

111TH CONGRESS  
1ST SESSION

# S. 982

To protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products.

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## IN THE SENATE OF THE UNITED STATES

MAY 5, 2009

Mr. REID (for Mr. KENNEDY (for himself, Mr. DODD, Ms. COLLINS, Mr. HARKIN, Ms. SNOWE, Mr. DURBIN, Mr. LUGAR, Ms. MIKULSKI, Mr. REED, Mrs. MURRAY, Mr. REID, Mr. BINGAMAN, Mr. SANDERS, Mr. BROWN, Mr. CASEY, Mr. MERKLEY, Mr. WHITEHOUSE, Mr. LEAHY, Mr. LAUTENBERG, Mr. KERRY, Mr. SCHUMER, Mr. LIEBERMAN, Mrs. FEINSTEIN, Mr. LEVIN, Mr. BAUCUS, Mr. WYDEN, Mr. AKAKA, Mr. NELSON of Florida, Ms. LANDRIEU, Mr. CARPER, Mrs. GILLIBRAND, Mr. BENNET, Mr. BEGICH, Mr. BURRIS, Mr. KAUFMAN, Mr. UDALL of New Mexico, Mr. UDALL of Colorado, Mr. KOHL, Mr. FEINGOLD, Ms. CANTWELL, and Mrs. LINCOLN)) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## A BILL

To protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the  
5 “Family Smoking Prevention and Tobacco Control Act”.

1 (b) TABLE OF CONTENTS.—The table of contents of  
 2 this Act is as follows:

- Sec. 1. Short title; table of contents.
- Sec. 2. Findings.
- Sec. 3. Purpose.
- Sec. 4. Scope and effect.
- Sec. 5. Severability.

TITLE I—AUTHORITY OF THE FOOD AND DRUG  
 ADMINISTRATION

- Sec. 101. Amendment of Federal Food, Drug, and Cosmetic Act.
- Sec. 102. Final rule.
- Sec. 103. Conforming and other amendments to general provisions.
- Sec. 104. Study on raising the minimum age to purchase tobacco products.
- Sec. 105. Enforcement action plan for advertising and promotion restrictions.

TITLE II—TOBACCO PRODUCT WARNINGS; CONSTITUENT AND  
 SMOKE CONSTITUENT DISCLOSURE

- Sec. 201. Cigarette label and advertising warnings.
- Sec. 202. Authority to revise cigarette warning label statements.
- Sec. 203. State regulation of cigarette advertising and promotion.
- Sec. 204. Smokeless tobacco labels and advertising warnings.
- Sec. 205. Authority to revise smokeless tobacco product warning label statements.
- Sec. 206. Tar, nicotine, and other smoke constituent disclosure to the public.

TITLE III—PREVENTION OF ILLICIT TRADE IN TOBACCO  
 PRODUCTS

- Sec. 301. Labeling, recordkeeping, records inspection.
- Sec. 302. Study and report.

3 **SEC. 2. FINDINGS.**

4 The Congress finds the following:

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

9 (2) A consensus exists within the scientific and  
 10 medical communities that tobacco products are in-

1 herently dangerous and cause cancer, heart disease,  
2 and other serious adverse health effects.

3 (3) Nicotine is an addictive drug.

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

7 (5) Tobacco advertising and marketing con-  
8 tribute significantly to the use of nicotine-containing  
9 tobacco products by adolescents.

10 (6) Because past efforts to restrict advertising  
11 and marketing of tobacco products have failed ade-  
12 quately to curb tobacco use by adolescents, com-  
13 prehensive restrictions on the sale, promotion, and  
14 distribution of such products are needed.

15 (7) Federal and State governments have lacked  
16 the legal and regulatory authority and resources  
17 they need to address comprehensively the public  
18 health and societal problems caused by the use of to-  
19 bacco products.

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

24 (9) Under article I, section 8 of the Constitu-  
25 tion, the Congress is vested with the responsibility

1 for regulating interstate commerce and commerce  
2 with Indian tribes.

3 (10) The sale, distribution, marketing, adver-  
4 tising, and use of tobacco products are activities in  
5 and substantially affecting interstate commerce be-  
6 cause they are sold, marketed, advertised, and dis-  
7 tributed in interstate commerce on a nationwide  
8 basis, and have a substantial effect on the Nation's  
9 economy.

10 (11) The sale, distribution, marketing, adver-  
11 tising, and use of such products substantially affect  
12 interstate commerce through the health care and  
13 other costs attributable to the use of tobacco prod-  
14 ucts.

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

22 (13) Tobacco use is the foremost preventable  
23 cause of premature death in America. It causes over  
24 400,000 deaths in the United States each year, and

1 approximately 8,600,000 Americans have chronic ill-  
2 nesses related to smoking.

3 (14) Reducing the use of tobacco by minors by  
4 50 percent would prevent well over 10,000,000 of to-  
5 day's children from becoming regular, daily smokers,  
6 saving over 3,000,000 of them from premature  
7 death due to tobacco-induced disease. Such a reduc-  
8 tion in youth smoking would also result in approxi-  
9 mately \$75,000,000,000 in savings attributable to  
10 reduced health care costs.

11 (15) Advertising, marketing, and promotion of  
12 tobacco products have been especially directed to at-  
13 tract young persons to use tobacco products, and  
14 these efforts have resulted in increased use of such  
15 products by youth. Past efforts to oversee these ac-  
16 tivities have not been successful in adequately pre-  
17 venting such increased use.

18 (16) In 2005, the cigarette manufacturers  
19 spent more than \$13,000,000,000 to attract new  
20 users, retain current users, increase current con-  
21 sumption, and generate favorable long-term atti-  
22 tudes toward smoking and tobacco use.

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

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

5           (19) Through advertisements during and spon-  
6           sorship of sporting events, tobacco has become  
7           strongly associated with sports and has become por-  
8           trayed as an integral part of sports and the healthy  
9           lifestyle associated with rigorous sporting activity.

10          (20) Children are exposed to substantial and  
11          unavoidable tobacco advertising that leads to favor-  
12          able beliefs about tobacco use, plays a role in leading  
13          young people to overestimate the prevalence of to-  
14          bacco use, and increases the number of young people  
15          who begin to use tobacco.

16          (21) The use of tobacco products in motion pic-  
17          tures and other mass media glamorizes its use for  
18          young people and encourages them to use tobacco  
19          products.

20          (22) Tobacco advertising expands the size of  
21          the tobacco market by increasing consumption of to-  
22          bacco products including tobacco use by young peo-  
23          ple.

24          (23) Children are more influenced by tobacco  
25          marketing than adults: more than 80 percent of

1 youth smoke three heavily marketed brands, while  
2 only 54 percent of adults, 26 and older, smoke these  
3 same brands.

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

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

13 (26) Restrictions on advertising are necessary  
14 to prevent unrestricted tobacco advertising from un-  
15 dermining legislation prohibiting access to young  
16 people and providing for education about tobacco  
17 use.

18 (27) International experience shows that adver-  
19 tising regulations that are stringent and comprehen-  
20 sive have a greater impact on overall tobacco use  
21 and young people's use than weaker or less com-  
22 prehensive ones.

23 (28) Text only requirements, although not as  
24 stringent as a ban, will help reduce underage use of

1 tobacco products while preserving the informational  
2 function of advertising.

