol will result in collection of the data or other information designated by the Secretary as necessary to protect the public health.

“(j) WITHDRAWAL OF APPROVAL.—The Secretary, after an opportunity for an informal hearing, shall withdraw the approval of an application under this section if the Secretary determines that—

“(1) the applicant, based on new information, can no longer make the demonstrations required under subsection (g), or the Secretary can no longer make the determinations required under subsection (g);

“(2) the application failed to include material information or included any untrue statement of material fact;

“(3) any explicit or implicit representation that the product reduces risk or exposure is no longer valid, including if—

“(A) a tobacco product standard is established pursuant to section 907;

“(B) an action is taken that affects the risks presented by other commercially marketed tobacco products that were compared to the product that is the subject of the application; or

“(C) any postmarket surveillance or studies reveal that the approval of the application is no longer consistent with the protection of the public health;

“(4) the applicant failed to conduct or submit the postmarket surveillance and studies required under subsection (g)(2)(C)(ii) or (i); or

“(5) the applicant failed to meet a condition imposed under subsection (h).

“(k) CHAPTER IV OR V.—A product approved in accordance with this section shall not be subject to chapter IV or V.

“(l) IMPLEMENTING REGULATIONS OR GUIDANCE.—

“(1) SCIENTIFIC EVIDENCE.—Not later than 2 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall issue regulations or guidance (or any combination

thereof) on the scientific evidence required for assessment and ongoing review of modified risk tobacco products. Such regulations or guidance shall—

“(A) establish minimum standards for scientific studies needed prior to approval to show that a substantial reduction in morbidity or mortality among individual tobacco users is likely;

“(B) include validated biomarkers, intermediate clinical endpoints, and other feasible outcome measures, as appropriate;

“(C) establish minimum standards for post market studies, that shall include regular and long-term assessments of health outcomes and mortality, intermediate clinical endpoints, consumer perception of harm reduction, and the impact on quitting behavior and new use of tobacco products, as appropriate;

“(D) establish minimum standards for required postmarket surveillance, including ongoing assessments of consumer perception; and

“(E) require that data from the required studies and surveillance be made available to the Secretary prior to the decision on renewal of a modified risk tobacco product.

“(2) CONSULTATION.—The regulations or guidance issued under paragraph (1) shall be developed in consultation with the Institute of Medicine, and with the input of other appropriate scientific and medical experts, on the design and conduct of such studies and surveillance.

“(3) REVISION.—The regulations or guidance under paragraph (1) shall be revised on a regular basis as new scientific information becomes available.

“(4) NEW TOBACCO PRODUCTS.—Not later than 2 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall issue a regulation or guidance that permits the filing of a single application for any tobacco product that is a new tobacco product under section 910 and for which the applicant seeks approval as a modified risk tobacco product under this section.

“(m) DISTRIBUTORS.—No distributor may take any action, after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, with respect to a tobacco product that would reasonably be expected to result in consumers believing that the tobacco product or its smoke may present a lower risk of disease or is less harmful than one or more commercially marketed tobacco products, or presents a reduced exposure to, or does not contain or is free of, a substance or substances.

#### “SEC. 912. JUDICIAL REVIEW.

“(a) RIGHT TO REVIEW.—

“(1) IN GENERAL.—Not later than 30 days after—

“(A) the promulgation of a regulation under section 907 establishing, amending, or revoking a tobacco product standard; or

“(B) a denial of an application for approval under section 910(c),

any person adversely affected by such regulation or denial may file a petition for judicial review of such regulation or denial with the United States Court of Appeals for the District of Columbia or for the circuit in which such person resides or has their principal place of business.

“(2) REQUIREMENTS.—

“(A) COPY OF PETITION.—A copy of the petition filed under paragraph (1) shall be transmitted by the clerk of the court involved to the Secretary.

“(B) RECORD OF PROCEEDINGS.—On receipt of a petition under subparagraph (A), the

Secretary shall file in the court in which such petition was filed—

“(i) the record of the proceedings on which the regulation or order was based; and

“(ii) a statement of the reasons for the issuance of such a regulation or order.

“(C) DEFINITION OF RECORD.—In this section, the term ‘record’ means—

“(i) all notices and other matter published in the Federal Register with respect to the regulation or order reviewed;

“(ii) all information submitted to the Secretary with respect to such regulation or order;

“(iii) proceedings of any panel or advisory committee with respect to such regulation or order;

“(iv) any hearing held with respect to such regulation or order; and

“(v) any other information identified by the Secretary, in the administrative proceeding held with respect to such regulation or order, as being relevant to such regulation or order.

“(b) STANDARD OF REVIEW.—Upon the filing of the petition under subsection (a) for judicial review of a regulation or order, the court shall have jurisdiction to review the regulation or order in accordance with chapter 7 of title 5, United States Code, and to grant appropriate relief, including interim relief, as provided for in such chapter. A regulation or denial described in subsection (a) shall be reviewed in accordance with section 706(2)(A) of title 5, United States Code.

“(c) FINALITY OF JUDGMENT.—The judgment of the court affirming or setting aside, in whole or in part, any regulation or order shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification, as provided in section 1254 of title 28, United States Code.

“(d) OTHER REMEDIES.—The remedies provided for in this section shall be in addition to, and not in lieu of, any other remedies provided by law.

“(e) REGULATIONS AND ORDERS MUST RECITE BASIS IN RECORD.—To facilitate judicial review, a regulation or order issued under section 906, 907, 908, 909, 910, or 916 shall contain a statement of the reasons for the issuance of such regulation or order in the record of the proceedings held in connection with its issuance.

#### “SEC. 913. EQUAL TREATMENT OF RETAIL OUTLETS.

“The Secretary shall issue regulations to require that retail establishments for which the predominant business is the sale of tobacco products comply with any advertising restrictions applicable to retail establishments accessible to individuals under the age of 18.

#### “SEC. 914. JURISDICTION OF AND COORDINATION WITH THE FEDERAL TRADE COMMISSION.

“(a) JURISDICTION.—

“(1) IN GENERAL.—Except where expressly provided in this chapter, nothing in this chapter shall be construed as limiting or diminishing the authority of the Federal Trade Commission to enforce the laws under its jurisdiction with respect to the advertising, sale, or distribution of tobacco products.

“(2) ENFORCEMENT.—Any advertising that violates this chapter or a provision of the regulations referred to in section 12 of the Family Smoking Prevention and Tobacco Control Act, is an unfair or deceptive act or practice under section 5(a) of the Federal Trade Commission Act (15 U.S.C. 45(a)) and shall be considered a violation of a rule promulgated under section 18 of that Act (15 U.S.C. 57a).

“(b) COORDINATION.—With respect to the requirements of section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) and section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4402)—

“(1) the Chairman of the Federal Trade Commission shall coordinate with the Secretary concerning the enforcement of such Act as such enforcement relates to unfair or deceptive acts or practices in the advertising of cigarettes or smokeless tobacco; and

“(2) the Secretary shall consult with the Chairman of such Commission in revising the label statements and requirements under such sections.

#### “SEC. 915. CONGRESSIONAL REVIEW PROVISIONS.

“In accordance with section 801 of title 5, United States Code, Congress shall review, and may disapprove, any rule under this chapter that is subject to section 801. This section and section 801 do not apply to the regulations referred to in section 12 of the Family Smoking Prevention and Tobacco Control Act.

#### “SEC. 916. REGULATION REQUIREMENT.

“(a) TESTING, REPORTING, AND DISCLOSURE.—Not later than 24 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary, acting through the Commissioner of the Food and Drug Administration, shall promulgate regulations under this Act that meet the requirements of subsection (b).

“(b) CONTENTS OF RULES.—The regulations promulgated under subsection (a) shall require testing and reporting of tobacco product constituents, ingredients, and additives, including smoke constituents, by brand and sub-brand that the Secretary determines should be tested to protect the public health. The regulations may require that tobacco product manufacturers, packagers, or importers make disclosures relating to the results of the testing of tar and nicotine through labels or advertising or other appropriate means, and make disclosures regarding the results of the testing of other constituents, including smoke constituents, ingredients, or additives, that the Secretary determines should be disclosed to the public to protect the public health and will not mislead consumers about the risk of tobacco related disease.

“(c) AUTHORITY.—The Food and Drug Administration shall have the authority under this chapter to conduct or to require the testing, reporting, or disclosure of tobacco product constituents, including smoke constituents.

#### “SEC. 917. PRESERVATION OF STATE AND LOCAL AUTHORITY.

“(a) IN GENERAL.—

“(1) PRESERVATION.—Nothing in this chapter, or rules promulgated under this chapter, shall be construed to limit the authority of a Federal agency (including the Armed Forces), a State or political subdivision of a State, or the government of an Indian tribe to enact, adopt, promulgate, and enforce any law, rule, regulation, or other measure with respect to tobacco products that is in addition to, or more stringent than, requirements established under this chapter, including a law, rule, regulation, or other measure relating to or 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 tobacco products. No provision of this chapter shall limit or otherwise affect any State, Tribal, or local taxation of tobacco products.

“(2) PREEMPTION OF CERTAIN STATE AND LOCAL REQUIREMENTS.—

“(A) IN GENERAL.—Except as provided in paragraph (1) and subparagraph (B), no State or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under the provisions of this chapter relating to tobacco product standards, premarket approval, adulteration, misbranding, labeling, registration, good manufacturing standards, or reduced risk products.

“(B) EXCEPTION.—Subparagraph (A) does not apply to requirements relating to the sale, distribution, possession, information reporting to the State, exposure to, access to, the advertising and promotion of, or use of, tobacco products by individuals of any age, or relating to fire safety standards for tobacco products. Information disclosed to a State under subparagraph (A) that is exempt from disclosure under section 554(b)(4) of title 5, United States Code, shall be treated as trade secret and confidential information by the State.

“(b) RULE OF CONSTRUCTION REGARDING PRODUCT LIABILITY.—No provision of this chapter relating to a tobacco product shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.

**“SEC. 918. TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE.**

“(a) ESTABLISHMENT.—Not later than 1 year after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall establish a 11-member advisory committee, to be known as the ‘Tobacco Products Scientific Advisory Committee’.

“(b) MEMBERSHIP.—

“(1) IN GENERAL.—

“(A) MEMBERS.—The Secretary shall appoint as members of the Tobacco Products Scientific Advisory Committee individuals who are technically qualified by training and experience in the medicine, medical ethics, science, or technology involving the manufacture, evaluation, or use of tobacco products, who are of appropriately diversified professional backgrounds. The committee shall be composed of—

“(i) 7 individuals who are physicians, dentists, scientists, or health care professionals practicing in the area of oncology, pulmonology, cardiology, toxicology, pharmacology, addiction, or any other relevant specialty;

“(ii) 1 individual who is an officer or employee of a State or local government or of the Federal Government;

“(iii) 1 individual as a representative of the general public;

“(iv) 1 individual as a representative of the interests in the tobacco manufacturing industry; and

“(v) 1 individual as a representative of the interests of the tobacco growers.

“(B) NONVOTING MEMBERS.—The members of the committee appointed under clauses (iv) and (v) of subparagraph (A) shall serve as consultants to those described in clauses (i) through (iii) of subparagraph (A) and shall be nonvoting representatives.

“(2) LIMITATION.—The Secretary may not appoint to the Advisory Committee any individual who is in the regular full-time employ of the Food and Drug Administration or any agency responsible for the enforcement of this Act. The Secretary may appoint Federal officials as ex officio members.

“(3) CHAIRPERSON.—The Secretary shall designate 1 of the members of the Advisory Committee to serve as chairperson.

“(c) DUTIES.—The Tobacco Products Scientific Advisory Committee shall provide advice, information, and recommendations to the Secretary—

“(1) as provided in this chapter;

“(2) on the effects of the alteration of the nicotine yields from tobacco products;

“(3) on whether there is a threshold level below which nicotine yields do not produce dependence on the tobacco product involved; and

“(4) on its review of other safety, dependence, or health issues relating to tobacco products as requested by the Secretary.

“(d) COMPENSATION; SUPPORT; FACA.—

“(1) COMPENSATION AND TRAVEL.—Members of the Advisory Committee who are not officers or employees of the United States, while attending conferences or meetings of the committee or otherwise engaged in its business, shall be entitled to receive compensation at rates to be fixed by the Secretary, which may not exceed the daily equivalent of the rate in effect for level 4 of the Senior Executive Schedule under section 5382 of title 5, United States Code, for each day (including travel time) they are so engaged; and while so serving away from their homes or regular places of business each member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5, United States Code, for persons in the Government service employed intermittently.

“(2) ADMINISTRATIVE SUPPORT.—The Secretary shall furnish the Advisory Committee clerical and other assistance.

“(3) NONAPPLICATION OF FACA.—Section 14 of the Federal Advisory Committee Act (5 U.S.C. App.) does not apply to the Advisory Committee.

“(e) PROCEEDINGS OF ADVISORY PANELS AND COMMITTEES.—The Advisory Committee shall make and maintain a transcript of any proceeding of the panel or committee. Each such panel and committee shall delete from any transcript made under this subsection information which is exempt from disclosure under section 552(b) of title 5, United States Code.

**“SEC. 919. DRUG PRODUCTS USED TO TREAT TOBACCO DEPENDENCE.**

The Secretary shall consider—

“(1) at the request of the applicant, designating nicotine replacement products as fast track research and approval products within the meaning of section 506;

“(2) direct the Commissioner to consider approving the extended use of nicotine replacement products (such as nicotine patches, nicotine gum, and nicotine lozenges) for the treatment of tobacco dependence;

“(3) review and consider the evidence for additional indications for nicotine replacement products, such as for craving relief or relapse prevention; and

“(4) consider—

“(A) relieving companies of premarket burdens under section 505 if the requirement is redundant considering other nicotine replacement therapies already on the market; and

“(B) time and extent applications for nicotine replacement therapies that have been approved by a regulatory body in a foreign country and have marketing experience in such country.

**“SEC. 920. USER FEE.**

“(a) ESTABLISHMENT OF QUARTERLY USER FEE.—The Secretary shall assess a quarterly user fee with respect to every quarter of each fiscal year commencing fiscal year 2004, calculated in accordance with this section, upon each manufacturer and importer of tobacco products subject to this chapter.

“(b) FUNDING OF FDA REGULATION OF TOBACCO PRODUCTS.—The Secretary shall make user fees collected pursuant to this section available to pay, in each fiscal year, for the costs of the activities of the Food and Drug Administration related to the regulation of tobacco products under this chapter.

“(c) ASSESSMENT OF USER FEE.—

“(1) AMOUNT OF ASSESSMENT.—Except as provided in paragraph (4), the total user fees assessed each year pursuant to this section shall be sufficient, and shall not exceed what is necessary, to pay for the costs of the activities described in subsection (b) for each fiscal year.