3 (29) It is in the public interest for Congress to  
4 adopt legislation to address the public health crisis  
5 created by actions of the tobacco industry.

6 (30) The final regulations promulgated by the  
7 Secretary of Health and Human Services in the Au-  
8 gust 28, 1996, issue of the Federal Register (61  
9 Fed. Reg. 44615–44618) for inclusion as part 897  
10 of title 21, Code of Federal Regulations, are con-  
11 sistent with the first amendment to the United  
12 States Constitution and with the standards set forth  
13 in the amendments made by this subtitle for the reg-  
14 ulation of tobacco products by the Food and Drug  
15 Administration, and the restriction on the sale and  
16 distribution of, including access to and the adver-  
17 tising and promotion of, tobacco products contained  
18 in such regulations are substantially related to ac-  
19 complishing the public health goals of this Act.

20 (31) The regulations described in paragraph  
21 (30) will directly and materially advance the Federal  
22 Government’s substantial interest in reducing the  
23 number of children and adolescents who use ciga-  
24 rettes and smokeless tobacco and in preventing the  
25 life-threatening health consequences associated with



1 tobacco use. An overwhelming majority of Americans  
2 who use tobacco products begin using such products  
3 while they are minors and become addicted to the  
4 nicotine in those products before reaching the age of  
5 18. Tobacco advertising and promotion play a cru-  
6 cial role in the decision of these minors to begin  
7 using tobacco products. Less restrictive and less  
8 comprehensive approaches have not and will not be  
9 effective in reducing the problems addressed by such  
10 regulations. The reasonable restrictions on the ad-  
11 vertising and promotion of tobacco products con-  
12 tained in such regulations will lead to a significant  
13 decrease in the number of minors using and becom-  
14 ing addicted to those products.

15 (32) The regulations described in paragraph  
16 (30) impose no more extensive restrictions on com-  
17 munication by tobacco manufacturers and sellers  
18 than are necessary to reduce the number of children  
19 and adolescents who use cigarettes and smokeless to-  
20 bacco and to prevent the life-threatening health con-  
21 sequences associated with tobacco use. Such regula-  
22 tions are narrowly tailored to restrict those adver-  
23 tising and promotional practices which are most like-  
24 ly to be seen or heard by youth and most likely to  
25 entice them into tobacco use, while affording tobacco

1 manufacturers and sellers ample opportunity to con-  
2vey information about their products to adult con-  
3sumers.

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

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

10 (35) Tobacco products have been used to facili-  
11tate and finance criminal activities both domestically  
12and internationally. Illicit trade of tobacco products  
13has been linked to organized crime and terrorist  
14groups.

15 (36) It is essential that the Food and Drug Ad-  
16ministration review products sold or distributed for  
17use to reduce risks or exposures associated with to-  
18bacco products and that it be empowered to review  
19any advertising and labeling for such products. It is  
20also essential that manufacturers, prior to marketing  
21such products, be required to demonstrate that such  
22products will meet a series of rigorous criteria, and  
23will benefit the health of the population as a whole,  
24taking into account both users of tobacco products

1 and persons who do not currently use tobacco prod-  
2 ucts.

3 (37) Unless tobacco products that purport to  
4 reduce the risks to the public of tobacco use actually  
5 reduce such risks, those products can cause substan-  
6 tial harm to the public health to the extent that the  
7 individuals, who would otherwise not consume to-  
8 bacco products or would consume such products less,  
9 use tobacco products purporting to reduce risk.  
10 Those who use products sold or distributed as modi-  
11 fied risk products that do not in fact reduce risk,  
12 rather than quitting or reducing their use of tobacco  
13 products, have a substantially increased likelihood of  
14 suffering disability and premature death. The costs  
15 to society of the widespread use of products sold or  
16 distributed as modified risk products that do not in  
17 fact reduce risk or that increase risk include thou-  
18 sands of unnecessary deaths and injuries and huge  
19 costs to our health care system.

20 (38) As the National Cancer Institute has  
21 found, many smokers mistakenly believe that “low  
22 tar” and “light” cigarettes cause fewer health prob-  
23 lems than other cigarettes. As the National Cancer  
24 Institute has also found, mistaken beliefs about the  
25 health consequences of smoking “low tar” and

1 “light” cigarettes can reduce the motivation to quit  
2 smoking entirely and thereby lead to disease and  
3 death.

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

9 (40) The dangers of products sold or distrib-  
10 uted as modified risk tobacco products that do not  
11 in fact reduce risk are so high that there is a com-  
12 pelling governmental interest in ensuring that state-  
13 ments about modified risk tobacco products are com-  
14 plete, accurate, and relate to the overall disease risk  
15 of the product.

16 (41) As the Federal Trade Commission has  
17 found, consumers have misinterpreted advertise-  
18 ments in which one product is claimed to be less  
19 harmful than a comparable product, even in the  
20 presence of disclosures and advisories intended to  
21 provide clarification.

22 (42) Permitting manufacturers to make unsub-  
23 stantiated statements concerning modified risk to-  
24 bacco products, whether express or implied, even if

1 accompanied by disclaimers would be detrimental to  
2 the public health.

3 (43) The only way to effectively protect the  
4 public health from the dangers of unsubstantiated  
5 modified risk tobacco products is to empower the  
6 Food and Drug Administration to require that prod-  
7 ucts that tobacco manufacturers sold or distributed  
8 for risk reduction be reviewed in advance of mar-  
9 keting, and to require that the evidence relied on to  
10 support claims be fully verified.

11 (44) The Food and Drug Administration is a  
12 regulatory agency with the scientific expertise to  
13 identify harmful substances in products to which  
14 consumers are exposed, to design standards to limit  
15 exposure to those substances, to evaluate scientific  
16 studies supporting claims about the safety of prod-  
17 ucts, and to evaluate the impact of labels, labeling,  
18 and advertising on consumer behavior in order to re-  
19 duce the risk of harm and promote understanding of  
20 the impact of the product on health. In connection  
21 with its mandate to promote health and reduce the  
22 risk of harm, the Food and Drug Administration  
23 routinely makes decisions about whether and how  
24 products may be marketed in the United States.

1           (45) The Federal Trade Commission was cre-  
2           ated to protect consumers from unfair or deceptive  
3           acts or practices, and to regulate unfair methods of  
4           competition. Its focus is on those marketplace prac-  
5           tices that deceive or mislead consumers, and those  
6           that give some competitors an unfair advantage. Its  
7           mission is to regulate activities in the marketplace.  
8           Neither the Federal Trade Commission nor any  
9           other Federal agency except the Food and Drug Ad-  
10          ministration possesses the scientific expertise needed  
11          to implement effectively all provisions of the Family  
12          Smoking Prevention and Tobacco Control Act.

13           (46) If manufacturers state or imply in commu-  
14          nications directed to consumers through the media  
15          or through a label, labeling, or advertising, that a to-  
16          bacco product is approved or inspected by the Food  
17          and Drug Administration or complies with Food and  
18          Drug Administration standards, consumers are like-  
19          ly to be confused and misled. Depending upon the  
20          particular language used and its context, such a  
21          statement could result in consumers being misled  
22          into believing that the product is endorsed by the  
23          Food and Drug Administration for use or in con-  
24          sumers being misled about the harmfulness of the

1 product because of such regulation, inspection, ap-  
2 proval, or compliance.

3 (47) In August 2006 a United States district  
4 court judge found that the major United States cig-  
5 arette companies continue to target and market to  
6 youth. *USA v. Philip Morris, USA, Inc., et al.* (Civil  
7 Action No. 99–2496 (GK), August 17, 2006).

8 (48) In August 2006 a United States district  
9 court judge found that the major United States cig-  
10 arette companies dramatically increased their adver-  
11 tising and promotional spending in ways that en-  
12 courage youth to start smoking subsequent to the  
13 signing of the Master Settlement Agreement in  
14 1998. *USA v. Philip Morris, USA, Inc., et al.* (Civil  
15 Action No. 99–2496 (GK), August 17, 2006).

16 (49) In August 2006 a United States district  
17 court judge found that the major United States cig-  
18 arette companies have designed their cigarettes to  
19 precisely control nicotine delivery levels and provide  
20 doses of nicotine sufficient to create and sustain ad-  
21 diction while also concealing much of their nicotine-  
22 related research. *USA v. Philip Morris, USA, Inc.,*  
23 *et al.* (Civil Action No. 99–2496 (GK), August 17,  
24 2006).

1 **SEC. 3. PURPOSE.**

2 The purposes of this Act are—

3 (1) to provide authority to the Food and Drug  
4 Administration to regulate tobacco products under  
5 the Federal Food, Drug, and Cosmetic Act (21  
6 U.S.C. 301 et seq.), by recognizing it as the primary  
7 Federal regulatory authority with respect to the  
8 manufacture, marketing, and distribution of tobacco  
9 products as provided for in this Act;

10 (2) to ensure that the Food and Drug Adminis-  
11 tration has the authority to address issues of par-  
12 ticular concern to public health officials, especially  
13 the use of tobacco by young people and dependence  
14 on tobacco;

15 (3) to authorize the Food and Drug Adminis-  
16 tration to set national standards controlling the  
17 manufacture of tobacco products and the identity,  
18 public disclosure, and amount of ingredients used in  
19 such products;

20 (4) to provide new and flexible enforcement au-  
21 thority to ensure that there is effective oversight of  
22 the tobacco industry's efforts to develop, introduce,  
23 and promote less harmful tobacco products;

24 (5) to vest the Food and Drug Administration  
25 with the authority to regulate the levels of tar, nico-



1       tine, and other harmful components of tobacco prod-  
2       ucts;

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

9               (7) to continue to permit the sale of tobacco  
10       products to adults in conjunction with measures to  
11       ensure that they are not sold or accessible to under-  
12       age purchasers;

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

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

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

20 **SEC. 4. SCOPE AND EFFECT.**

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

23              (1) establish a precedent with regard to any  
24       other industry, situation, circumstance, or legal ac-  
25       tion; or

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

4           (b) **AGRICULTURAL ACTIVITIES.**—The provisions of  
5 this Act (or an amendment made by this Act) which au-  
6 thorize the Secretary to take certain actions with regard  
7 to tobacco and tobacco products shall not be construed to  
8 affect any authority of the Secretary of Agriculture under  
9 existing law regarding the growing, cultivation, or curing  
10 of raw tobacco.

11          (c) **REVENUE ACTIVITIES.**—The provisions of this  
12 Act (or an amendment made by this Act) which authorize  
13 the Secretary to take certain actions with regard to to-  
14 bacco products shall not be construed to affect any author-  
15 ity of the Secretary of the Treasury under chapter 52 of  
16 the Internal Revenue Code of 1986.

17 **SEC. 5. SEVERABILITY.**

18          If any provision of this Act, of the amendments made  
19 by this Act, or of the regulations promulgated under this  
20 Act (or under such amendments), or the application of any  
21 such provision to any person or circumstance is held to  
22 be invalid, the remainder of this Act, such amendments  
23 and such regulations, and the application of such provi-  
24 sions to any other person or circumstance shall not be af-

1 fected and shall continue to be enforced to the fullest ex-  
2 tent possible.

3 **TITLE I—AUTHORITY OF THE**  
4 **FOOD AND DRUG ADMINIS-**  
5 **TRATION**

6 **SEC. 101. AMENDMENT OF FEDERAL FOOD, DRUG, AND**  
7 **COSMETIC ACT.**

8 (a) DEFINITION OF TOBACCO PRODUCTS.—Section  
9 201 of the Federal Food, Drug, and Cosmetic Act (21  
10 U.S.C. 321) is amended by adding at the end the fol-  
11 lowing:

12 “(rr)(1) The term ‘tobacco product’ means any prod-  
13 uct made or derived from tobacco that is intended for  
14 human consumption, including any component, part, or  
15 accessory of a tobacco product (except for raw materials  
16 other than tobacco used in manufacturing a component,  
17 part, or accessory of a tobacco product).

18 “(2) The term ‘tobacco product’ does not mean an  
19 article that is a drug under subsection (g)(1), a device  
20 under subsection (h), or a combination product described  
21 in section 503(g).

22 “(3) The products described in paragraph (2) shall  
23 be subject to chapter V of this Act.

24 “(4) A tobacco product shall not be marketed in com-  
25 bination with any other article or product regulated under

1 this Act (including a drug, biologic, food, cosmetic, med-  
2 ical device, or a dietary supplement).”.

3 (b) FDA AUTHORITY OVER TOBACCO PRODUCTS.—  
4 The Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
5 301 et seq.) is amended—

6 (1) by redesignating chapter IX as chapter X;

7 (2) by redesignating sections 901 through 910  
8 as sections 1001 through 1010; and

9 (3) by inserting after chapter VIII the fol-  
10 lowing:

11 **“CHAPTER IX—TOBACCO PRODUCTS**

12 **“SEC. 900. DEFINITIONS.**

13 “In this chapter:

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

1           “(2) BRAND.—The term ‘brand’ means a vari-  
2           ety of tobacco product distinguished by the tobacco  
3           used, tar content, nicotine content, flavoring used,  
4           size, filtration, packaging, logo, registered trade-  
5           mark, brand name, identifiable pattern of colors, or  
6           any combination of such attributes.

7           “(3) CIGARETTE.—The term ‘cigarette’—

8                   “(A) means a product that—

9                           “(i) is a tobacco product; and

10                           “(ii) meets the definition of the term  
11                           ‘cigarette’ in section 3(1) of the Federal  
12                           Cigarette Labeling and Advertising Act;  
13                           and

14                   “(B) includes tobacco, in any form, that is  
15                   functional in the product, which, because of its  
16                   appearance, the type of tobacco used in the  
17                   filler, or its packaging and labeling, is likely to  
18                   be offered to, or purchased by, consumers as a  
19                   cigarette or as roll-your-own tobacco.

20           “(4) CIGARETTE TOBACCO.—The term ‘ciga-  
21           rette tobacco’ means any product that consists of  
22           loose tobacco that is intended for use by consumers  
23           in a cigarette. Unless otherwise stated, the require-  
24           ments applicable to cigarettes under this chapter  
25           shall also apply to cigarette tobacco.

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

4           “(6) COUNTERFEIT TOBACCO PRODUCT.—The  
5 term ‘counterfeit tobacco product’ means a tobacco  
6 product (or the container or labeling of such a prod-  
7 uct) that, without authorization, bears the trade-  
8 mark, trade name, or other identifying mark, im-  
9 print, or device, or any likeness thereof, of a tobacco  
10 product listed in a registration under section  
11 905(i)(1).