“(2) ALLOCATION OF ASSESSMENT BY CLASS OF TOBACCO PRODUCTS.—

“(A) IN GENERAL.—Subject to paragraph (3), the total user fees assessed each fiscal year with respect to each class of importers and manufacturers shall be equal to an amount that is the applicable percentage of the total costs of activities of the Food and Drug Administration described in subsection (b).

“(B) APPLICABLE PERCENTAGE.—For purposes of subparagraph (A) the applicable percentage for a fiscal year shall be the following:

“(i) 92.07 percent shall be assessed on manufacturers and importers of cigarettes;

“(ii) 0.05 percent shall be assessed on manufacturers and importers of little cigars;

“(iii) 7.15 percent shall be assessed on manufacturers and importers of cigars other than little cigars;

“(iv) 0.43 percent shall be assessed on manufacturers and importers of snuff;

“(v) 0.10 percent shall be assessed on manufacturers and importers of chewing tobacco;

“(vi) 0.06 percent shall be assessed on manufacturers and importers of pipe tobacco; and

“(vii) 0.14 percent shall be assessed on manufacturers and importers of roll-your-own tobacco.

“(3) DISTRIBUTION OF FEE SHARES OF MANUFACTURERS AND IMPORTERS EXEMPT FROM USER FEE.—Where a class of tobacco products is not subject to a user fee under this section, the portion of the user fee assigned to such class under subsection (d)(2) shall be allocated by the Secretary on a pro rata basis among the classes of tobacco products that are subject to a user fee under this section. Such pro rata allocation for each class of tobacco products that are subject to a user fee under this section shall be the quotient of—

“(A) the sum of the percentages assigned to all classes of tobacco products subject to this section; divided by

“(B) the percentage assigned to such class under paragraph (2).

“(4) ANNUAL LIMIT ON ASSESSMENT.—The total assessment under this section—

“(A) for fiscal year 2004 shall be \$85,000,000;

“(B) for fiscal year 2005 shall be \$175,000,000;

“(C) for fiscal year 2006 shall be \$300,000,000;

and

“(D) for each subsequent fiscal year, shall not exceed the limit on the assessment imposed during the previous fiscal year, as adjusted by the Secretary (after notice, published in the Federal Register) to reflect the greater of—

“(i) the total percentage change that occurred in the Consumer Price Index for all urban consumers (all items; United States city average) for the 12-month period ending on June 30 of the preceding fiscal year for which fees are being established; or

“(ii) the total percentage change for the previous fiscal year in basic pay under the General Schedule in accordance with section

5332 of title 5, United States Code, as adjusted by any locality-based comparability payment pursuant to section 5304 of such title for Federal employees stationed in the District of Columbia.

“(5) **TIMING OF USER FEE ASSESSMENT.**—The Secretary shall notify each manufacturer and importer of tobacco products subject to this section of the amount of the quarterly assessment imposed on such manufacturer or importer under subsection (f) during each quarter of each fiscal year. Such notifications shall occur not earlier than 3 months prior to the end of the quarter for which such assessment is made, and payments of all assessments shall be made not later than 60 days after each such notification.

“(d) **DETERMINATION OF USER FEE BY COMPANY MARKET SHARE.**—

“(1) **IN GENERAL.**—The user fee to be paid by each manufacturer or importer of a given class of tobacco products shall be determined in each quarter by multiplying—

“(A) such manufacturer’s or importer’s market share of such class of tobacco products; by

“(B) the portion of the user fee amount for the current quarter to be assessed on manufacturers and importers of such class of tobacco products as determined under subsection (e).

“(2) **NO FEE IN EXCESS OF MARKET SHARE.**—No manufacturer or importer of tobacco products shall be required to pay a user fee in excess of the market share of such manufacturer or importer.

“(e) **DETERMINATION OF VOLUME OF DOMESTIC SALES.**—

“(1) **IN GENERAL.**—The calculation of gross domestic volume of a class of tobacco product by a manufacturer or importer, and by all manufacturers and importers as a group, shall be made by the Secretary using information provided by manufacturers and importers pursuant to subsection (f), as well as any other relevant information provided to or obtained by the Secretary.

“(2) **MEASUREMENT.**—For purposes of the calculations under this subsection and the information provided under subsection (f) by the Secretary, gross domestic volume shall be measured by—

“(A) in the case of cigarettes, the number of cigarettes sold;

“(B) in the case of little cigars, the number of little cigars sold;

“(C) in the case of large cigars, the number of cigars weighing more than 3 pounds per thousand sold; and

“(D) in the case of other classes of tobacco products, in terms of number of pounds, or fraction thereof, of these products sold.

“(f) **MEASUREMENT OF GROSS DOMESTIC VOLUME.**—

“(1) **IN GENERAL.**—Each manufacturer and importer of tobacco products shall submit to the Secretary a certified copy of each of the returns or forms described by this paragraph that are required to be filed with a Government agency on the same date that those returns or forms are filed, or required to be filed, with such agency. The returns and forms described by this paragraph are those returns and forms related to the release of tobacco products into domestic commerce, as defined by section 5702(k) of the Internal Revenue Code of 1986, and the repayment of the taxes imposed under chapter 52 of such Code (ATF Form 500.24 and United States Customs Form 7501 under currently applicable regulations).

“(2) **PENALTIES.**—Any person that knowingly fails to provide information required under this subsection or that provides false

information under this subsection shall be subject to the penalties described in section 1003 of title 18, United States Code. In addition, such person may be subject to a civil penalty in an amount not to exceed 2 percent of the value of the kind of tobacco products manufactured or imported by such person during the applicable quarter, as determined by the Secretary.

“(h) **EFFECTIVE DATE.**—The user fees prescribed by this section shall be assessed in fiscal year 2004, based on domestic sales of tobacco products during fiscal year 2003 and shall be assessed in each fiscal year thereafter.”

#### SEC. 12. INTERIM FINAL RULE.

(a) **CIGARETTES AND SMOKELESS TOBACCO.**—

(1) **IN GENERAL.**—Not later than 30 days after the date of enactment of this Act, the Secretary of Health and Human Services shall publish in the Federal Register an interim final rule regarding cigarettes and smokeless tobacco, which is hereby deemed to be in compliance with the Administrative Procedures Act and other applicable law.

(2) **CONTENTS OF RULE.**—Except as provided in this subsection, the interim final rule published under paragraph (1), shall be identical in its provisions to part 897 of the regulations promulgated by the Secretary of Health and Human Services in the August 28, 1996, issue of the Federal Register (61 Fed. Reg., 44615–44618). Such rule shall—

(A) provide for the designation of jurisdictional authority that is in accordance with this subsection;

(B) strike Subpart C—Labeling and section 897.32(c); and

(C) become effective not later than 1 year after the date of enactment of this Act.

(3) **AMENDMENTS TO RULE.**—Prior to making amendments to the rule published under paragraph (1), the Secretary shall promulgate a proposed rule in accordance with the Administrative Procedures Act.

(4) **RULE OF CONSTRUCTION.**—Except as provided in paragraph (3), nothing in this section shall be construed to limit the authority of the Secretary to amend, in accordance with the Administrative Procedures Act, the regulation promulgated pursuant to this section.

(b) **LIMITATION ON ADVISORY OPINIONS.**—As of the date of enactment of this Act, the following documents issued by the Food and Drug Administration shall not constitute advisory opinions under section 10.85(d)(1) of title 21, Code of Federal Regulations, except as they apply to tobacco products, and shall not be cited by the Secretary of Health and Human Services or the Food and Drug Administration as binding precedent:

(1) The preamble to the proposed rule in the document entitled “Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents” (60 Fed. Reg. 43134–43172 (August 11, 1995)).

(2) The document entitled “Nicotine in Cigarettes and Smokeless Tobacco Products is a Drug and These Products Are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act” (60 Fed. Reg. 41453–41787 (August 11, 1995)).

(3) The preamble to the final rule in the document entitled “Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents” (61 Fed. Reg. 44396–44615 (August 28, 1996)).

(4) The document entitled “Nicotine in Cigarettes and Smokeless Tobacco is a Drug and These Products Are Nicotine Delivery Devices Under the Federal Food, Drug, and

Cosmetic Act; Jurisdictional Determination” (61 Fed. Reg. 44619–45318 (August 28, 1996)).

#### SEC. 13. CONFORMING AND OTHER AMENDMENTS TO GENERAL PROVISIONS.

(a) **AMENDMENT OF FEDERAL FOOD, DRUG, AND COSMETIC ACT.**—Except as otherwise expressly provided, whenever in this section an amendment is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference is to a section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(b) **SECTION 301.**—Section 301 (21 U.S.C. 331) is amended—

(1) in subsection (a), by inserting “tobacco product,” after “device,”;

(2) in subsection (b), by inserting “tobacco product,” after “device,”;

(3) in subsection (c), by inserting “tobacco product,” after “device,”;

(4) in subsection (e), by striking “515(f), or 519” and inserting “515(f), 519, or 909”;

(5) in subsection (g), by inserting “tobacco product,” after “device,”;

(6) in subsection (h), by inserting “tobacco product,” after “device,”;

(7) in subsection (j), by striking “708, or 721” and inserting “708, 721, 904, 905, 906, 907, 908, 909, or section 921(b)”;

(8) in subsection (k), by inserting “tobacco product,” after “device,”;

(9) by striking subsection (p) and inserting the following:

“(p) The failure to register in accordance with section 510 or 905, the failure to provide any information required by section 510(j), 510(k), 905(i), or 905(j), or the failure to provide a notice required by section 510(j)(2) or 905(i)(2).”;

(10) by striking subsection (q)(1) and inserting the following:

“(q)(1) The failure or refusal—

“(A) to comply with any requirement prescribed under section 518, 520(g), 903(b)(8), or 908, or condition prescribed under section 903(b)(6)(B)(ii);

“(B) to furnish any notification or other material or information required by or under section 519, 520(g), 904, 909, or section 921; or

“(C) to comply with a requirement under section 522 or 913.”;

(11) in subsection (q)(2), by striking “device,” and inserting “device or tobacco product,”;

(12) in subsection (r), by inserting “or tobacco product” after “device” each time that it appears; and

(13) by adding at the end the following:

“(aa) The sale of tobacco products in violation of a no-tobacco-sale order issued under section 303(f).

“(bb) The introduction or delivery for introduction into interstate commerce of a tobacco product in violation of section 911.

“(cc)(1) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp (including tax stamp), tag, label, or other identification device upon any tobacco product or container or labeling thereof so as to render such tobacco product a counterfeit tobacco product.

“(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other item that is designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any tobacco product or container or labeling thereof so as to render such tobacco product a counterfeit tobacco product.

“(3) The doing of any act that causes a tobacco product to be a counterfeit tobacco

product, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit tobacco product.

“(dd) The charitable distribution of tobacco products.

“(ee) The failure of a manufacturer or distributor to notify the Attorney General of their knowledge of tobacco products used in illicit trade.”.

(c) SECTION 303.—Section 303 (21 U.S.C. 333(f)) is amended in subsection (f)—

(1) by striking the subsection heading and inserting the following:

“(f) CIVIL PENALTIES; NO-TOBACCO-SALE ORDERS.—”;

(2) in paragraph (1)(A), by inserting “or tobacco products” after “devices”;

(3) by redesignating paragraphs (3), (4), and (5) as paragraphs (4), (5), and (6), and inserting after paragraph (2) the following:

“(3) If the Secretary finds that a person has committed repeated violations of restrictions promulgated under section 906(d) at a particular retail outlet then the Secretary may impose a no-tobacco-sale order on that person prohibiting the sale of tobacco products in that outlet. A no-tobacco-sale order may be imposed with a civil penalty under paragraph (1).”;

(4) in paragraph (4) as so redesignated—

(A) in subparagraph (A)—

(i) by striking “assessed” the first time it appears and inserting “assessed, or a no-tobacco-sale order may be imposed,”; and

(ii) by striking “penalty” and inserting “penalty, or upon whom a no-tobacco-order is to be imposed,”;

(B) in subparagraph (B)—

(i) by inserting after “penalty,” the following: “or the period to be covered by a no-tobacco-sale order,”; and

(ii) by adding at the end the following: “A no-tobacco-sale order permanently prohibiting an individual retail outlet from selling tobacco products shall include provisions that allow the outlet, after a specified period of time, to request that the Secretary compromise, modify, or terminate the order.”; and

(C) by adding at the end, the following:

“(D) The Secretary may compromise, modify, or terminate, with or without conditions, any no-tobacco-sale order.”;

(5) in paragraph (5) as so redesignated—

(A) by striking “(3)(A)” as redesignated, and inserting “(4)(A)”;

(B) by inserting “or the imposition of a no-tobacco-sale order” after “penalty” the first 2 places it appears; and

(C) by striking “issued,” and inserting “issued, or on which the no-tobacco-sale order was imposed, as the case may be.”; and

(6) in paragraph (6), as so redesignated, by striking “paragraph (4)” each place it appears and inserting “paragraph (5)”.

(d) SECTION 304.—Section 304 (21 U.S.C. 334) is amended—

(1) in subsection (a)(2)—

(A) by striking “and” before “(D)”;

(B) by striking “device,” and inserting the following: “, (E) Any adulterated or misbranded tobacco product.”;

(2) in subsection (d)(1), by inserting “tobacco product,” after “device,”;

(3) in subsection (g)(1), by inserting “or tobacco product” after “device” each place it appears; and

(4) in subsection (g)(2)(A), by inserting “or tobacco product” after “device” each place it appears.

(e) SECTION 702.—Section 702(a) (21 U.S.C. 372(a)) is amended—

(1) by inserting “(1)” after “(a)”;

(2) by adding at the end thereof the following:

“(2) For a tobacco product, to the extent feasible, the Secretary shall contract with the States in accordance with paragraph (1) to carry out inspections of retailers in connection with the enforcement of this Act.”.

(f) SECTION 703.—Section 703 (21 U.S.C. 373) is amended—

(1) by inserting “tobacco product,” after “device,” each place it appears; and

(2) by inserting “tobacco products,” after “devices,” each place it appears.

(g) SECTION 704.—Section 704 (21 U.S.C. 374) is amended—

(1) in subsection (a)(1)(A), by inserting “tobacco products,” after “devices,” each place it appears;

(2) in subsection (a)(1)(B), by inserting “or tobacco product” after “restricted devices” each place it appears; and

(3) in subsection (b), by inserting “tobacco product,” after “device,”.

(h) SECTION 705.—Section 705(b) (21 U.S.C. 375(b)) is amended by inserting “tobacco products,” after “devices,”.

(i) SECTION 709.—Section 709 (21 U.S.C. 379) is amended by inserting “or tobacco product” after “device”.