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

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

1           “(9) INDIAN COUNTRY.—The term ‘Indian  
2 country’ has the meaning given such term in section  
3 1151 of title 18, United States Code.

4           “(10) INDIAN TRIBE.—The term ‘Indian tribe’  
5 has the meaning given such term in section 4(e) of  
6 the Indian Self-Determination and Education Assist-  
7 ance Act.

8           “(11) LITTLE CIGAR.—The term ‘little cigar’  
9 means a product that—

10                   “(A) is a tobacco product; and

11                   “(B) meets the definition of the term ‘little  
12 cigar’ in section 3(7) of the Federal Cigarette  
13 Labeling and Advertising Act.

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

18           “(13) PACKAGE.—The term ‘package’ means a  
19 pack, box, carton, or container of any kind or, if no  
20 other container, any wrapping (including cello-  
21 phane), in which a tobacco product is offered for  
22 sale, sold, or otherwise distributed to consumers.

23           “(14) RETAILER.—The term ‘retailer’ means  
24 any person, government, or entity who sells tobacco  
25 products to individuals for personal consumption, or

1 who operates a facility where self-service displays of  
2 tobacco products are permitted.

3 “(15) ROLL-YOUR-OWN TOBACCO.—The term  
4 ‘roll-your-own tobacco’ means any tobacco product  
5 which, because of its appearance, type, packaging, or  
6 labeling, is suitable for use and likely to be offered  
7 to, or purchased by, consumers as tobacco for mak-  
8 ing cigarettes.

9 “(16) SMALL TOBACCO PRODUCT MANUFAC-  
10 Turer.—The term ‘small tobacco product manufac-  
11 turer’ means a tobacco product manufacturer that  
12 employs fewer than 350 employees. For purposes of  
13 determining the number of employees of a manufac-  
14 turer under the preceding sentence, the employees of  
15 a manufacturer are deemed to include the employees  
16 of each entity that controls, is controlled by, or is  
17 under common control with such manufacturer.

18 “(17) SMOKE CONSTITUENT.—The term ‘smoke  
19 constituent’ means any chemical or chemical com-  
20 pound in mainstream or sidestream tobacco smoke  
21 that either transfers from any component of the cig-  
22 arette to the smoke or that is formed by the combus-  
23 tion or heating of tobacco, additives, or other compo-  
24 nent of the tobacco product.



1           “(18) SMOKELESS TOBACCO.—The term  
2           ‘smokeless tobacco’ means any tobacco product that  
3           consists of cut, ground, powdered, or leaf tobacco  
4           and that is intended to be placed in the oral or nasal  
5           cavity.

6           “(19) STATE; TERRITORY.—The terms ‘State’  
7           and ‘Territory’ shall have the meanings given to  
8           such terms in section 201.

9           “(20) TOBACCO PRODUCT MANUFACTURER.—  
10          The term ‘tobacco product manufacturer’ means any  
11          person, including any repacker or relabeler, who—

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

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

16          “(21) TOBACCO WAREHOUSE.—

17                   “(A) Subject to subparagraphs (B) and  
18                   (C), the term ‘tobacco warehouse’ includes any  
19                   person—

20                           “(i) who—

21                                   “(I) removes foreign material  
22                                   from tobacco leaf through nothing  
23                                   other than a mechanical process;

1                   “(II) humidifies tobacco leaf with  
2                   nothing other than potable water in  
3                   the form of steam or mist; or

4                   “(III) de-stems, dries, and packs  
5                   tobacco leaf for storage and shipment;

6                   “(ii) who performs no other actions  
7                   with respect to tobacco leaf; and

8                   “(iii) who provides to any manufac-  
9                   turer to whom the person sells tobacco all  
10                  information related to the person’s actions  
11                  described in clause (i) that is necessary for  
12                  compliance with this Act.

13                  “(B) The term ‘tobacco warehouse’ ex-  
14                  cludes any person who—

15                   “(i) reconstitutes tobacco leaf;

16                   “(ii) is a manufacturer, distributor, or  
17                   retailer of a tobacco product; or

18                   “(iii) applies any chemical, additive,  
19                   or substance to the tobacco leaf other than  
20                   potable water in the form of steam or mist.

21                  “(C) The definition of the term ‘tobacco  
22                  warehouse’ in subparagraph (A) shall not apply  
23                  to the extent to which the Secretary determines,  
24                  through rulemaking, that regulation under this  
25                  chapter of the actions described in such sub-

1 paragraph is appropriate for the protection of  
2 the public health.

3 “(22) UNITED STATES.—The term ‘United  
4 States’ means the 50 States of the United States of  
5 America and the District of Columbia, the Common-  
6 wealth of Puerto Rico, Guam, the Virgin Islands,  
7 American Samoa, Wake Island, Midway Islands,  
8 Kingman Reef, Johnston Atoll, the Northern Mar-  
9 iana Islands, and any other trust territory or posses-  
10 sion of the United States.

11 **“SEC. 901. FDA AUTHORITY OVER TOBACCO PRODUCTS.**

12 “(a) IN GENERAL.—Tobacco products, including  
13 modified risk tobacco products for which an order has  
14 been issued in accordance with section 911, shall be regu-  
15 lated by the Secretary under this chapter and shall not  
16 be subject to the provisions of chapter V.

17 “(b) APPLICABILITY.—This chapter shall apply to all  
18 cigarettes, cigarette tobacco, roll-your-own tobacco, and  
19 smokeless tobacco and to any other tobacco products that  
20 the Secretary by regulation deems to be subject to this  
21 chapter.

22 “(c) SCOPE.—

23 “(1) IN GENERAL.—Nothing in this chapter, or  
24 any policy issued or regulation promulgated there-  
25 under, or in sections 101(a), 102, or 103 of title I,

1 title II, or title III of the Family Smoking Preven-  
2 tion and Tobacco Control Act, shall be construed to  
3 affect, expand, or limit the Secretary's authority  
4 over (including the authority to determine whether  
5 products may be regulated), or the regulation of,  
6 products under this Act that are not tobacco prod-  
7 ucts under chapter V or any other chapter.

8 “(2) LIMITATION OF AUTHORITY.—

9 “(A) IN GENERAL.—The provisions of this  
10 chapter shall not apply to tobacco leaf that is  
11 not in the possession of a manufacturer of to-  
12 bacco products, or to the producers of tobacco  
13 leaf, including tobacco growers, tobacco ware-  
14 houses, and tobacco grower cooperatives, nor  
15 shall any employee of the Food and Drug Ad-  
16 ministration have any authority to enter onto a  
17 farm owned by a producer of tobacco leaf with-  
18 out the written consent of such producer.

19 “(B) EXCEPTION.—Notwithstanding sub-  
20 paragraph (A), if a producer of tobacco leaf is  
21 also a tobacco product manufacturer or con-  
22 trolled by a tobacco product manufacturer, the  
23 producer shall be subject to this chapter in the  
24 producer's capacity as a manufacturer. The ex-  
25 ception in this subparagraph shall not apply to

1 a producer of tobacco leaf who grows tobacco  
2 under a contract with a tobacco product manu-  
3 facturer and who is not otherwise engaged in  
4 the manufacturing process.