(j) SECTION 801.—Section 801 (21 U.S.C. 381) is amended—

(1) in subsection (a)—

(A) by inserting “tobacco products,” after “devices,” the first time it appears;

(B) by inserting “or section 905(j)” after “section 510”; and

(C) by striking “drugs or devices” each time it appears and inserting “drugs, devices, or tobacco products”;

(2) in subsection (e)(1), by inserting “tobacco product,” after “device,”; and

(3) by adding at the end the following:

“(p)(1) Not later than 2 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, and annually thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report regarding—

“(A) the nature, extent, and destination of United States tobacco product exports that do not conform to tobacco product standards established pursuant to this Act;

“(B) the public health implications of such exports, including any evidence of a negative public health impact; and

“(C) recommendations or assessments of policy alternatives available to Congress and the Executive Branch to reduce any negative public health impact caused by such exports.

“(2) The Secretary is authorized to establish appropriate information disclosure requirements to carry out this subsection.”.

(k) SECTION 1003.—Section 1003(d)(2)(C) (as redesignated by section 101(a)) is amended—

(1) by striking “and” after “cosmetics,”; and

(2) inserting a comma and “and tobacco products” after “devices”.

(l) EFFECTIVE DATE FOR NO-TOBACCO-SALE ORDER AMENDMENTS.—The amendments made by subsection (c), other than the amendment made by paragraph (2) of such subsection, shall take effect upon the issuance of guidance by the Secretary of Health and Human Services—

(1) defining the term “repeated violation”, as used in section 303(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(f)) as amended by subsection (c), by identifying the number of violations of particular requirements over a specified period of time at a particular retail outlet that constitute a repeated violation;

(2) providing for timely and effective notice to the retailer of each alleged violation at a particular retail outlet and an expedited procedure for the administrative appeal of an alleged violation;

(3) providing that a person may not be charged with a violation at a particular retail outlet unless the Secretary has provided notice to the retailer of all previous violations at that outlet;

(4) establishing a period of time during which, if there are no violations by a particular retail outlet, that outlet will not be considered to have been the site of repeated violations when the next violation occurs; and

(5) providing that good faith reliance on the presentation of a false government issued photographic identification that contains the bearer’s date of birth does not constitute a violation of any minimum age requirement for the sale of tobacco products if the retailer has taken effective steps to prevent such violations, including—

(A) adopting and enforcing a written policy against sales to minors;

(B) informing its employees of all applicable laws;

(C) establishing disciplinary sanctions for employee noncompliance; and

(D) requiring its employees to verify age by way of photographic identification or electronic scanning device.

## CHAPTER 2—TOBACCO PRODUCT WARNINGS; CONSTITUENT AND SMOKE CONSTITUENT DISCLOSURE

### SEC. —21. CIGARETTE LABEL AND ADVERTISING WARNINGS.

Section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) is amended to read as follows:

#### “SEC. 4. LABELING.

“(a) LABEL REQUIREMENTS.—

“(1) IN GENERAL.—It shall be unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any cigarettes the package of which fails to bear, in accordance with the requirements of this section, one of the following labels:

‘WARNING: Cigarettes are addictive’.

‘WARNING: Tobacco smoke can harm your children’.

‘WARNING: Cigarettes cause fatal lung disease’.

‘WARNING: Cigarettes cause cancer’.

‘WARNING: Cigarettes cause strokes and heart disease’.

‘WARNING: Smoking during pregnancy can harm your baby’.

‘WARNING: Smoking can kill you’.

‘WARNING: Tobacco smoke causes fatal lung disease in non-smokers’.

‘WARNING: Quitting smoking now greatly reduces serious risks to your health’.

“(2) PLACEMENT; TYPOGRAPHY; ETC.—

“(A) IN GENERAL.—Each label statement required by paragraph (1) shall be located in the upper portion of the front and rear panels of the package, directly on the package underneath the cellophane or other clear wrapping. Except as provided in subparagraph (B), each label statement shall comprise at least the top 30 percent of the front and rear panels of the package. The word ‘WARNING’ shall appear in capital letters and all text shall be in conspicuous and legible 17-point type, unless the text of the label statement would occupy more than 70 percent of such area, in which case the text may be in a smaller conspicuous and legible type size, provided that at least 60 percent of such area is occupied by required text. The text



shall be black on a white background, or white on a black background, in a manner that contrasts, by typography, layout, or color, with all other printed material on the package, in an alternating fashion under the plan submitted under subsection (b)(4).

“(B) FLIP-TOP BOXES.—For any cigarette brand package manufactured or distributed before January 1, 2000, which employs a flip-top style (if such packaging was used for that brand in commerce prior to June 21, 1997), the label statement required by paragraph (1) shall be located on the flip-top area of the package, even if such area is less than 25 percent of the area of the front panel. Except as provided in this paragraph, the provisions of this subsection shall apply to such packages.

“(3) DOES NOT APPLY TO FOREIGN DISTRIBUTION.—The provisions of this subsection do not apply to a tobacco product manufacturer or distributor of cigarettes which does not manufacture, package, or import cigarettes for sale or distribution within the United States.

“(4) APPLICABILITY TO RETAILERS.—A retailer of cigarettes shall not be in violation of this subsection for packaging that is supplied to the retailer by a tobacco product manufacturer, importer, or distributor and is not altered by the retailer in a way that is material to the requirements of this subsection except that this paragraph shall not relieve a retailer of liability if the retailer sells or distributes tobacco products that are not labeled in accordance with this subsection.

“(b) ADVERTISING REQUIREMENTS.—

“(1) IN GENERAL.—It shall be unlawful for any tobacco product manufacturer, importer, distributor, or retailer of cigarettes to advertise or cause to be advertised within the United States any cigarette unless its advertising bears, in accordance with the requirements of this section, one of the labels specified in subsection (a) of this section.

“(2) TYPOGRAPHY, ETC.—Each label statement required by subsection (a) of this section in cigarette advertising shall comply with the standards set forth in this paragraph. For press and poster advertisements, each such statement and (where applicable) any required statement relating to tar, nicotine, or other constituent (including a smoke constituent) yield shall comprise at least 20 percent of the area of the advertisement and shall appear in a conspicuous and prominent format and location at the top of each advertisement within the trim area. The Secretary may revise the required type sizes in such area in such manner as the Secretary determines appropriate. The word ‘WARNING’ shall appear in capital letters, and each label statement shall appear in conspicuous and legible type. The text of the label statement shall be black if the background is white and white if the background is black, under the plan submitted under paragraph (4) of this subsection. The label statements shall be enclosed by a rectangular border that is the same color as the letters of the statements and that is the width of the first downstroke of the capital ‘W’ of the word ‘WARNING’ in the label statements. The text of such label statements shall be in a typeface pro rata to the following requirements: 45-point type for a whole-page broadsheet newspaper advertisement; 39-point type for a half-page broadsheet newspaper advertisement; 39-point type for a whole-page tabloid newspaper advertisement; 27-point type for a half-page tabloid newspaper advertisement; 31.5-point type for a double page spread magazine or whole-page

magazine advertisement; 22.5-point type for a 28 centimeter by 3 column advertisement; and 15-point type for a 20 centimeter by 2 column advertisement. The label statements shall be in English, except that in the case of—

“(A) an advertisement that appears in a newspaper, magazine, periodical, or other publication that is not in English, the statements shall appear in the predominant language of the publication; and

“(B) in the case of any other advertisement that is not in English, the statements shall appear in the same language as that principally used in the advertisement.

“(3) MATCHBOOKS.—Notwithstanding paragraph (2), for matchbooks (defined as containing not more than 20 matches) customarily given away with the purchase of tobacco products, each label statement required by subsection (a) may be printed on the inside cover of the matchbook.

“(4) ADJUSTMENT BY SECRETARY.—The Secretary may, through a rulemaking under section 553 of title 5, United States Code, adjust the format and type sizes for the label statements required by this section or the text, format, and type sizes of any required tar, nicotine yield, or other constituent (including smoke constituent) disclosures, or to establish the text, format, and type sizes for any other disclosures required under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et. seq.). The text of any such label statements or disclosures shall be required to appear only within the 20 percent area of cigarette advertisements provided by paragraph (2) of this subsection. The Secretary shall promulgate regulations which provide for adjustments in the format and type sizes of any text required to appear in such area to ensure that the total text required to appear by law will fit within such area.

“(5) MARKETING REQUIREMENTS.—

“(A) The label statements specified in subsection (a)(1) shall be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product and be randomly distributed in all areas of the United States in which the product is marketed in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer and approved by the Secretary.

“(B) The label statements specified in subsection (a)(1) shall be rotated quarterly in alternating sequence in advertisements for each brand of cigarettes in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer to, and approved by, the Secretary.

“(C) The Secretary shall review each plan submitted under subparagraph (B) and approve it if the plan—

“(i) will provide for the equal distribution and display on packaging and the rotation required in advertising under this subsection; and

“(ii) assures that all of the labels required under this section will be displayed by the tobacco product manufacturer, importer, distributor, or retailer at the same time.

“(6) APPLICABILITY TO RETAILERS.—This subsection applies to a retailer only if that retailer is responsible for or directs the label statements required under this section except that this paragraph shall not relieve a retailer of liability if the retailer displays, in a location open to the public, an advertisement that is not labeled in accordance with the requirements of this subsection.”

#### SEC. 22. AUTHORITY TO REVISE CIGARETTE WARNING LABEL STATEMENTS.

Section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333), as

amended by section 21, is further amended by adding at the end the following:

“(c) CHANGE IN REQUIRED STATEMENTS.—The Secretary may, by a rulemaking conducted under section 553 of title 5, United States Code, adjust the format, type size, and text of any of the label requirements, require color graphics to accompany the text, increase the required label area from 30 percent up to 50 percent of the front and rear panels of the package, or establish the format, type size, and text of any other disclosures required under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), if the Secretary finds that such a change would promote greater public understanding of the risks associated with the use of tobacco products.”

#### SEC. 23. STATE REGULATION OF CIGARETTE ADVERTISING AND PROMOTION.

Section 5 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1334) is amended by adding at the end the following:

“(c) EXCEPTION.—Notwithstanding subsection (b), a State or locality may enact statutes and promulgate regulations, based on smoking and health, that take effect after the effective date of the Family Smoking Prevention and Tobacco Control Act, imposing specific bans or restrictions on the time, place, and manner, but not content, of the advertising or promotion of any cigarettes.”

#### SEC. 24. SMOKELESS TOBACCO LABELS AND ADVERTISING WARNINGS.

Section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4402) is amended to read as follows:

##### “SEC. 3. SMOKELESS TOBACCO WARNING.

“(a) GENERAL RULE.—

“(1) It shall be unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any smokeless tobacco product unless the product package bears, in accordance with the requirements of this Act, one of the following labels:

‘WARNING: This product can cause mouth cancer’.

‘WARNING: This product can cause gum disease and tooth loss’.

‘WARNING: This product is not a safe alternative to cigarettes’.

‘WARNING: Smokeless tobacco is addictive’.

“(2) Each label statement required by paragraph (1) shall be—

“(A) located on the 2 principal display panels of the package, and each label statement shall comprise at least 30 percent of each such display panel; and

“(B) in 17-point conspicuous and legible type and in black text on a white background, or white text on a black background, in a manner that contrasts by typography, layout, or color, with all other printed material on the package, in an alternating fashion under the plan submitted under subsection (b)(3), except that if the text of a label statement would occupy more than 70 percent of the area specified by subparagraph (A), such text may appear in a smaller type size, so long as at least 60 percent of such warning area is occupied by the label statement.

“(3) The label statements required by paragraph (1) shall be introduced by each tobacco product manufacturer, packager, importer, distributor, or retailer of smokeless tobacco products concurrently into the distribution chain of such products.

“(4) The provisions of this subsection do not apply to a tobacco product manufacturer or distributor of any smokeless tobacco product that does not manufacture, package, or import smokeless tobacco products for

sale or distribution within the United States.

“(5) A retailer of smokeless tobacco products shall not be in violation of this subsection for packaging that is supplied to the retailer by a tobacco products manufacturer, importer, or distributor and that is not altered by the retailer unless the retailer offers for sale, sells, or distributes a smokeless tobacco product that is not labeled in accordance with this subsection.

“(b) REQUIRED LABELS.—

“(1) It shall be unlawful for any tobacco product manufacturer, packager, importer, distributor, or retailer of smokeless tobacco products to advertise or cause to be advertised within the United States any smokeless tobacco product unless its advertising bears, in accordance with the requirements of this section, one of the labels specified in subsection (a).

“(2) Each label statement required by subsection (a) in smokeless tobacco advertising shall comply with the standards set forth in this paragraph. For press and poster advertisements, each such statement and (where applicable) any required statement relating to tar, nicotine, or other constituent yield shall—

“(A) comprise at least 20 percent of the area of the advertisement, and the warning area shall be delineated by a dividing line of contrasting color from the advertisement; and

“(B) the word ‘WARNING’ shall appear in capital letters and each label statement shall appear in conspicuous and legible type. The text of the label statement shall be black on a white background, or white on a black background, in an alternating fashion under the plan submitted under paragraph (3).

“(3)(A) The label statements specified in subsection (a)(1) shall be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product and be randomly distributed in all areas of the United States in which the product is marketed in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer and approved by the Secretary.

“(B) The label statements specified in subsection (a)(1) shall be rotated quarterly in alternating sequence in advertisements for each brand of smokeless tobacco product in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer to, and approved by, the Secretary.

“(C) The Secretary shall review each plan submitted under subparagraph (B) and approve it if the plan—

“(i) will provide for the equal distribution and display on packaging and the rotation required in advertising under this subsection; and

“(ii) assures that all of the labels required under this section will be displayed by the tobacco product manufacturer, importer, distributor, or retailer at the same time.

“(D) This paragraph applies to a retailer only if that retailer is responsible for or directs the label statements under this section, unless the retailer displays in a location open to the public, an advertisement that is not labeled in accordance with the requirements of this subsection.

“(c) TELEVISION AND RADIO ADVERTISING.—It is unlawful to advertise smokeless tobacco on any medium of electronic communications subject to the jurisdiction of the Federal Communications Commission.”.

**SEC. 25. AUTHORITY TO REVISE SMOKELESS TOBACCO PRODUCT WARNING LABEL STATEMENTS.**

Section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4402), as amended by section 23, is further amended by adding at the end the following:

“(d) **AUTHORITY TO REVISE WARNING LABEL STATEMENTS.**—The Secretary may, by a rulemaking conducted under section 553 of title 5, United States Code, adjust the format, type size, and text of any of the label requirements, require color graphics to accompany the text, increase the required label area from 30 percent up to 50 percent of the front and rear panels of the package, or establish the format, type size, and text of any other disclosures required under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), if the Secretary finds that such a change would promote greater public understanding of the risks associated with the use of smokeless tobacco products.”.