5 “(C) RULE OF CONSTRUCTION.—Nothing  
6 in this chapter shall be construed to grant the  
7 Secretary authority to promulgate regulations  
8 on any matter that involves the production of  
9 tobacco leaf or a producer thereof, other than  
10 activities by a manufacturer affecting produc-  
11 tion.

12 “(d) RULEMAKING PROCEDURES.—Each rulemaking  
13 under this chapter shall be in accordance with chapter 5  
14 of title 5, United States Code. This subsection shall not  
15 be construed to affect the rulemaking provisions of section  
16 102(a) of the Family Smoking Prevention and Tobacco  
17 Control Act.

18 “(e) CENTER FOR TOBACCO PRODUCTS.—Not later  
19 than 90 days after the date of enactment of the Family  
20 Smoking Prevention and Tobacco Control Act, the Sec-  
21 retary shall establish within the Food and Drug Adminis-  
22 tration the Center for Tobacco Products, which shall re-  
23 port to the Commissioner of Food and Drugs in the same  
24 manner as the other agency centers within the Food and  
25 Drug Administration. The Center shall be responsible for

1 the implementation of this chapter and related matters as-  
2 signed by the Commissioner.

3       “(f) OFFICE TO ASSIST SMALL TOBACCO PRODUCT  
4 MANUFACTURERS.—The Secretary shall establish within  
5 the Food and Drug Administration an identifiable office  
6 to provide technical and other nonfinancial assistance to  
7 small tobacco product manufacturers to assist them in  
8 complying with the requirements of this Act.

9       “(g) CONSULTATION PRIOR TO RULEMAKING.—Prior  
10 to promulgating rules under this chapter, the Secretary  
11 shall endeavor to consult with other Federal agencies as  
12 appropriate.

13 **“SEC. 902. ADULTERATED TOBACCO PRODUCTS.**

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

16               “(1) it consists in whole or in part of any filthy,  
17 putrid, or decomposed substance, or is otherwise  
18 contaminated by any added poisonous or added dele-  
19 terious substance that may render the product inju-  
20 rious to health;

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

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

4           “(4) the manufacturer or importer of the to-  
5 bacco product fails to pay a user fee assessed to  
6 such manufacturer or importer pursuant to section  
7 919 by the date specified in section 919 or by the  
8 30th day after final agency action on a resolution of  
9 any dispute as to the amount of such fee;

10           “(5) it is, or purports to be or is represented  
11 as, a tobacco product which is subject to a tobacco  
12 product standard established under section 907 un-  
13 less such tobacco product is in all respects in con-  
14 formity with such standard;

15           “(6)(A) it is required by section 910(a) to have  
16 premarket review and does not have an order in ef-  
17 fect under section 910(c)(1)(A)(i); or

18           “(B) it is in violation of an order under section  
19 910(c)(1)(A);

20           “(7) the methods used in, or the facilities or  
21 controls used for, its manufacture, packing, or stor-  
22 age are not in conformity with applicable require-  
23 ments under section 906(e)(1) or an applicable con-  
24 dition prescribed by an order under section  
25 906(e)(2); or

1           “(8) it is in violation of section 911.

2   **“SEC. 903. MISBRANDED TOBACCO PRODUCTS.**

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

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

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

9           “(A) the name and place of business of the  
10 tobacco product manufacturer, packer, or dis-  
11 tributor;

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

15           “(C) an accurate statement of the percent-  
16 age of the tobacco used in the product that is  
17 domestically grown tobacco and the percentage  
18 that is foreign grown tobacco; and

19           “(D) the statement required under section  
20 920(a),

21 except that under subparagraph (B) reasonable vari-  
22 ations shall be permitted, and exemptions as to  
23 small packages shall be established, by regulations  
24 prescribed by the Secretary;



1           “(3) if any word, statement, or other informa-  
2           tion required by or under authority of this chapter  
3           to appear on the label or labeling is not prominently  
4           placed thereon with such conspicuousness (as com-  
5           pared with other words, statements, or designs in  
6           the labeling) and in such terms as to render it likely  
7           to be read and understood by the ordinary individual  
8           under customary conditions of purchase and use;

9           “(4) if it has an established name, unless its  
10          label bears, to the exclusion of any other nonpropri-  
11          etary name, its established name prominently print-  
12          ed in type as required by the Secretary by regula-  
13          tion;

14          “(5) if the Secretary has issued regulations re-  
15          quiring that its labeling bear adequate directions for  
16          use, or adequate warnings against use by children,  
17          that are necessary for the protection of users unless  
18          its labeling conforms in all respects to such regula-  
19          tions;

20          “(6) if it was manufactured, prepared, propa-  
21          gated, compounded, or processed in an establishment  
22          not duly registered under section 905(b), 905(c),  
23          905(d), or 905(h), if it was not included in a list re-  
24          quired by section 905(i), if a notice or other infor-  
25          mation respecting it was not provided as required by

1 such section or section 905(j), or if it does not bear  
2 such symbols from the uniform system for identifica-  
3 tion of tobacco products prescribed under section  
4 905(e) as the Secretary by regulation requires;

5 “(7) if, in the case of any tobacco product dis-  
6 tributed or offered for sale in any State—

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

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

11 “(8) unless, in the case of any tobacco product  
12 distributed or offered for sale in any State, the man-  
13 ufacturer, packer, or distributor thereof includes in  
14 all advertisements and other descriptive printed mat-  
15 ter issued or caused to be issued by the manufac-  
16 turer, packer, or distributor with respect to that to-  
17 bacco product—

18 “(A) a true statement of the tobacco prod-  
19 uct’s established name as described in para-  
20 graph (4), printed prominently; and

21 “(B) a brief statement of—

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

1                   “(ii) in the case of specific tobacco  
2                   products made subject to a finding by the  
3                   Secretary after notice and opportunity for  
4                   comment that such action is appropriate to  
5                   protect the public health, a full description  
6                   of the components of such tobacco product  
7                   or the formula showing quantitatively each  
8                   ingredient of such tobacco product to the  
9                   extent required in regulations which shall  
10                  be issued by the Secretary after an oppor-  
11                  tunity for a hearing;

12                  “(9) if it is a tobacco product subject to a to-  
13                  bacco product standard established under section  
14                  907, unless it bears such labeling as may be pre-  
15                  scribed in such tobacco product standard; or

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

17                          “(A) to comply with any requirement pre-  
18                          scribed under section 904 or 908; or

19                          “(B) to furnish any material or informa-  
20                          tion required under section 909.

21                  “(b) PRIOR APPROVAL OF LABEL STATEMENTS.—

22                  The Secretary may, by regulation, require prior approval  
23                  of statements made on the label of a tobacco product to  
24                  ensure that such statements do not violate the mis-  
25                  branding provisions of subsection (a) and that such state-

1 ments comply with other provisions of the Family Smok-  
2 ing Prevention and Tobacco Control Act (including the  
3 amendments made by such Act). No regulation issued  
4 under this subsection may require prior approval by the  
5 Secretary of the content of any advertisement, except for  
6 modified risk tobacco products as provided in section 911.  
7 No advertisement of a tobacco product published after the  
8 date of enactment of the Family Smoking Prevention and  
9 Tobacco Control Act shall, with respect to the language  
10 of label statements as prescribed under section 4 of the  
11 Federal Cigarette Labeling and Advertising Act and sec-  
12 tion 3 of the Comprehensive Smokeless Tobacco Health  
13 Education Act of 1986 or the regulations issued under  
14 such sections, be subject to the provisions of sections 12  
15 through 15 of the Federal Trade Commission Act.

16 **“SEC. 904. SUBMISSION OF HEALTH INFORMATION TO THE**  
17 **SECRETARY.**

18 “(a) REQUIREMENT.—Each tobacco product manu-  
19 facturer or importer, or agents thereof, shall submit to  
20 the Secretary the following information:

21 “(1) Not later than 6 months after the date of  
22 enactment of the Family Smoking Prevention and  
23 Tobacco Control Act, a listing of all ingredients, in-  
24 cluding tobacco, substances, compounds, and addi-  
25 tives that are, as of such date, added by the manu-

1        manufacturer to the tobacco, paper, filter, or other part  
2        of each tobacco product by brand and by quantity in  
3        each brand and subbrand.

4            “(2) A description of the content, delivery, and  
5        form of nicotine in each tobacco product measured  
6        in milligrams of nicotine in accordance with regula-  
7        tions promulgated by the Secretary in accordance  
8        with section 4(e) of the Federal Cigarette Labeling  
9        and Advertising Act.

10           “(3) Beginning 3 years after the date of enact-  
11        ment of the Family Smoking Prevention and To-  
12        bacco Control Act, a listing of all constituents, in-  
13        cluding smoke constituents as applicable, identified  
14        by the Secretary as harmful or potentially harmful  
15        to health in each tobacco product, and as applicable  
16        in the smoke of each tobacco product, by brand and  
17        by quantity in each brand and subbrand. Effective  
18        beginning 3 years after such date of enactment, the  
19        manufacturer, importer, or agent shall comply with  
20        regulations promulgated under section 915 in re-  
21        porting information under this paragraph, where ap-  
22        plicable.

23           “(4) Beginning 6 months after the date of en-  
24        actment of the Family Smoking Prevention and To-  
25        bacco Control Act, all documents developed after

1 such date of enactment that relate to health, toxi-  
2 cological, behavioral, or physiologic effects of current  
3 or future tobacco products, their constituents (in-  
4 cluding smoke constituents), ingredients, compo-  
5 nents, and additives.

6 “(b) DATA SUBMISSION.—At the request of the Sec-  
7 retary, each tobacco product manufacturer or importer of  
8 tobacco products, or agents thereof, shall submit the fol-  
9 lowing:

10 “(1) Any or all documents (including under-  
11 lying scientific information) relating to research ac-  
12 tivities, and research findings, conducted, supported,  
13 or possessed by the manufacturer (or agents thereof)  
14 on the health, toxicological, behavioral, or physio-  
15 logic effects of tobacco products and their constitu-  
16 ents (including smoke constituents), ingredients,  
17 components, and additives.

18 “(2) Any or all documents (including under-  
19 lying scientific information) relating to research ac-  
20 tivities, and research findings, conducted, supported,  
21 or possessed by the manufacturer (or agents thereof)  
22 that relate to the issue of whether a reduction in  
23 risk to health from tobacco products can occur upon  
24 the employment of technology available or known to  
25 the manufacturer.

1           “(3) Any or all documents (including under-  
2           lying scientific or financial information) relating to  
3           marketing research involving the use of tobacco  
4           products or marketing practices and the effective-  
5           ness of such practices used by tobacco manufactur-  
6           ers and distributors.

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

10          “(c) TIME FOR SUBMISSION.—

11           “(1) IN GENERAL.—At least 90 days prior to  
12           the delivery for introduction into interstate com-  
13           merce of a tobacco product not on the market on the  
14           date of enactment of the Family Smoking Preven-  
15           tion and Tobacco Control Act, the manufacturer of  
16           such product shall provide the information required  
17           under subsection (a).

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

1           “(3) DISCLOSURE OF OTHER ACTIONS.—If at  
2           any time a tobacco product manufacturer eliminates  
3           or decreases an existing additive, or adds or in-  
4           creases an additive that has by regulation been des-  
5           ignated by the Secretary as an additive that is not  
6           a human or animal carcinogen, or otherwise harmful  
7           to health under intended conditions of use, the man-  
8           ufacturer shall within 60 days of such action so ad-  
9           vise the Secretary in writing.

10          “(d) DATA LIST.—

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

19                 “(2) CONSUMER RESEARCH.—The Secretary  
20                 shall conduct periodic consumer research to ensure  
21                 that the list published under paragraph (1) is not  
22                 misleading to lay persons. Not later than 5 years  
23                 after the date of enactment of the Family Smoking  
24                 Prevention and Tobacco Control Act, the Secretary  
25                 shall submit to the appropriate committees of Con-



1       gress a report on the results of such research, to-  
2       gether with recommendations on whether such publi-  
3       cation should be continued or modified.

4       “(e) DATA COLLECTION.—Not later than 24 months  
5       after the date of enactment of the Family Smoking Pre-  
6       vention and Tobacco Control Act, the Secretary shall es-  
7       tablish, and periodically revise as appropriate, a list of  
8       harmful and potentially harmful constituents, including  
9       smoke constituents, to health in each tobacco product by  
10      brand and by quantity in each brand and subbrand. The  
11      Secretary shall publish a public notice requesting the sub-  
12      mission by interested persons of scientific and other infor-  
13      mation concerning the harmful and potentially harmful  
14      constituents in tobacco products and tobacco smoke.

15      **“SEC. 905. ANNUAL REGISTRATION.**

16      “(a) DEFINITIONS.—In this section:

17              “(1)        MANUFACTURE,        PREPARATION,  
18        COMPOUNDING, OR PROCESSING.—The term ‘manu-  
19        facture, preparation, compounding, or processing’  
20        shall include repackaging or otherwise changing the  
21        container, wrapper, or labeling of any tobacco prod-  
22        uct package in furtherance of the distribution of the  
23        tobacco product from the original place of manufac-  
24        ture to the person who makes final delivery or sale  
25        to the ultimate consumer or user.

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

6           “(b) REGISTRATION BY OWNERS AND OPERATORS.—  
7           On or before December 31 of each year, every person who  
8           owns or operates any establishment in any State engaged  
9           in the manufacture, preparation, compounding, or proc-  
10          essing of a tobacco product or tobacco products shall reg-  
11          ister with the Secretary the name, places of business, and  
12          all such establishments of that person. If enactment of the  
13          Family Smoking Prevention and Tobacco Control Act oc-  
14          curs in the second half of the calendar year, the Secretary  
15          shall designate a date no later than 6 months into the  
16          subsequent calendar year by which registration pursuant  
17          to this subsection shall occur.

18          “(c) REGISTRATION BY NEW OWNERS AND OPERA-  
19          TORS.—Every person upon first engaging in the manufac-  
20          ture, preparation, compounding, or processing of a tobacco  
21          product or tobacco products in any establishment owned  
22          or operated in any State by that person shall immediately  
23          register with the Secretary that person’s name, place of  
24          business, and such establishment.

1       “(d) REGISTRATION OF ADDED ESTABLISHMENTS.—  
2 Every person required to register under subsection (b) or  
3 (c) shall immediately register with the Secretary any addi-  
4 tional establishment which that person owns or operates  
5 in any State and in which that person begins the manufac-  
6 ture, preparation, compounding, or processing of a tobacco  
7 product or tobacco products.