**SEC. 26. TAR, NICOTINE, AND OTHER SMOKE CONSTITUENT DISCLOSURE TO THE PUBLIC.**

Section 4(a) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333 (a)), as amended by section 21, is further amended by adding at the end the following:

“(4)(A) The Secretary shall, by a rulemaking conducted under section 553 of title 5, United States Code, determine (in the Secretary’s sole discretion) whether cigarette and other tobacco product manufacturers shall be required to include in the area of each cigarette advertisement specified by subsection (b) of this section, or on the package label, or both, the tar and nicotine yields of the advertised or packaged brand. Any such disclosure shall be in accordance with the methodology established under such regulations, shall conform to the type size requirements of subsection (b) of this section, and shall appear within the area specified in subsection (b) of this section.

“(B) Any differences between the requirements established by the Secretary under subparagraph (A) and tar and nicotine yield reporting requirements established by the Federal Trade Commission shall be resolved by a memorandum of understanding between the Secretary and the Federal Trade Commission.

“(C) In addition to the disclosures required by subparagraph (A) of this paragraph, the Secretary may, under a rulemaking conducted under section 553 of title 5, United States Code, prescribe disclosure requirements regarding the level of any cigarette or other tobacco product constituent including any smoke constituent. Any such disclosure may be required if the Secretary determines that disclosure would be of benefit to the public health, or otherwise would increase consumer awareness of the health consequences of the use of tobacco products, except that no such prescribed disclosure shall be required on the face of any cigarette package or advertisement. Nothing in this section shall prohibit the Secretary from requiring such prescribed disclosure through a cigarette or other tobacco product package or advertisement insert, or by any other means under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

“(D) This paragraph applies to a retailer only if that retailer is responsible for or directs the label statements required under this section, except that this paragraph shall not relieve a retailer of liability if the retailer sells or distributes tobacco products that are not labeled in accordance with the requirements of this subsection.”.

**CHAPTER 3—PREVENTION OF ILLICIT TRADE IN TOBACCO PRODUCTS**

**SEC. 31. LABELING, RECORDKEEPING, RECORDS INSPECTION.**

Chapter IX of the Federal Food, Drug, and Cosmetic Act, as added by section 11, is further amended by adding at the end the following:

**“SEC. 921. LABELING, RECORDKEEPING, RECORDS INSPECTION.**

“(a) **ORIGIN LABELING.**—The label, packaging, and shipping containers of tobacco products for introduction or delivery for introduction into interstate commerce shall bear the statement ‘sale only allowed in the United States.’

“(b) **REGULATIONS CONCERNING RECORDKEEPING FOR TRACKING AND TRACING.**—

“(1) **IN GENERAL.**—Not later than 9 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall promulgate regulations regarding the establishment and maintenance of records by any person who manufactures, processes, transports, distributes, receives, packages, holds, exports, or imports tobacco products.

“(2) **INSPECTION.**—In promulgating the regulations described in paragraph (1), the Secretary shall consider which records are needed for inspection to monitor the movement of tobacco products from the point of manufacture through distribution to retail outlets to assist in investigating potential illicit trade, smuggling or counterfeiting of tobacco products.

“(3) **CODES.**—The Secretary may require codes on the labels of tobacco products or other designs or devices for the purpose of tracking or tracing the tobacco product through the distribution system.

“(4) **SIZE OF BUSINESS.**—The Secretary shall take into account the size of a business in promulgating regulations under this section.

“(5) **RECORDKEEPING BY RETAILERS.**—The Secretary shall not require any retailer to maintain records relating to individual purchasers of tobacco products for personal consumption.

“(c) **RECORDS INSPECTION.**—If the Secretary has a reasonable belief that a tobacco product is part of an illicit trade or smuggling or is a counterfeit product, each person who manufactures, processes, transports, distributes, receives, holds, packages, exports, or imports tobacco products shall, at the request of an officer or employee duly designated by the Secretary, permit such officer or employee, at reasonable times and within reasonable limits and in a reasonable manner, upon the presentation of appropriate credentials and a written notice to such person, to have access to and copy all records (including financial records) relating to such article that are needed to assist the Secretary in investigating potential illicit trade, smuggling or counterfeiting of tobacco products.

“(d) **KNOWLEDGE OF ILLEGAL TRANSACTION.**—If the manufacturer or distributor of a tobacco product has knowledge which reasonably supports the conclusion that a tobacco product manufactured or distributed by such manufacturer or distributor that has left the control of such person may be or has been—

“(A) imported, exported, distributed or offered for sale in interstate commerce by a person without paying duties or taxes required by law; or

“(B) imported, exported, distributed or diverted for possible illicit marketing, the manufacturer or distributor shall promptly notify the Attorney General of such knowledge.

“(2) KNOWLEDGE DEFINED.—For purposes of this subsection, the term ‘knowledge’ as applied to a manufacturer or distributor means—

“(A) the actual knowledge that the manufacturer or distributor had; or

“(B) the knowledge which a reasonable person would have had under like circumstances or which would have been obtained upon the exercise of due care.

#### SEC. 32. STUDY AND REPORT.

(a) STUDY.—The Comptroller General of the United States shall conduct a study of cross-border trade in tobacco products to—

(1) collect data on cross-border trade in tobacco products, including illicit trade and trade of counterfeit tobacco products and make recommendations on the monitoring of such trade;

(2) collect data on cross-border advertising (any advertising intended to be broadcast, transmitted, or distributed from the United States to another country) of tobacco products and make recommendations on how to prevent or eliminate, and what technologies could help facilitate the elimination of, cross-border advertising.

(b) REPORT.—Not later than 18 months after the date of enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the study described in subsection (a).

#### Subtitle B—Tobacco Market Transition

#### SEC. 40. SHORT TITLE OF SUBTITLE.

This subtitle may be cited as the “Tobacco Market Transition Act of 2004”.

#### CHAPTER 1—TERMINATION OF CURRENT TOBACCO PROGRAMS

#### SEC. 41. TERMINATION OF TOBACCO PRODUCTION ADJUSTMENT PROGRAMS.

(a) TOBACCO STATISTICS.—The Act of January 14, 1929 (45 Stat. 1079; 7 U.S.C. 501 et seq.) is repealed.

(b) TOBACCO STANDARDS.—The Tobacco Inspection Act (7 U.S.C. 511 et seq.) is repealed.

(c) TOBACCO INSPECTIONS.—Section 213 of the Tobacco Adjustment Act of 1933 (7 U.S.C. 511r) is repealed.

(d) TOBACCO CONTROL.—The Act of April 25, 1936 (commonly known as the Tobacco Control Act; 7 U.S.C. 515 et seq.), is repealed.

(e) COMMODITY HANDLING ORDERS.—Section 8c(2)(A) of the Agricultural Adjustment Act (7 U.S.C. 608c(2)(A)), reenacted with amendments by the Agricultural Marketing Agreement Act of 1937, is amended by striking “tobacco,”.

(f) PROCESSING TAX.—Section 9(b) of the Agricultural Adjustment Act (7 U.S.C. 609(b)), reenacted with amendments by the Agricultural Marketing Agreement Act of 1937, is amended—

(1) in paragraph (2), by striking “tobacco,”; and

(2) in paragraph (6)(B)(i), by striking “, or, in the case of tobacco, is less than the fair exchange value by not more than 10 per centum.”.

(g) BURLEY TOBACCO IMPORT REVIEW.—Section 3 of Public Law 98–59 (7 U.S.C. 625) is repealed.

(h) DECLARATION OF POLICY.—Section 2 of the Agricultural Adjustment Act of 1938 (7 U.S.C. 1282) is amended by striking “tobacco,”.

(i) DEFINITIONS.—Section 301(b) of the Agricultural Adjustment Act of 1938 (7 U.S.C. 1301(b)) is amended—

(1) in paragraph (3)—

(A) by striking subparagraph (C); and

(B) by redesignating subparagraph (D) as subparagraph (C);

(2) in paragraph (6)(A), by striking “tobacco,”;

(3) in paragraph (10)—

(A) by striking subparagraph (B); and

(B) by redesignating subparagraph (C) as subparagraph (B);

(4) in paragraph (11)(B), by striking “and tobacco”;

(5) in paragraph (12), by striking “tobacco,”;

(6) in paragraph (14)—

(A) in subparagraph (A), by striking “(A)”;

and

(B) by striking subparagraphs (B), (C), and (D);

(7) by striking paragraph (15);

(8) in paragraph (16)—

(A) by striking subparagraph (B); and

(B) by redesignating subparagraph (C) as subparagraph (B);

(9) by striking paragraph (17); and

(10) by redesignating paragraph (16) as paragraph (15).

(j) PARITY PAYMENTS.—Section 303 of the Agricultural Adjustment Act of 1938 (7 U.S.C. 1303) is amended in the first sentence by striking “rice, or tobacco,” and inserting “or rice,”.

(k) MARKETING QUOTAS.—Part I of subtitle B of title III of the Agricultural Adjustment Act of 1938 (7 U.S.C. 1311 et seq.) is repealed.

(l) ADMINISTRATIVE PROVISIONS.—Section 361 of the Agricultural Adjustment Act of 1938 (7 U.S.C. 1361) is amended by striking “tobacco,”.

(m) ADJUSTMENT OF QUOTAS.—Section 371 of the Agricultural Adjustment Act of 1938 (7 U.S.C. 1371) is amended—

(1) in the first sentence of subsection (a), by striking “rice, or tobacco” and inserting “or rice”; and

(2) in the first sentence of subsection (b), by striking “rice, or tobacco” and inserting “or rice”.

(n) REPORTS AND RECORDS.—Section 373 of the Agricultural Adjustment Act of 1938 (7 U.S.C. 1373) is amended—

(1) by striking “rice, or tobacco” each place it appears in subsections (a) and (b) and inserting “or rice”; and

(2) in subsection (a)—

(A) in the first sentence, by striking “all persons engaged in the business of redrying, prizing, or stemming tobacco for producers,”; and

(B) in the last sentence, by striking “\$500,” and all that follows through the period at the end of the sentence and inserting “\$500.”.

(o) REGULATIONS.—Section 375 of the Agricultural Adjustment Act of 1938 (7 U.S.C. 1375) is amended—

(1) in subsection (a), by striking “peanuts, or tobacco” and inserting “or peanuts”; and

(2) by striking subsection (c).

(p) EMINENT DOMAIN.—Section 378 of the Agricultural Adjustment Act of 1938 (7 U.S.C. 1378) is amended—

(1) in the first sentence of subsection (c), by striking “cotton, and tobacco” and inserting “and cotton”; and

(2) by striking subsections (d), (e), and (f).

(q) BURLEY TOBACCO FARM RECONSTITUTION.—Section 379 of the Agricultural Adjustment Act of 1938 (7 U.S.C. 1379) is amended—

(1) in subsection (a)—

(A) by striking “(a)”;

(B) in paragraph (6), by striking “, but this

clause (6) shall not be applicable in the case of burley tobacco”;

(2) by striking subsections (b) and (c).

(r) ACREAGE-POUNDAGE QUOTAS.—Section 4 of the Act of April 16, 1955 (Public Law 89–12; 7 U.S.C. 1314c note), is repealed.

(s) BURLEY TOBACCO ACREAGE ALLOTMENTS.—The Act of July 12, 1952 (7 U.S.C. 1315), is repealed.

(t) TRANSFER OF ALLOTMENTS.—Section 703 of the Food and Agriculture Act of 1965 (7 U.S.C. 1316) is repealed.

(u) ADVANCE RECOURSE LOANS.—Section 13(a)(2)(B) of the Food Security Improvements Act of 1986 (7 U.S.C. 1433c–1(a)(2)(B)) is amended by striking “tobacco and”.

(v) TOBACCO FIELD MEASUREMENT.—Section 1112 of the Omnibus Budget Reconciliation Act of 1987 (Public Law 100–203) is amended by striking subsection (c).

#### SEC. 42. TERMINATION OF TOBACCO PRICE SUPPORT PROGRAM.

(a) PARITY PRICE SUPPORT.—Section 101 of the Agricultural Act of 1949 (7 U.S.C. 1441) is amended—

(1) in the first sentence of subsection (a), by striking “tobacco (except as otherwise provided herein), corn,” and inserting “corn”;

(2) by striking subsections (c), (g), (h), and (i);

(3) in subsection (d)(3)—

(A) by striking “, except tobacco,”; and

(B) by striking “and no price support shall be made available for any crop of tobacco for which marketing quotas have been disapproved by producers,”; and

(4) by redesignating subsections (d) and (e) as subsections (c) and (d), respectively.

(b) TERMINATION OF TOBACCO PRICE SUPPORT AND NO NET COST PROVISIONS.—Sections 106, 106A, and 106B of the Agricultural Act of 1949 (7 U.S.C. 1445, 1445–1, 1445–2) are repealed.

(c) DEFINITION OF BASIC AGRICULTURAL COMMODITY.—Section 408(c) of the Agricultural Act of 1949 (7 U.S.C. 1428(c)) is amended by striking “tobacco,”.

(d) REVIEW OF BURLEY TOBACCO IMPORTS.—Section 3 of Public Law 98–59 (7 U.S.C. 625) is repealed.

(e) POWERS OF COMMODITY CREDIT CORPORATION.—Section 5 of the Commodity Credit Corporation Charter Act (15 U.S.C. 714c) is amended by inserting “(other than tobacco)” after “agricultural commodities” each place it appears.

#### SEC. 43. LIABILITY.

This title and the amendments made by this title shall not affect the liability of any person under any provision of law with respect to any crop of tobacco planted before the effective date prescribed in section 62.

#### CHAPTER 2—TOBACCO ASSISTANCE

#### SEC. 51. TOBACCO ASSISTANCE.

Title III of the Agricultural Adjustment Act of 1938 is amended by inserting after subtitle D (7 U.S.C. 1379a et seq.) the following:

#### “Subtitle E—Tobacco Assistance

#### “SEC. 380A. DEFINITIONS.

“In this subtitle:

“(1) ACTIVE PRODUCER OF TOBACCO.—The term ‘active producer of tobacco’ means a person that—

“(A) is actively engaged in the production of tobacco marketed or considered planted; and

“(B) shares in the risk of producing the tobacco.

“(2) APPLICABLE FISCAL YEAR.—The term ‘applicable fiscal year’ means each of fiscal years 2004 through 2013.

“(3) BASE PERIOD.—The term ‘base period’ means the 1-year period ending the June 30 preceding each applicable fiscal year.

“(4) CONSIDERED PLANTED.—The term ‘considered planted’ means tobacco planted but failed to be produced as a result of a natural disaster, as determined by the Secretary.

“(5) DEPARTMENT.—The term ‘Department’ means the Department of Agriculture.

“(6) ELIGIBLE STATE.—The term ‘eligible State’ means—

“(A) in the case of section 380O, each of the States of Maryland, Pennsylvania, South Carolina, and North Carolina; and

“(B) in the case of section 380Q, each of the States of Alabama, Arkansas, Florida, Georgia, Indiana, Kansas, Kentucky, Minnesota, Missouri, North Carolina, Ohio, Oklahoma, South Carolina, Tennessee, Virginia, West Virginia, and Wisconsin.