8       “(e) UNIFORM PRODUCT IDENTIFICATION SYS-  
9 TEM.—The Secretary may by regulation prescribe a uni-  
10 form system for the identification of tobacco products and  
11 may require that persons who are required to list such  
12 tobacco products under subsection (i) shall list such to-  
13 bacco products in accordance with such system.

14       “(f) PUBLIC ACCESS TO REGISTRATION INFORMA-  
15 TION.—The Secretary shall make available for inspection,  
16 to any person so requesting, any registration filed under  
17 this section.

18       “(g) BIENNIAL INSPECTION OF REGISTERED ESTAB-  
19 LISHMENTS.—Every establishment registered with the  
20 Secretary under this section shall be subject to inspection  
21 under section 704 or subsection (h), and every such estab-  
22 lishment engaged in the manufacture, compounding, or  
23 processing of a tobacco product or tobacco products shall  
24 be so inspected by 1 or more officers or employees duly  
25 designated by the Secretary at least once in the 2-year

1 period beginning with the date of registration of such es-  
2 tablishment under this section and at least once in every  
3 successive 2-year period thereafter.

4       “(h) REGISTRATION BY FOREIGN ESTABLISH-  
5 MENTS.—Any establishment within any foreign country  
6 engaged in the manufacture, preparation, compounding,  
7 or processing of a tobacco product or tobacco products,  
8 shall register under this section under regulations promul-  
9 gated by the Secretary. Such regulations shall require  
10 such establishment to provide the information required by  
11 subsection (i) and shall include provisions for registration  
12 of any such establishment upon condition that adequate  
13 and effective means are available, by arrangement with the  
14 government of such foreign country or otherwise, to enable  
15 the Secretary to determine from time to time whether to-  
16 bacco products manufactured, prepared, compounded, or  
17 processed in such establishment, if imported or offered for  
18 import into the United States, shall be refused admission  
19 on any of the grounds set forth in section 801(a).

20       “(i) REGISTRATION INFORMATION.—

21               “(1) PRODUCT LIST.—Every person who reg-  
22 isters with the Secretary under subsection (b), (c),  
23 (d), or (h) shall, at the time of registration under  
24 any such subsection, file with the Secretary a list of  
25 all tobacco products which are being manufactured,

1 prepared, compounded, or processed by that person  
2 for commercial distribution and which have not been  
3 included in any list of tobacco products filed by that  
4 person with the Secretary under this paragraph or  
5 paragraph (2) before such time of registration. Such  
6 list shall be prepared in such form and manner as  
7 the Secretary may prescribe and shall be accom-  
8 panied by—

9 “(A) in the case of a tobacco product con-  
10 tained in the applicable list with respect to  
11 which a tobacco product standard has been es-  
12 tablished under section 907 or which is subject  
13 to section 910, a reference to the authority for  
14 the marketing of such tobacco product and a  
15 copy of all labeling for such tobacco product;

16 “(B) in the case of any other tobacco prod-  
17 uct contained in an applicable list, a copy of all  
18 consumer information and other labeling for  
19 such tobacco product, a representative sampling  
20 of advertisements for such tobacco product,  
21 and, upon request made by the Secretary for  
22 good cause, a copy of all advertisements for a  
23 particular tobacco product; and

24 “(C) if the registrant filing a list has de-  
25 termined that a tobacco product contained in

1           such list is not subject to a tobacco product  
2           standard established under section 907, a brief  
3           statement of the basis upon which the reg-  
4           istrant made such determination if the Sec-  
5           retary requests such a statement with respect  
6           to that particular tobacco product.

7           “(2) CONSULTATION WITH RESPECT TO  
8           FORMS.—The Secretary shall consult with the Sec-  
9           retary of the Treasury in developing the forms to be  
10          used for registration under this section to minimize  
11          the burden on those persons required to register  
12          with both the Secretary and the Tax and Trade Bu-  
13          reau of the Department of the Treasury.

14          “(3) BIENNIAL REPORT OF ANY CHANGE IN  
15          PRODUCT LIST.—Each person who registers with the  
16          Secretary under this section shall report to the Sec-  
17          retary once during the month of June of each year  
18          and once during the month of December of each  
19          year the following:

20                 “(A) A list of each tobacco product intro-  
21                 duced by the registrant for commercial distribu-  
22                 tion which has not been included in any list  
23                 previously filed by that person with the Sec-  
24                 retary under this subparagraph or paragraph  
25                 (1). A list under this subparagraph shall list a

1 tobacco product by its established name and  
2 shall be accompanied by the other information  
3 required by paragraph (1).

4 “(B) If since the date the registrant last  
5 made a report under this paragraph that person  
6 has discontinued the manufacture, preparation,  
7 compounding, or processing for commercial dis-  
8 tribution of a tobacco product included in a list  
9 filed under subparagraph (A) or paragraph (1),  
10 notice of such discontinuance, the date of such  
11 discontinuance, and the identity of its estab-  
12 lished name.

13 “(C) If since the date the registrant re-  
14 ported under subparagraph (B) a notice of dis-  
15 continuance that person has resumed the manu-  
16 facture, preparation, compounding, or proc-  
17 essing for commercial distribution of the to-  
18 bacco product with respect to which such notice  
19 of discontinuance was reported, notice of such  
20 resumption, the date of such resumption, the  
21 identity of such tobacco product by established  
22 name, and other information required by para-  
23 graph (1), unless the registrant has previously  
24 reported such resumption to the Secretary  
25 under this subparagraph.

1           “(D) Any material change in any informa-  
2           tion previously submitted under this paragraph  
3           or paragraph (1).

4           “(j) REPORT PRECEDING INTRODUCTION OF CER-  
5 TAIN SUBSTANTIALLY EQUIVALENT PRODUCTS INTO  
6 INTERSTATE COMMERCE.—

7           “(1) IN GENERAL.—Each person who is re-  
8           quired to register under this section and who pro-  
9           poses to begin the introduction or delivery for intro-  
10          duction into interstate commerce for commercial dis-  
11          tribution of a tobacco product intended for human  
12          use that was not commercially marketed (other than  
13          for test marketing) in the United States as of Feb-  
14          ruary 15, 2007, shall, at least 90 days prior to mak-  
15          ing such introduction or delivery, report to the Sec-  
16          retary (in such form and manner as the Secretary  
17          shall prescribe)—

18                  “(A) the basis for such person’s determina-  
19          tion that—

20                          “(i) the tobacco product is substan-  
21                          tially equivalent, within the meaning of  
22                          section 910, to a tobacco product commer-  
23                          cially marketed (other than for test mar-  
24                          keting) in the United States as of Feb-  
25                          ruary 15, 2007, or to a tobacco product



1           that the Secretary has previously deter-  
2           mined, pursuant to subsection (a)(3) of  
3           section 910, is substantially equivalent and  
4           that is in compliance with the require-  
5           ments of this Act; or

6           “(ii) the tobacco product is modified  
7           within the meaning of paragraph (3), the  
8           modifications are to a product that is com-  
9           mercially marketed and in compliance with  
10          the requirements of this Act, and all of the  
11          modifications are covered by exemptions  
12          granted by the Secretary pursuant to para-  
13          graph (3); and

14          “(B) action taken by such person to com-  
15          ply with the requirements under section 907  
16          that are applicable to the tobacco product.