“(7) IMPACTED COMMUNITY.—The term ‘impacted community’ means a community in an eligible State that is adversely affected by a reduction in gross receipts from the sale of tobacco.

“(8) MARKET SHARE.—The term ‘market share’ means the share of each manufacturer or importer of a class of tobacco product (expressed as a decimal to the fourth place) of the total volume of domestic sales of the class of tobacco product during the base period for the applicable fiscal year for an assessment under section 380T.

“(9) PRODUCTION BOARD.—The term ‘Production Board’ means a Production Board established for a kind of tobacco under section 380H.

“(10) QUOTA TOBACCO.—The term ‘quota tobacco’ means a kind of tobacco that is subject to a farm marketing quota or farm acreage allotment for the 2002 tobacco marketing years under a marketing quota or allotment program established under part I of subtitle B (as in effect before the effective date of this subtitle).

“(11) TOBACCO.—The term ‘tobacco’ means each of the following kinds of tobacco:

“(A) Flue-cured tobacco, comprising types 11, 12, 13, and 14.

“(B) Fire-cured tobacco, comprising types 22 and 23.

“(C) Dark air-cured tobacco, comprising types 35 and 36.

“(D) Virginia sun-cured tobacco, comprising type 37.

“(E) Virginia fire-cured tobacco, comprising type 21.

“(F) Burley tobacco, comprising type 31.

“(G) Cigar-filler and cigar-binder tobacco, comprising types 42, 43, 44, 53, 54, and 55.

“(12) TOBACCO QUALITY BOARD.—The term ‘Tobacco Quality Board’ means the Tobacco Quality Board established under section 380G.

“(13) TOBACCO QUOTA HOLDER.—The term ‘tobacco quota holder’ means a person that is considered an tobacco quota holder under section 380B(b).

“(14) TOBACCO TRUST FUND.—The term ‘Tobacco Trust Fund’ means the Tobacco Trust Fund established under section 380S.

“(15) TRADITIONAL PRODUCER OF TOBACCO.—The term ‘traditional producer of tobacco’ means a person that, for at least 1 of the 2000, 2001, or 2002 tobacco marketing years—

“(A) was actively engaged in the production of tobacco marketed, or considered planted, under a marketing quota established under part I of subtitle B (as in effect before the effective date of this subtitle); and

“(B) shared in the risk of producing the tobacco.

“(16) TRADITIONAL TOBACCO COUNTY.—

“(A) IN GENERAL.—The term ‘traditional tobacco county’ means a county in the United States that had 1 or more farms operated by traditional producers of tobacco under a marketing quota for at least 1 of the marketing years described in paragraph (15).

“(B) INCLUSION.—For the purpose of determining the crop acreage base of an active

producer of tobacco for a kind of tobacco produced in the State of Georgia under section 380I(c)(3), the term ‘traditional tobacco county’ includes a county that is contiguous to a county described in subparagraph (A).

#### “CHAPTER 1—PAYMENTS TO TOBACCO QUOTA HOLDERS AND TRADITIONAL PRODUCERS

##### “SEC. 380B. TRANSITION PAYMENTS TO TOBACCO QUOTA HOLDERS.

“(a) IN GENERAL.—The Secretary shall make transition payments to each tobacco quota holder.

“(b) TOBACCO QUOTA HOLDER.—

“(1) IN GENERAL.—Except as otherwise provided in this subsection, the Secretary shall consider a person to be a tobacco quota holder under this section if the person held, as of July 1, 2002, a basic quota or farm acreage allotment (as applicable) for quota tobacco established for the 2002 tobacco marketing year under a marketing quota program established under part I of subtitle B (as in effect before the effective date of this subtitle).

“(2) EFFECT OF PURCHASE CONTRACT.—If there was an agreement for the purchase of all or part of a farm described in paragraph (1) as of July 1, 2002, and the parties to the sale are unable to agree to the disposition of eligibility for payments under this section, the Secretary, taking into account any transfer of quota that has been agreed to, shall provide for the equitable division of the payments among the parties by adjusting the determination of who is the tobacco quota holder with respect to particular pounds of the quota.

“(3) EFFECT OF AGREEMENT FOR PERMANENT QUOTA TRANSFER.—If the Secretary determines that there was in existence, as of July 1, 2002, an agreement for the permanent transfer of quota, but that the transfer was not completed by that date, the Secretary shall consider the tobacco quota holder to be the party to the agreement that, as of that date, was the owner of the farm to which the quota was to be transferred.

“(4) PROTECTED BASES.—A person that owns a farm with a tobacco poundage quota that is protected under a conservation reserve program contract entered into under section 1231 of the Food Security Act of 1985 (16 U.S.C. 3831) shall be considered to be a tobacco quota holder with respect to the protected poundage.

“(5) QUANTITY OF QUOTA HELD.—

“(A) IN GENERAL.—A person shall be considered a tobacco quota holder for purposes of this section only with respect to that quantity of quota that qualifies the person as a tobacco quota holder.

“(B) INCLUDED QUOTA.—The determination of the tobacco poundage amount for which the person qualifies shall—

“(i) be based on the quantity of quota held by person on January 1, 2004;

“(ii) subject to clause (iii), not be greater than the quantity of quota held by the person for the 2002 crop; and

“(iii) take into account—

“(I) sales of quota that occurred during the period beginning July 1, 2002, and ending December 31, 2004; and

“(II) any transfers of quota that took place after July 1, 2002.

“(c) APPLICATION.—

“(1) IN GENERAL.—To be eligible to receive a payment under this section, a person shall submit to the Secretary an application containing such information as the Secretary may require to demonstrate to the satisfaction of the Secretary that the person is a tobacco quota holder.

“(2) ADMINISTRATION.—The application shall be submitted within such time, in such form, and in such manner as the Secretary may require.

“(d) BASE QUOTA LEVEL.—

“(1) IN GENERAL.—The Secretary shall establish a base quota level applicable to each tobacco quota holder, as determined under this subsection.

“(2) LEVEL.—The base quota level for each tobacco quota holder shall be equal to the quantity of quota that qualifies a person as the tobacco quota holder under subsection (b)(5).

“(e) PAYMENT.—The Secretary shall make payments to each tobacco quota holder under subsection (b) in an amount obtained by multiplying—

“(1) 80 cents per pound for each of fiscal years 2004 through 2013; by

“(2) the base quota level established for the quota holder under subsection (d).

“(f) TIME FOR PAYMENT.—Subject to section 380D(c), the payments to tobacco quota holders required under this section shall be made by, to the maximum extent practicable, the date that is 180 days after the date of enactment of this subtitle and each November 1 thereafter.

##### “SEC. 380C. DIRECT PAYMENTS TO TRADITIONAL PRODUCERS OF TOBACCO.

“(a) IN GENERAL.—The Secretary shall make direct payments under this section to traditional producers of tobacco.

“(b) ELIGIBILITY.—

“(1) IN GENERAL.—To be eligible to receive a payment under this section, a person shall submit to the Secretary an application containing such information as the Secretary may require to demonstrate to the satisfaction of the Secretary that the person is a traditional producer of tobacco.

“(2) ADMINISTRATION.—The application shall be submitted within such time, in such form, and in such manner as the Secretary may require.

“(c) BASE QUOTA LEVEL.—

“(1) IN GENERAL.—The Secretary shall establish a base quota level applicable to each traditional producer of tobacco, as determined under this subsection.

“(2) FLUE-CURED AND BURLEY TOBACCO.—In the case of Flue-cured tobacco (types 11, 12, 13, and 14) and Burley tobacco (type 31), the base quota level for each tobacco quota holder shall be equal to the effective tobacco marketing quota (irrespective of disaster lease and transfers) under part I of subtitle B (as in effect before the effective date of this subtitle) for the 2002 marketing year for quota tobacco produced on the farm.

“(3) OTHER KINDS OF TOBACCO.—In the case of each kind of tobacco other than Flue-cured tobacco (types 11, 12, 13, and 14) and Burley tobacco (type 31), for the purpose of calculating a payment to a traditional producer of tobacco, the base quota level for the traditional producer of tobacco shall be the quantity obtained by multiplying—

“(A) the basic tobacco farm acreage allotment for the 2002 marketing year established by the Secretary for quota tobacco produced on the farm; by

“(B) the actual yield of the crop of quota tobacco produced on the farm.

“(d) PAYMENT.—

“(1) IN GENERAL.—Subject to paragraph (2), the Secretary shall make payments to each traditional producer of tobacco, as determined under subsection (b), in an amount obtained by multiplying—

“(A) 40 cents per pound for each of fiscal years 2004 through 2013; by

“(B) the base quota level established for the traditional producer of tobacco under subsection (c).

“(2) PAYMENT RATE.—The rate for payments to a traditional producer of quota tobacco under paragraph (1)(A) shall be equal to—

“(A) in the case of a person that produced quota tobacco marketed, or considered planted, under a marketing quota for all 3 of the 2000, 2001, and 2002 tobacco marketing years, the rate prescribed under paragraph (1)(A) for the applicable fiscal year;

“(B) in the case of a person that produced quota tobacco marketed, or considered planted, under a marketing quota for not more than 2 of the 2000, 2001, and 2002 tobacco marketing years,  $\frac{2}{3}$  of the rate prescribed under paragraph (1)(A) for the applicable fiscal year; and

“(C) in the case of a person that produced quota tobacco marketed, or considered planted, under a marketing quota for not more than 1 of the 2000, 2001, and 2002 tobacco marketing years,  $\frac{1}{3}$  of the rate prescribed under paragraph (1)(A) for the applicable fiscal year.

“(e) TIME FOR PAYMENT.—Subject to section 380D(c), the payments to traditional producers of tobacco required under this section shall be made by, to the maximum extent practicable, the date that is 180 days after the date of enactment of this subtitle and each November 1 thereafter.

#### “SEC. 380D. ADMINISTRATION.

“(a) RESOLUTION OF DISPUTES.—

“(1) IN GENERAL.—Any dispute regarding the eligibility of a person to receive a payment under this subtitle, or the amount of the payment, may be appealed to the county committee established under section 8 of the Soil Conservation and Domestic Allotment Act (16 U.S.C. 590h) for the county or other area in which the farming operation of the person is located.

“(2) NATIONAL APPEALS DIVISION.—Any adverse determination of a county committee under subsection (a) may be appealed to the National Appeals Division established under subtitle H of the Department of Agriculture Reorganization Act of 1994 (7 U.S.C. 6991 et seq.).

“(b) USE OF QUALIFIED FINANCIAL INSTITUTIONS.—The Secretary may use qualified financial institutions to manage assets, make payments, and otherwise carry out this subtitle.

“(c) ADVANCED PAYMENTS.—

“(1) IN GENERAL.—The Secretary shall permit a tobacco quota holder and a traditional producer of tobacco to elect to receive advanced payments for 2 or more fiscal years under this chapter by selecting 1 of 4 advance payment options established by the Secretary, including a lump sum payment option.

“(2) RISK.—A tobacco quota holder or traditional producer of tobacco that elects to receive accelerated payments shall bear the expense of the discount in value for acceleration of the payments.

“(3) QUALIFIED FINANCIAL INSTITUTIONS.—

“(A) IN GENERAL.—The Secretary shall provide advanced payments under this subsection through 1 or more qualified financial institutions designated by the Secretary.

“(B) ADMINISTRATION.—In providing advanced payments under this subsection, a qualified financial institution shall (in accordance with guidance issued by the Secretary)—

“(i) offer the advanced payments regardless of the location or size of the payments;

“(ii) apply updated discount rates that vary only by payment term; and

“(iii) distribute the advanced payments in accordance with the option elected by the tobacco quota holder or traditional producer of tobacco.

“(4) COUNTY OFFICES.—A county office of the Department may receive applications and other documentation necessary to receive advanced payments under this subsection, on behalf of the Secretary and qualified financial institutions.

“(d) TREATMENT OF PAYMENTS.—Payments received by a tobacco quota holder or traditional producer of tobacco under this chapter shall be considered received not earlier than the date the tobacco quota holder or traditional producer of tobacco first receives the payments.

### “CHAPTER 2—TOBACCO QUALITY AND QUANTITY

#### “SEC. 380G. TOBACCO QUALITY BOARD.

“(a) IN GENERAL.—The Secretary shall establish a permanent advisory board within the Department, to be known as the ‘Tobacco Quality Board’.

“(b) MEMBERSHIP.—

“(1) IN GENERAL.—The Tobacco Quality Board shall consist of 13 members, of which—

“(A) 5 members shall be appointed by the Secretary from nominations submitted by representatives of tobacco producers in the United States, including at least—

“(i) 1 representative of Flue-cured tobacco producers;

“(ii) 1 representative of Burley tobacco producers; and

“(iii) 1 representative of dark fire-cured tobacco producers;

“(B) 5 members shall be appointed by the Secretary from nominations submitted by representatives of tobacco product manufacturers in the United States, including at least—

“(i) 1 representative of smokeless tobacco product manufacturers; and

“(ii) 1 representative of export dealers of tobacco; and

“(C) 3 at-large members shall be appointed by the Secretary, including at least 1 officer or employee of the Department.

“(2) CHAIRPERSON.—The Secretary shall appoint the chairperson of the Tobacco Quality Board, with a different member serving as chairperson of the Tobacco Quality Board each term.

“(3) TERMS.—Each member of the Tobacco Quality Board shall serve for 2-year terms, except that the terms of the members first appointed to the Tobacco Quality Board shall be staggered so as to establish a rotating membership of the Tobacco Quality Board, as determined by the Secretary.

“(c) DUTIES.—The Tobacco Quality Board shall—

“(1) determine and describe the physical characteristics of tobacco produced in the United States and unmanufactured tobacco imported into the United States;

“(2) assemble and evaluate, in a systematic manner, concerns and problems with the quality of tobacco produced in the United States, expressed by domestic and foreign buyers and manufacturers of tobacco products;

“(3) review data collected by Federal agencies on the physical and chemical integrity of tobacco produced in the United States and unmanufactured tobacco imported into the United States, to ensure that tobacco being used in domestically-manufactured tobacco products is of the highest quality and is free from prohibited physical and chemical agents;

“(4) investigate and communicate to the Secretary—

“(A) conditions with respect to the production of tobacco that discourage improvements in the quality of tobacco produced in the United States; and

“(B) recommendations for regulatory changes that would address tobacco quality issues;

“(5) conduct oversight regarding tobacco marketing issues (such as opening sales dates and marketing regulations) applicable to auction markets;

“(6) provide assistance to Federal agencies on actions taken by the Federal agencies that affect the quality or quantity of tobacco produced in the United States;

“(7) not later than a date determined by the Secretary, make recommendations to the Secretary, and the applicable Production Board established for the kind of tobacco, on the range of base years for the maximum crop acreage base under section 380I(c)(3)(B), and for the maximum crop poundage base under section 380I(d)(3)(B), for each crop of each kind of tobacco, except that the range of base years shall be the crop years for the 1998 through 2002 crops unless otherwise determined by the Tobacco Quality Board; and

“(8) carry out such other related activities as are assigned to the Tobacco Quality Board by the Secretary.

“(d) ADMINISTRATION.—The Secretary shall provide the Tobacco Quality Board with (as determined by the Secretary)—

“(1) a staff that is—

“(A) experienced in the sampling and analysis of unmanufactured tobacco; and

“(B) capable of collecting data and monitoring tobacco production information; and

“(2) other resources and information necessary for the Tobacco Quality Board to perform the duties of the Tobacco Quality Board under this subtitle, including—

“(A) information concerning acreage devoted to the production of each kind of tobacco; and

“(B) international information from the Foreign Agricultural Service.

“(e) APPLICABILITY OF FEDERAL ADVISORY COMMITTEE ACT.—The Federal Advisory Committee Act (5 U.S.C. App.) shall not apply to the Tobacco Quality Board.

#### “SEC. 380H. PRODUCTION BOARDS.

“(a) IN GENERAL.—The Secretary shall establish a permanent advisory board for each kind of tobacco, to be known as a ‘Production Board’.

“(b) MEMBERSHIP.—

“(1) IN GENERAL.—Subject to paragraph (2), a Production Board for a kind of tobacco shall consist of—

“(A) not more than 10 members appointed by the Secretary from nominations submitted by representatives of producers of that kind of tobacco in the United States; and

“(B) 1 officer or employee of the Department appointed by the Secretary.

“(2) ALLOCATION OF MEMBERSHIP.—In appointing members to a Production Board established for a kind of tobacco, the number of members appointed by the Secretary to represent each State shall, to the maximum extent practicable, bear the same ratio to the total number of members of the Production Board as—

“(A) the total volume of domestic sales of the kind of tobacco produced in the State during the most recent period for which data is available; bears to

“(B) the total volume of domestic sales of the kind of tobacco produced in all States during the most recent period for which data is available.

“(3) CHAIRPERSON.—The Secretary shall appoint the chairperson of a Production Board,

with a different member serving as chairperson of the Production Board each term.

“(4) TERMS.—Each member of a Production Board shall serve for 2-year terms, except that the terms of the members first appointed to the Production Board shall be staggered so as to establish a rotating membership of the Production Board, as determined by the Secretary.

“(c) DUTIES.—A Production Board established for a kind of tobacco shall—

“(1) not later than a date determined by the Secretary, make recommendations to the Secretary on the base year, within the range of base years recommended by the Tobacco Quality Board under section 380G(c)(7), for the maximum crop acreage base under section 380I(c)(3)(B) for each crop of each kind of tobacco; and

“(2) carry out such other related activities as are assigned to the Production Board by the Secretary.

“(d) ADMINISTRATION.—The Secretary shall provide each Production Board established for a kind of tobacco with (as determined by the Secretary)—

“(1) a staff that is knowledgeable about production and marketing of that kind of tobacco; and

“(2) other resources and information necessary for the Production Board to perform the duties of the Production Board under this subtitle, including information concerning acreage devoted to the production of each kind of tobacco.

“(e) APPLICABILITY OF FEDERAL ADVISORY COMMITTEE ACT.—The Federal Advisory Committee Act (5 U.S.C. App.) shall not apply to a Production Board.

**“SEC. 380I. TOBACCO PRODUCTION LIMITATION PROGRAMS.**

“(a) DEFINITIONS.—In this section:

“(1) CROP ACREAGE BASE.—The term ‘crop acreage base’ means the crop acreage base for a kind of tobacco for a crop for an active producer of tobacco, as determined by the Secretary.

“(2) CROP POUNDAGE BASE.—The term ‘crop poundage base’ means the crop poundage base for a kind of tobacco for a crop for an active producer of tobacco, as determined by the Secretary.

“(3) PERMITTED ACREAGE.—The term ‘permitted acreage’ means the number of acres that may be devoted to the production of a kind of tobacco by an active producer of tobacco, consistent with the annual acreage limitation program, as determined by the Secretary.

“(4) PERMITTED POUNDAGE.—The term ‘permitted poundage’ means the number of pounds of a kind of tobacco for a crop may be produced by an active tobacco producer, consistent with the annual poundage limitation program, as determined by the Secretary.

“(b) ESTABLISHMENT.—

“(1) IN GENERAL.—The Secretary shall establish for each crop of each kind of tobacco—

“(A) an acreage limitation program in accordance with subsection (c); or

“(B) a poundage limitation in accordance with subsection (d).

“(2) CONSULTATION.—The Secretary shall carry out the acreage limitation program and the poundage limitation program for a kind of tobacco in consultation with the Tobacco Advisory Board and the applicable Production Board established for that kind of tobacco.

“(3) SUPPLY.—In carrying out an acreage limitation program or a poundage limitation program for a crop of a kind of tobacco, the Secretary shall determine whether the total

supply of that kind of tobacco, in the absence of the respective production limitation program, will be excessive, taking into account the need for an adequate carryover to maintain reasonable and stable supplies and prices.

“(4) ANNOUNCEMENT.—

“(A) IN GENERAL.—Except as provided in subparagraph (B), the Secretary shall announce an acreage limitation program or poundage limitation program for each kind of tobacco not later than December 15 of the calendar year preceding the year in which the crop is harvested.

“(B) SPECIAL RULE FOR 2004 CROP.—In the case of the 2004 crop for a kind of tobacco, the Secretary shall announce an acreage limitation program or poundage limitation for each kind of tobacco as soon as practicable after the date of the enactment of the Tobacco Market Transition Act of 2004.

“(c) ACREAGE LIMITATION PROGRAM.—

“(1) IN GENERAL.—Under an acreage limitation program for a crop of a kind of tobacco announced under subsection (b), the limitation shall be achieved by applying a uniform percentage reduction to the crop acreage base for the kind of tobacco for the crop for active producers of that kind of tobacco in each traditional tobacco county, as determined by the Secretary.

“(2) CROP ACREAGE BASES.—

“(A) IN GENERAL.—The crop acreage base for an active producer of tobacco for a crop of each kind of tobacco shall equal the number of acres that is equal to—

“(i) in the case of the 2004 crop year, the average of the acreage planted and considered planted by the active producer of tobacco to the kind of tobacco for harvest in a traditional tobacco county in each of the 5 crop years preceding the crop year, as determined and adjusted by the Secretary (in consultation with the Tobacco Quality Board and the applicable Production Board); and

“(ii) in the case of each subsequent crop year, the number of acres planted and considered planted by the active producer of tobacco to the kind of tobacco for harvest in a traditional tobacco county in the preceding crop year, as determined and adjusted by the Secretary (in consultation with the Tobacco Quality Board and the applicable Production Board).

“(B) MAXIMUM CROP ACREAGE BASES.—

“(i) IN GENERAL.—The total quantity of acreage devoted to a kind of tobacco by active producers of tobacco during a crop year shall not exceed the total quantity of acreage devoted to the kind of tobacco by active producers during a crop year determined by the Secretary.

“(ii) ADJUSTMENT.—If the active producers of a kind of tobacco demonstrate to the Secretary that the application of clause (i) to a crop of a kind of tobacco will result in unbalanced supply and demand conditions, the Secretary may adjust the total quantity of acreage that may be devoted to the kind of tobacco by active producers during the crop year.

“(C) SALE, LEASE, OR TRANSFER OF CROP ACREAGE BASES.—An active producer of tobacco shall not sell, lease, or transfer to another person a crop acreage base established for the active producer of tobacco under this paragraph.

“(D) REALLOCATION OF UNUSED CROP ACREAGE BASES.—

“(i) COUNTY POOL.—If an active producer of tobacco with a crop acreage base for a kind of tobacco elects not to use all or part of the crop acreage base to continue to produce that kind of tobacco, the unused crop acre-

age base shall be placed in a pool established for the traditional tobacco county for reallocation by the Secretary to other producers of that kind of tobacco in the traditional tobacco county that request the crop acreage base.

“(ii) STATE POOL.—If any crop acreage base for a kind of tobacco remains after the crop acreage base is made available to producers of that kind of tobacco in the traditional tobacco county in a State, the unused crop acreage base shall be placed in a pool established for the State for reallocation by the Secretary to other producers of that kind of tobacco in a traditional tobacco county.

“(iii) NEW PRODUCERS.—In reallocating unused crop acreage bases for a kind of tobacco in a traditional tobacco county made available under each of clauses (i) and (ii), the Secretary shall make available to any new producers of that kind of tobacco in the traditional tobacco county up to 10 percent of the crop acreage bases available for reallocation for the kind of tobacco in the traditional tobacco county.

“(d) POUNDAGE LIMITATION PROGRAM.—

“(1) IN GENERAL.—Under a poundage limitation program for a crop of a kind of tobacco, the Secretary shall achieve the limitation by applying a uniform percentage adjustment to the crop poundage base of an active producer of tobacco for the kind of tobacco in each traditional tobacco county, as determined by the Secretary.

“(2) DETERMINATION OF CROP POUNDAGE BASES.—

“(A) 2004 CROP YEAR.—The crop poundage base for an active tobacco producer for the 2004 crop of a kind of tobacco shall equal the average of the number of pounds of that kind of tobacco harvested by the active tobacco producer in a traditional tobacco county and marketed in each of the 5 crop years preceding the crop year, as determined by the Secretary.

“(B) SUBSEQUENT CROP YEARS.—In the case of the 2005 and subsequent crops of each kind of tobacco, the crop poundage base for an active tobacco producer of a kind of tobacco shall equal the number of pounds of that kind of tobacco harvested by the active tobacco producer in a traditional tobacco county and marketed in the preceding crop year, as determined and adjusted by the Secretary.

“(3) MAXIMUM CROP POUNDAGE BASES.—

“(A) IN GENERAL.—The total number of pounds devoted to a kind of tobacco by active tobacco producers during a crop year shall not exceed the total number of pounds devoted to the kind of tobacco by active tobacco producers during a crop year determined by the Secretary.

“(B) ADJUSTMENT.—If the active tobacco producers of a kind of tobacco demonstrate to the Secretary that the application of paragraph (1) to a crop of a kind of tobacco will result in unbalanced supply and demand conditions, the Secretary may adjust the total number of pounds that may be devoted to the kind of tobacco by active tobacco producers during the crop year.

“(4) SALE, LEASE, OR TRANSFER OF CROP POUNDAGE BASES.—

“(A) PROHIBITION.—An active producer of tobacco shall not directly or indirectly sell, lease, or transfer to another person or other legal entity a crop poundage base established for an active tobacco producer under this subsection.

“(B) EXCEPTION.—If the crop poundage base of an active producer of tobacco for a type of tobacco covers tobacco that was produced by



the producer in more than 1 traditional tobacco county, the producer may elect to consolidate the base in a single traditional tobacco county in which the producer bore or shared in the risk of producing a crop of that kind of tobacco for the 2002 crop year.

“(5) REALLOCATION OF UNUSED CROP POUNDAGE BASES.—

“(A) COUNTY POOL.—If an active producer of tobacco with a crop poundage base for a kind of tobacco elects not to use all or part of the crop poundage base, the unused crop poundage base shall be placed in a pool established for the traditional tobacco county where the unused crop poundage base was originally located for reallocation by the Secretary to other active producers of tobacco of that kind of tobacco in the traditional tobacco county, in a manner determined by the Secretary.

“(B) STATE POOL.—If any crop poundage base for a kind of tobacco remains after the crop poundage base is made available to producers of that kind of tobacco in the traditional tobacco county in a State under subparagraph (A), the unused crop poundage base shall be placed in a pool established for the State for reallocation by the Secretary to other producers of that kind of tobacco in traditional tobacco counties, in a manner determined by the Secretary.

“(C) TRADITIONAL GROWING AREA POOL.—If any crop poundage base for a kind of tobacco remains after the crop poundage base is made available to producers of that kind of tobacco under subparagraphs (A) and (B), the unused crop poundage base shall be placed in a pool established for reallocation by the Secretary to other producers of that kind of tobacco in a traditional tobacco county for that kind of tobacco.

“(D) NEW PRODUCERS.—In reallocating unused crop poundage bases for a kind of tobacco in a traditional tobacco county made available under any of subparagraphs (A) through (C), the Secretary shall make available to any new producers of that kind of tobacco in the traditional tobacco county up to 10 percent of the crop poundage bases available for reallocation for the kind of tobacco in the traditional tobacco county.

“(e) COMPLIANCE.—

“(1) LOANS, PURCHASES, OR PAYMENTS.—An active producer of tobacco that knowingly produces a kind of tobacco in excess of the permitted acreage or permitted poundage, as applicable, for the kind of tobacco, or violates any lease or transfer requirements of this section, shall be ineligible for any loans, purchases, or payments for that crop of the kind of tobacco.

“(2) NO CARRYOVER.—An active producer of tobacco may not carry over permitted poundage or permitted acreage, as applicable, for a crop of a kind of tobacco, that is not produced by the producer, for production in a subsequent crop year.

“(3) PENALTIES.—

“(A) CRIMINAL PENALTY.—An active producer of tobacco that violates paragraph (1) shall be fined not more than \$100,000 or imprisoned not more than 2 years, or both.

“(B) CIVIL PENALTY.—An active producer of tobacco that violates paragraph (2) shall be subject to a civil penalty in an amount not to exceed 2 percent of the value of the kind of tobacco produced by the producer during the applicable crop year, as determined by the Secretary.

“(C) ADDITIONAL PENALTIES.—A civil penalty under subparagraph (B) for a violation shall be in addition to any criminal penalty under subparagraph (A) for the violation.

“(D) JURISDICTION TO PREVENT AND RESTRAIN VIOLATIONS.—A United States district

court shall have jurisdiction to prevent and restrain an active producer of tobacco from producing a kind of tobacco in excess of the permitted acreage for the kind of tobacco.

“(4) COMPLIANCE WITH CONSERVATION AND AGRICULTURAL REQUIREMENTS.—As a condition of the establishment of a crop acreage base or crop poundage base, as applicable, for active producers of tobacco for a crop of a kind of tobacco, the active producers of tobacco shall agree, during the crop year for which the crop acreage base or crop poundage base is established—

“(A) to comply with applicable conservation requirements under subtitle B of title XII of the Food Security Act of 1985 (16 U.S.C. 3811 et seq.);

“(B) to comply with applicable wetland protection requirements under subtitle C of title XII of the Act (16 U.S.C. 3821 et seq.);

“(C) to use the land of the active producer of tobacco, in a quantity equal to the crop acreage base for an agricultural or conserving use, and not for a nonagricultural commercial or industrial use, as determined by the Secretary; and

“(D) to effectively control noxious weeds and otherwise maintain the land in accordance with sound agricultural practices, as determined by the Secretary, if the agricultural or conserving use involves the noncultivation of any portion of the land referred to in subparagraph (C).

#### “CHAPTER 3—TOBACCO COMMUNITY ECONOMIC DEVELOPMENT GRANTS

##### “SEC. 3800. TOBACCO COMMUNITY ECONOMIC DEVELOPMENT GRANTS.

“(a) IN GENERAL.—The Secretary shall make grants to eligible States in accordance with this section to pay the cost of carrying out economic development initiatives in impacted communities.

“(b) APPLICATION.—To be eligible to receive payments under this section, an eligible State shall prepare and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including—

“(1) a description of the activities that the eligible State will carry out using amounts received under the grant; and

“(2) a description of the State department of agriculture that will administer amounts received under the grant.

“(c) AMOUNT OF GRANT.—From the amounts available to carry out this section, the Secretary shall allot—

“(1) \$20,000,000 to the State of Maryland;

“(2) \$14,000,000 to the State of Pennsylvania; and

“(3) \$50,000,000 to the State of South Carolina; and

“(4) 50,000,000 to the State of North Carolina.

“(d) PAYMENTS.—An eligible State that has an application approved by the Secretary under subsection (b) shall be entitled to a payment under this section, in 5 equal installments, in an amount that is equal to its allotment under subsection (c).

“(e) USE OF FUNDS.—Amounts received by an eligible State under this section shall be used to carry out economic development activities in impacted communities of the eligible State, as determined by the eligible State.

“(f) TERMINATION DATE.—The authority provided by this section terminates on September 30, 2008.

#### “CHAPTER 4—COMPETITIVE GRANTS FOR TOBACCO RESEARCH

##### “SEC. 380Q. COMPETITIVE GRANTS FOR TOBACCO RESEARCH.

“(a) IN GENERAL.—Notwithstanding any other provision of law, the Secretary shall make competitive grants under section 406 of the Agricultural Research, Extension, and Education Reform Act of 1998 (7 U.S.C. 7626) to colleges and universities located in eligible States to conduct research—

“(1) to assist tobacco producers to diversify crops or implement other means to reduce or eliminate the reliance of the producers on the production of tobacco or to promote alternative uses of tobacco or enhance the quality of tobacco produced in the United States; and

“(2) to foster and facilitate development, evaluation, and implementation of economically viable new agricultural technologies and enterprises for rural communities.

“(b) GRANT DISTRIBUTION.—In making grants under this section, the Secretary shall provide for an equitable distribution of the grants based on the volume of each kind of tobacco that is produced in each eligible State, as determined by the Secretary.

“(c) TERMINATION DATE.—The authority provided by this section terminates on September 30, 2008.

#### “CHAPTER 5—FUNDING

##### “SEC. 380S. TOBACCO TRUST FUND.

“(a) ESTABLISHMENT.—There is established in the Commodity Credit Corporation a revolving trust fund to be used in carrying out this subtitle (referred to in this section as the ‘Fund’), consisting of—

“(1) such amounts as are deposited in the Fund under subsection (b);

“(2) such amounts as are necessary from the Commodity Credit Corporation; and

“(3) any interest earned on investment of amounts in the Fund under subsection (d).

“(b) DEPOSITS.—Revenues from assessments collected under section 380T shall be deposited in the Fund.

“(c) EXPENDITURES.—

“(1) IN GENERAL.—Subject to paragraphs (2) and (3) and notwithstanding any other provision of law, in addition to any other funds that may be available, the Secretary may use from the Fund such amounts as the Secretary determines are necessary—

“(A) to make payments to tobacco quota holders and traditional producers under chapter 1;

“(B) to pay necessary expenses of the Tobacco Quality Board and Production Boards and to carry out the acreage limitation program under chapter 2;

“(C) to make tobacco community economic development grants under chapter 3, in an amount equal to \$16,800,000 for each of fiscal years 2004 through 2008;

“(D) to make competitive grants for tobacco research under chapter 4, in an amount equal to \$12,000,000 for each of fiscal years 2004 through 2008;

“(E) to make grants to each association that has entered into a loan agreement with the Commodity Credit Corporation under section 106A or 106B of the Agricultural Act of 1949 (7 U.S.C. 1445-1, 1445-2) (as in effect before the effective date of this subtitle) to assist the association to transition to alternative methods of marketing tobacco in accordance with a plan approved by the Secretary, with the grants allocated on the basis of the proportion of tobacco marketed by each association, in an amount not to exceed \$1,000,000 for each association for each kind of tobacco for each of fiscal years 2004 through 2008;



“(F) to make payments to appropriate tobacco warehouse associations, as determined by the Secretary, in an amount not to exceed \$500,000 for each of fiscal years 2004 through 2008;

“(G) to pay administrative costs incurred by the Secretary in carrying out this subtitle; and

“(H) to reimburse the Commodity Credit Corporation for costs incurred by the Commodity Credit Corporation under paragraph (2).

“(2) EXPENDITURES BY COMMODITY CREDIT CORPORATION.—

“(A) IN GENERAL.—Subject to subparagraph (B) and notwithstanding any other provision of law, the Secretary shall use funds of the Commodity Credit Corporation to make payments under paragraph (1).

“(B) REIMBURSEMENT TO COMMODITY CREDIT CORPORATION.—Not later than January 1, 2013, the Commodity Credit Corporation shall be reimbursed in full, with interest, for all funds of the Commodity Credit Corporation expended under subparagraph (A).

“(3) ADMINISTRATIVE EXPENSES.—

“(A) IN GENERAL.—An amount not to exceed \$20,000,000 for each fiscal year of the amounts in the Fund shall be available to pay the administrative expenses necessary to carry out this subtitle.

“(B) TERMINATION DATE.—The authority provided by this paragraph terminates on September 30, 2013.

“(d) INVESTMENT OF AMOUNTS.—

“(1) IN GENERAL.—The Commodity Credit Corporation shall invest such portion of the Fund as is not, in the judgment of the Commodity Credit Corporation, required to meet current withdrawals.

“(2) INTEREST-BEARING OBLIGATIONS.—Investments may be made only in interest-bearing obligations of the United States.

“(3) ACQUISITION OF OBLIGATIONS.—For the purpose of investments under paragraph (1), obligations may be acquired—

“(A) on original issue at the issue price; or

“(B) by purchase of outstanding obligations at the market price.

“(4) SALE OF OBLIGATIONS.—Any obligation acquired by the Fund may be sold by the Commodity Credit Corporation at the market price.

“(5) CREDITS TO FUND.—The interest on, and the proceeds from the sale or redemption of, any obligations held in the Fund shall be credited to and form a part of the Fund.

“(e) ADMINISTRATION.—In administering the Fund, the Secretary shall make payments, reimburse agencies of the Department, and accept deposits without regard to limitations on total amounts of allotments and fund transfers under section 11 of the Commodity Credit Corporation Charter Act (15 U.S.C. 714i).

#### “SEC. 380T. ASSESSMENTS.

“(a) DEFINITION OF GROSS DOMESTIC VOLUME.—In this section, the term ‘gross domestic volume’ means the volume of tobacco products—

“(1) removed (as defined by section 5702 of the Internal Revenue Code of 1986); and

“(2) not exempt from tax under chapter 52 of the Internal Revenue Code of 1986 at the time of their removal under that chapter or the Harmonized Tariff Schedule of the United States (19 U.S.C. 1202).

“(b) ASSESSMENTS.—The Secretary, acting through the Commodity Credit Corporation, shall impose quarterly assessments, calculated in accordance with this section, on each tobacco product manufacturer and tobacco product importer that sells tobacco products in domestic commerce in the United States.

“(c) TOBACCO TRUST FUND.—Assessments collected under this section shall be deposited in the Tobacco Trust Fund.

“(d) ASSESSMENT FOR EACH CLASS OF TOBACCO PRODUCT.—

“(1) ALLOCATION BY CLASS OF TOBACCO PRODUCTS.—The percentage of the total amount to be assessed against, and paid by, the manufacturers and importers of each class of tobacco product in each applicable fiscal year shall be—

“(A) for cigarette manufacturers and importers, 99.409 percent;

“(B) for snuff manufacturers and importers, 0.428 percent;

“(C) for chewing tobacco manufacturers and importers, 0.098 percent;

“(D) for pipe tobacco manufacturers and importers, 0.021 percent; and

“(E) for roll-your-own tobacco manufacturers and importers, 0.044 percent.

“(2) ADJUSTMENT.—The Secretary shall adjust the percentage of the total amount to be assessed against, as determined under paragraph (1), and paid by, the manufacturers and importers of each class of tobacco product in each applicable fiscal year by multiplying the percentage of the total amount to be assessed, as determined under paragraph (1), by a fraction—

“(A) the numerator of which is the total volume of domestic sales of that class of tobacco product during the preceding applicable fiscal year; and

“(B) the denominator of which is the total volume of domestic sales of that class of tobacco product during fiscal year 2003.

“(3) TOTAL ASSESSMENT.—

“(A) IN GENERAL.—The total amount to be assessed against all manufacturers and importers of all classes of tobacco product in each applicable fiscal year shall be equal to the amount required to carry out this subtitle during the applicable fiscal year, as determined by the Secretary.

“(B) ADDITIONAL AMOUNT.—

“(i) IN GENERAL.—If the amount to be assessed after the application of paragraphs (1) and (2) is insufficient to carry out this subtitle during the applicable fiscal year, the Secretary may assess such additional amount as the Secretary determines to be necessary to carry out this subtitle during the applicable fiscal year.

“(ii) ALLOCATION.—The additional amount shall be allocated to the manufacturers and importers of each class of tobacco product in the same manner and based on the same percentages applied in determining the total amount to be assessed under paragraph (1), as adjusted under paragraph (2) during the applicable fiscal year.

“(4) NOTIFICATION OF ASSESSMENTS.—

“(A) IN GENERAL.—The Secretary shall notify all manufacturers and importers of tobacco products of the amount of the assessment for each quarterly payment period.

“(B) CONTENTS.—The notice for a quarterly payment period shall describe gross domestic sales and market shares for the quarterly payment period and conform with the requirements of subsection (i).

“(5) TIMING OF ASSESSMENT PAYMENTS.—

“(A) IN GENERAL.—Assessments shall be collected at the end of each calendar year quarter.

“(B) BASE PERIOD QUARTER.—The assessment for a calendar year quarter shall correspond to the base period quarter that ended at the end of the preceding calendar year quarter.

“(C) AMOUNTS.—Subject to subparagraph (D), beginning with the calendar quarter ending on December 31 of each applicable fiscal

year, the payments over 4 calendar quarters shall be sufficient to cover—

“(i) the payments required under chapter 1 on November 1 of that same applicable fiscal year; and

“(ii) other expenditures from the Tobacco Trust Fund required under section 380S during the base quarter periods corresponding to those 4 calendar quarters.

“(D) SPECIAL RULE.—In the case of payments required under chapter 1 that are due on September 30, 2004, the assessments shall be paid on that same date and correspond to the first base period of 6 months.

“(e) ALLOCATION OF ASSESSMENT WITHIN EACH CLASS OF TOBACCO PRODUCT.—

“(1) IN GENERAL.—The assessment for each class of tobacco product shall be allocated on a pro rata basis among manufacturers and importers based on each manufacturer's or importer's share of gross domestic volume.

“(2) LIMITATION.—No manufacturer or importer shall be required to pay an assessment that is based on a share that is in excess of the manufacturer's or importer's share of domestic volume.

“(f) ALLOCATION OF TOTAL ASSESSMENTS BY MARKET SHARE.—The amount of the assessment for each class of tobacco product to be paid by each manufacturer or importer of the class of tobacco product under subsection (b) shall be determined for each quarterly payment period by multiplying—

“(1) the market share of the manufacturer or importer, as calculated with respect to that payment period, of the class of tobacco product; by

“(2) the total amount of the assessment for that quarterly payment period under subsection (d), for the class of tobacco product.

“(g) DETERMINATION OF VOLUME OF DOMESTIC SALES.—

“(1) IN GENERAL.—The calculation of the volume of domestic sales of a class of tobacco product by a manufacturer or importer, and by all manufacturers and importers as a group, shall be made by the Secretary based on information provided by the manufacturers and importers pursuant to subsection (h), as well as any other relevant information provided to or obtained by the Secretary.

“(2) GROSS DOMESTIC VOLUME.—The volume of domestic sales shall be calculated based on gross domestic volume.

“(3) MEASUREMENT.—For purposes of the calculations under this subsection and the certifications under subsection (h) by the Secretary, the volumes of domestic sales shall be measured by—

“(A) in the case of cigarettes, the numbers of cigarettes; and

“(B) in the case of other classes of tobacco products, in terms of number of pounds, or fraction thereof, of those products.

“(h) MEASUREMENT OF VOLUME OF DOMESTIC SALES.—

“(1) IN GENERAL.—Each manufacturer and importer of tobacco products shall submit to the Secretary a certified copy of each of the returns or forms described by paragraph (2) that are required to be filed with a Federal Government agency on the same date that those returns or forms are filed, or required to be filed, with the agency.

“(2) RETURNS AND FORMS.—The returns and forms described by this paragraph are those returns and forms that relate to—

“(A) the removal of tobacco products into domestic commerce (as defined by section 5702 of the Internal Revenue Code of 1986); and

“(B) the payment of the taxes imposed under chapter 52 of the Internal Revenue

Code of 1986, including AFT Form 5000.24 and United States Customs Form 7501 under currently applicable regulations.

“(3) PENALTIES.—

“(A) IN GENERAL.—Any person that knowingly fails to provide information required under this subsection or that provides false information under this subsection shall be subject to the penalties described in section 1003 of title 18, United States Code.

“(B) ADDITIONAL CIVIL PENALTY.—In addition, the Secretary may assess against the person a civil penalty in an amount not to exceed 2 percent of the value of the kind of tobacco products manufactured or imported by the person during the applicable fiscal year, as determined by the Secretary.

“(i) ASSESSMENT NOTIFICATION; CONTENT.—

“(1) IN GENERAL.—The Secretary shall provide each manufacturer or importer subject to an assessment under subsection (b) with written notice setting forth the amount to be assessed against the manufacturer or importer for the applicable quarterly period.

“(2) DEADLINE.—The notice for a quarterly period shall be provided not later than 30 days before the date payment is due under subsection (d)(5).

“(3) CONTENTS.—The notice shall include the following information with respect to the quarterly period used by the Secretary in calculating the amount:

“(A) The total combined assessment for all manufacturers and importers of tobacco products.

“(B) The total assessment with respect to the class of tobacco products manufactured or imported by the manufacturer or importer.

“(C) Any adjustments to the percentage allocations among the classes of tobacco products made pursuant to subsection (d)(2).

“(D) The volume of gross sales of the applicable class of tobacco product treated as made by the manufacturer or importer for purposes of calculating the manufacturer's or importer's market share under subsection (f).

“(E) The total volume of gross sales of the applicable class of tobacco product that the Secretary treated as made by all manufacturers and importers for purposes of calculating the manufacturer's or importer's market share under subsection (f).

“(F) The manufacturer's or importer's market share of the applicable class of tobacco product as determined by the Secretary under subsection (f).

“(G) The market share, as determined by the Secretary under subsection (f), of each other manufacturer and importer, for each applicable class of tobacco product.

“(j) CHALLENGE TO ASSESSMENT.—

“(1) APPEAL TO SECRETARY.—A manufacturer or importer subject to this section may contest an assessment imposed on the person under this section by notifying the Secretary not later than 10 business days after receiving the assessment notification required by subsection (i).

“(2) ESCROW.—The manufacturer and importer may place into escrow, in accordance with rules promulgated by the Secretary, only the portion of the assessment being challenged in good faith pending final determination of the assessment under this subsection.

“(3) INFORMATION.—The Secretary shall by regulation establish a procedure under which a person contesting an assessment under this subsection may present information to the Secretary to demonstrate that the assessment is incorrect, including information to demonstrate the following:

“(A) The total combined assessment imposed by the Secretary on all manufacturers and importers is excessive.

“(B) The Secretary's allocation of the total assessment among the classes of tobacco products is incorrect.

“(C) The total volume of gross domestic sales of all manufacturers and importers of the relevant class of tobacco product calculated by the Secretary under subsection (f) is incorrect.

“(D) The level of gross domestic sales attributed to the person by the Secretary for purposes of calculating the person's market share under subsection (f) exceeds the person's actual domestic sales of that class of tobacco product.

“(E) The amount of the assessment attributed to the person by the Secretary exceeds the person's pro rata share based on the person's share of gross domestic sales.

“(4) CHALLENGE.—

“(A) IN GENERAL.—In challenging an assessment under this subsection, the manufacturer or importer may use any information that is available, including third party data on industry or individual company sales volumes.

“(B) INCORRECT DETERMINATION.—The information may constitute evidence sufficient to establish that the Secretary's initial determination was incorrect, in which event the assessment shall be revised so that the manufacturer or importer is required only to pay the amount correctly determined.

“(5) TIME FOR REVIEW.—Not later than 30 days after receiving notice from a manufacturer or importer under paragraph (2), the Secretary shall—

“(A) decide whether the information provided to the Secretary pursuant to that paragraph, and any other information that the Secretary determines, is appropriate is sufficient to establish that the original assessment was incorrect; and

“(B) make any revisions necessary to ensure that each manufacturer and importer pays only its correct pro rata share of total gross domestic volume from all sources.

“(6) IMMEDIATE PAYMENT OF UNDISPUTED AMOUNTS.—The regulations promulgated by the Secretary under paragraph (2) shall provide for the immediate payment by a manufacturer or importer challenging an assessment of that portion of the assessment that is not in dispute.

“(7) JUDICIAL REVIEW.—

“(A) IN GENERAL.—Any manufacturer or importer aggrieved by a determination of the Secretary with respect to the amount of any assessment may seek review of the determination in the United States District Court for the District of Columbia or for the district in which the manufacturer or importer resides or has its principal place of business at any time following exhaustion of the administrative remedies under this subsection.

“(B) TIME LIMITS.—Administrative remedies shall be deemed exhausted if no decision by the Secretary is made within the time limits established under paragraph (5).

“(C) EXCESSIVE ASSESSMENTS.—The court shall restrain collection of the excessive portion of any assessment or order a refund of excessive assessments already paid, along with interest calculated at the rate prescribed in section 3717 of title 31, United States Code, if it finds that the Secretary's determination is not supported by a preponderance of the information available to the Secretary.

“(8) REGULATIONS.—Not later than 180 days after the date of enactment of this subtitle, the Secretary shall promulgate regulations

to implement this subsection (in accordance with section 301 of the Tobacco Market Transition Act of 2004).

“(k) USE OF QUALIFIED FINANCIAL INSTITUTIONS.—The Secretary may use qualified financial institutions to manage assets, make payments, and otherwise carry out this subtitle.

“(l) TERMINATION DATE.—The authority provided by this section terminates on September 30, 2013.

“SEC. 380U. COMMODITY CREDIT CORPORATION.

The Secretary shall use the funds, facilities, and authorities of the Commodity Credit Corporation to carry out this subtitle, to remain available until expended.

“SEC. 380V. TRANSITION PROVISIONS.

“(a) TOBACCO STOCKS.—

“(1) IN GENERAL.—To provide for the orderly disposition of quota tobacco held by an association that has entered into a loan agreement with the Commodity Credit Corporation under section 106A or 106B of the Agricultural Act of 1949 (7 U.S.C. 1445-1, 1445-2) (referred to in this section as an ‘association’), loan pool stocks for each kind of tobacco held by the association shall be disposed of in accordance with this subsection.

“(2) ASSOCIATIONS.—For each kind of tobacco held by an association, the proportion of loan pool stocks for each kind of tobacco held by the association that shall be transferred to the association shall be equal to—

“(A) the amount of funds held by the association in the No Net Cost Tobacco Fund and the No Net Cost Tobacco Account established under sections 106A and 106B of the Agricultural Act of 1949 (7 U.S.C. 1445-1, 1445-2), respectively, for the kind of tobacco; divided by

“(B) the average list price per pound for the kind of tobacco, as determined by the Secretary.

“(3) COMMODITY CREDIT CORPORATION.—Any loan pool stocks of a kind of tobacco of an association that are not disposed of in accordance with paragraph (2) shall be—

“(A) transferred by the association to the Commodity Credit Corporation; and

“(B) disposed of in a manner determined by the Secretary.

“(b) NO NET COST FUNDS.—

“(1) IN GENERAL.—Any funds in the No Net Cost Tobacco Fund or the No Net Cost Tobacco Account of an association established under sections 106A and 106B of the Agricultural Act of 1949 (7 U.S.C. 1445-1, 1445-2), respectively, that remain after the application of subsection (a) and sections 106A and 106B of the Agricultural Act of 1949 (7 U.S.C. 1445, 1445-1) (as in effect before the effective date of this subtitle) shall be transferred to the association for distribution to traditional producers of tobacco in accordance with a plan approved by the Secretary.

“(2) ASSOCIATIONS WITH NO LOAN POOL STOCKS.—In the case of an association that does not hold any loan pool stocks that are covered by subsection (a)(2), any funds in the No Net Cost Tobacco Fund or the No Net Cost Tobacco Account of the association established under sections 106A and 106B of the Agricultural Act of 1949 (7 U.S.C. 1445-1, 1445-2), respectively, shall be transferred to the association for distribution to traditional producers of tobacco in accordance with a plan approved by the Secretary.

“(c) REIMBURSEMENT TO COMMODITY CREDIT CORPORATION.—There shall be transferred from the Tobacco Trust Fund to each No Net Cost Tobacco Fund or the No Net Cost Tobacco Account of an association established under sections 106A and 106B of the Agricultural Act of 1949 (7 U.S.C. 1445-1, 1445-2), respectively, such amounts as the Secretary

determines will be adequate to reimburse the Commodity Credit Corporation for any net losses that the Corporation may sustain under its loan agreements with the association.”.

**SEC. 52. TOBACCO INSURANCE RESEARCH AND DEVELOPMENT.**

(a) IN GENERAL.—Section 522(b)(1) of the Federal Crop Insurance Act (7 U.S.C. 1522(b)(1)) is amended—

(1) by redesignating subparagraphs (A) and (B) as clauses (i) and (ii), respectively, and indenting appropriately;

(2) by striking “The Corporation” and inserting the following—

“(A) IN GENERAL.—The”; and

(3) by adding at the end the following:

“(B) TOBACCO RESEARCH AND DEVELOPMENT.—Subject to the availability of funds under subsection (e)(5), the Corporation shall provide a payment to reimburse an applicant for research and development costs directly related to a policy that is—

“(i) submitted to the Board and approved by the Board under section 508(h) for reinsurance;

“(ii) if applicable, offered for sale to producers; and

“(iii) addresses risk in the production of tobacco.”.

(b) ASSESSMENTS.—Section 522(e) of the Federal Crop Insurance Act (7 U.S.C. 1522(e)) is amended by adding at the end the following:

“(5) TOBACCO ASSESSMENT.—

“(A) IN GENERAL.—Effective for each marketing year for a kind of tobacco for which a commodity-specific plan of insurance is offered under this Act, subject to subparagraphs (B) through (D), each producer and purchaser of that kind of tobacco shall remit to the Insurance Fund established under section 516(c) a nonrefundable marketing assessment in an amount determined by the Secretary pursuant to subparagraphs (B) and (C).

“(B) TOTAL AMOUNT.—The total amount of producer and purchaser assessments for a kind of tobacco collected under this paragraph shall be equal to the amount that is necessary to carry out subsection (b)(1)(B).

“(C) ADMINISTRATION.—Producer and purchaser assessments for a kind of tobacco under this paragraph—

“(i) shall be determined in such a manner that producers and purchasers share equally, to the maximum extent practicable, in paying assessments required under this paragraph; and

“(ii) shall not exceed 5 cents per pound.

“(D) TERMINATION.—Effective beginning with the 2010 crop of each kind of tobacco, the Secretary may terminate the collection of assessments for that kind of tobacco if the Secretary determines that further research and development under subsection (b)(1)(B) would not be productive.”.

(c) INSURANCE FUND.—Section 516(c)(1) of the Federal Crop Insurance Act (7 U.S.C. 1516(c)(1)) is amended by inserting “assessments for tobacco research made available under section 522(e)(5),” after “under subsection (a)(2).”.

**SEC. 53. CONFORMING AMENDMENTS.**

Section 320B(c)(1) of the Agricultural Adjustment Act of 1938 (7 U.S.C. 1314h(c)(1)) is amended—

(1) by inserting “(A)” after “(1)”;

(2) by striking “by” at the end and inserting “or”; and

(3) by adding at the end the following:

“(B) In the case of the 2003 marketing year, the price support rate for the kind of tobacco involved in effect under section 106 of the

Agricultural Act of 1949 (7 U.S.C. 1445) at the time of the violation; by”.

**CHAPTER 3—IMPLEMENTATION**

**SEC. 61. REGULATIONS.**

(a) IN GENERAL.—The Secretary of Agriculture may promulgate such regulations as are necessary to implement this subtitle and the amendments made by this subtitle.

(b) PROCEDURE.—The promulgation of the regulations and administration of this subtitle shall be made without regard to—

(1) the notice and comment provisions of section 553 of title 5, United States Code;

(2) the Statement of Policy of the Secretary of Agriculture effective July 24, 1971 (36 Fed. Reg. 13804), relating to notices of proposed rulemaking and public participation in rulemaking; and

(3) chapter 35 of title 44, United States Code (commonly known as the “Paperwork Reduction Act”).

(c) CONGRESSIONAL REVIEW OF AGENCY RULEMAKING.—In carrying out this section, the Secretary shall use the authority provided under section 808 of title 5, United States Code.

**SEC. 62. EFFECTIVE DATE.**

This subtitle and the amendments made by this subtitle shall apply to the 2004 and subsequent crops of each kind of tobacco.

**SA 3564.** Mr. ROBERTS (for himself and Mr. ROCKEFELLER) submitted an amendment intended to be proposed by him to the bill S. 2386, to authorize appropriations for fiscal year 2005 for intelligence and intelligence-related activities of the United States Government, the Intelligence Community Management Account, and the Central Intelligence Agency Retirement and Disability System, and for other purposes; which was ordered to lie on the table; as follows:

On page 9, line 16, add at the end the following: “Such funds shall remain available until September 30, 2005.”.

On page 19, strike lines 7 through 15 and insert the following:

“(1) IN GENERAL.—The Director may establish and administer a nonofficial cover employee retirement system for designated employees (and the spouse, former spouses, and survivors of such designated employees). A des-

On page 21, strike line 18 and all that follows through page 22, line 1, and insert the following:

“(iii) in the case of a designated employee who participated in an employee investment retirement system established under paragraph (1) and is converted to coverage under subchapter III of chapter 84 of title 5, United States Code, the Director may transmit any or all amounts of that designated employee in that employee investment retirement system (or similar

On page 22, strike line 24 and all that follows through page 23, line 5, and insert the following:

“(1) IN GENERAL.—The Director may establish and administer a nonofficial cover employee health insurance program for designated employees (and the family of such designated employees). A designated employee

On page 25, strike lines 6 through 12 and insert the following:

“(1) IN GENERAL.—The Director may establish and administer a nonofficial cover employee life insurance program for designated

employees (and the family of such designated employees). A designated employee may not

On page 27, line 8, strike “(B)(iii)” and insert “(B)(iv)”.

**AUTHORITY FOR COMMITTEES TO MEET**

**COMMITTEE ON ARMED SERVICES**

Mr. DEWINE. Mr. President, I ask unanimous consent that the Committee on Armed Services be authorized to meet during the session of the Senate on July 15, 2004, at 9:30 a.m., in closed session to receive a briefing regarding ICRC reports on U.S. military detainee operations in Iraq.

The PRESIDING OFFICER. Without objection, it is so ordered.

**COMMITTEE ON BANKING, HOUSING, AND URBAN AFFAIRS**

Mr. DEWINE. Mr. President, I ask unanimous consent that the Committee on Banking, Housing, and Urban Affairs be authorized to meet during the session of the Senate on Thursday, July 15, 2004, at 10 a.m., to conduct a hearing on “Regulation of the Hedge Fund Industry.”

The PRESIDING OFFICER. Without objection, it is so ordered.

**COMMITTEE ON BANKING, HOUSING, AND URBAN AFFAIRS**

Mr. DEWINE. Mr. President, I ask unanimous consent that the Committee on Banking, Housing, and Urban Affairs be authorized to meet during the session of the Senate on Thursday, July 15, 2004, at 2:30 p.m., to conduct a hearing on the nominations of Mr. Stuart Levey, of Maryland, to be Under Secretary of the Treasury for Enforcement; Mr. Juan Carlos Zarate, of California, to be Assistant Secretary of the Treasury for Terrorist Financing and Financial Crimes; and Ms. Carin M. Barth, of Texas, to be the Chief Financial Officer, Department of Housing and Urban Development.

The PRESIDING OFFICER. Without objection, it is so ordered.

**COMMITTEE ON FOREIGN RELATIONS**

Mr. DEWINE. Mr. President, I ask unanimous consent that the Committee on Foreign Relations be authorized to meet during the session of the Senate on Thursday, July 15, 2004, at 9:30 a.m., to hold a hearing on North Korea.

The PRESIDING OFFICER. Without objection, it is so ordered.

**COMMITTEE ON FOREIGN RELATIONS**

Mr. DEWINE. Mr. President, I ask unanimous consent that the Committee on Foreign Relations be authorized to meet during the session of the Senate on Thursday, July 15, 2004, at 1 p.m., to hold a hearing on the Gulf of Guinea and U.S. Strategic Energy Policy.

The PRESIDING OFFICER. Without objection, it is so ordered.