17          “(2) APPLICATION TO CERTAIN POST-FEB-  
18          RUARY 15, 2007, PRODUCTS.—A report under this  
19          subsection for a tobacco product that was first intro-  
20          duced or delivered for introduction into interstate  
21          commerce for commercial distribution in the United  
22          States after February 15, 2007, and prior to the  
23          date that is 21 months after the date of enactment  
24          of the Family Smoking Prevention and Tobacco

1 Control Act shall be submitted to the Secretary not  
2 later than 21 months after such date of enactment.

3 “(3) EXEMPTIONS.—

4 “(A) IN GENERAL.—The Secretary may  
5 exempt from the requirements of this sub-  
6 section relating to the demonstration that a to-  
7 bacco product is substantially equivalent within  
8 the meaning of section 910, tobacco products  
9 that are modified by adding or deleting a to-  
10 bacco additive, or increasing or decreasing the  
11 quantity of an existing tobacco additive, if the  
12 Secretary determines that—

13 “(i) such modification would be a  
14 minor modification of a tobacco product  
15 that can be sold under this Act;

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

21 “(iii) an exemption is otherwise appro-  
22 priate.

23 “(B) REGULATIONS.—Not later than 15  
24 months after the date of enactment of the Fam-  
25 ily Smoking Prevention and Tobacco Control

1 Act, the Secretary shall issue regulations to im-  
2 plement this paragraph.

3 **“SEC. 906. GENERAL PROVISIONS RESPECTING CONTROL**  
4 **OF TOBACCO PRODUCTS.**

5 “(a) IN GENERAL.—Any requirement established by  
6 or under section 902, 903, 905, or 909 applicable to a  
7 tobacco product shall apply to such tobacco product until  
8 the applicability of the requirement to the tobacco product  
9 has been changed by action taken under section 907, sec-  
10 tion 910, section 911, or subsection (d) of this section,  
11 and any requirement established by or under section 902,  
12 903, 905, or 909 which is inconsistent with a requirement  
13 imposed on such tobacco product under section 907, sec-  
14 tion 910, section 911, or subsection (d) of this section  
15 shall not apply to such tobacco product.

16 “(b) INFORMATION ON PUBLIC ACCESS AND COM-  
17 MENT.—Each notice of proposed rulemaking or other noti-  
18 fication under section 907, 908, 909, 910, or 911 or under  
19 this section, any other notice which is published in the  
20 Federal Register with respect to any other action taken  
21 under any such section and which states the reasons for  
22 such action, and each publication of findings required to  
23 be made in connection with rulemaking under any such  
24 section shall set forth—

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

4           “(2) the period within which interested persons  
5           may present their comments on the notice or find-  
6           ings (including the need therefore) orally or in writ-  
7           ing, which period shall be at least 60 days but may  
8           not exceed 90 days unless the time is extended by  
9           the Secretary by a notice published in the Federal  
10          Register stating good cause therefore.

11          “(c) LIMITED CONFIDENTIALITY OF INFORMA-  
12          TION.—Any information reported to or otherwise obtained  
13          by the Secretary or the Secretary’s representative under  
14          section 903, 904, 907, 908, 909, 910, 911, or 704, or  
15          under subsection (e) or (f) of this section, which is exempt  
16          from disclosure under subsection (a) of section 552 of title  
17          5, United States Code, by reason of subsection (b)(4) of  
18          that section shall be considered confidential and shall not  
19          be disclosed, except that the information may be disclosed  
20          to other officers or employees concerned with carrying out  
21          this chapter, or when relevant in any proceeding under  
22          this chapter.

23          “(d) RESTRICTIONS.—

24                 “(1) IN GENERAL.—The Secretary may by reg-  
25                 ulation require restrictions on the sale and distribu-

1       tion of a tobacco product, including restrictions on  
2       the access to, and the advertising and promotion of,  
3       the tobacco product, if the Secretary determines that  
4       such regulation would be appropriate for the protec-  
5       tion of the public health. The Secretary may by reg-  
6       ulation impose restrictions on the advertising and  
7       promotion of a tobacco product consistent with and  
8       to full extent permitted by the first amendment to  
9       the Constitution. The finding as to whether such  
10      regulation would be appropriate for the protection of  
11      the public health shall be determined with respect to  
12      the risks and benefits to the population as a whole,  
13      including users and nonusers of the tobacco product,  
14      and taking into account—

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

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

21      No such regulation may require that the sale or dis-  
22      tribution of a tobacco product be limited to the writ-  
23      ten or oral authorization of a practitioner licensed  
24      by law to prescribe medical products.

1           “(2) LABEL STATEMENTS.—The label of a to-  
2           bacco product shall bear such appropriate state-  
3           ments of the restrictions required by a regulation  
4           under subsection (a) as the Secretary may in such  
5           regulation prescribe.

6           “(3) LIMITATIONS.—

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

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

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

15                   “(B) MATCHBOOKS.—For purposes of any  
16           regulations issued by the Secretary, matchbooks  
17           of conventional size containing not more than  
18           20 paper matches, and which are customarily  
19           given away for free with the purchase of to-  
20           bacco products, shall be considered as adult-  
21           written publications which shall be permitted to  
22           contain advertising. Notwithstanding the pre-  
23           ceding sentence, if the Secretary finds that such  
24           treatment of matchbooks is not appropriate for  
25           the protection of the public health, the Sec-

1           retary may determine by regulation that match-  
2           books shall not be considered adult-written pub-  
3           lications.

4           “(4) REMOTE SALES.—

5                 “(A) IN GENERAL.—The Secretary shall—

6                     “(i) within 18 months after the date  
7                     of enactment of the Family Smoking Pre-  
8                     vention and Tobacco Control Act, promul-  
9                     gate regulations regarding the sale and  
10                    distribution of tobacco products that occur  
11                    through means other than a direct, face-to-  
12                    face exchange between a retailer and a  
13                    consumer in order to prevent the sale and  
14                    distribution of tobacco products to individ-  
15                    uals who have not attained the minimum  
16                    age established by applicable law for the  
17                    purchase of such products, including re-  
18                    quirements for age verification; and

19                    “(ii) within 2 years after such date of  
20                    enactment, issue regulations to address the  
21                    promotion and marketing of tobacco prod-  
22                    ucts that are sold or distributed through  
23                    means other than a direct, face-to-face ex-  
24                    change between a retailer and a consumer  
25                    in order to protect individuals who have

1 not attained the minimum age established  
2 by applicable law for the purchase of such  
3 products.

4 “(B) RELATION TO OTHER AUTHORITY.—  
5 Nothing in this paragraph limits the authority  
6 of the Secretary to take additional actions  
7 under the other paragraphs of this subsection.

8 “(e) GOOD MANUFACTURING PRACTICE REQUIRE-  
9 MENTS.—

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

12 “(A) IN GENERAL.—In applying manufac-  
13 turing restrictions to tobacco, the Secretary  
14 shall, in accordance with subparagraph (B),  
15 prescribe regulations (which may differ based  
16 on the type of tobacco product involved) requir-  
17 ing that the methods used in, and the facilities  
18 and controls used for, the manufacture,  
19 preproduction design validation (including a  
20 process to assess the performance of a tobacco  
21 product), packing, and storage of a tobacco  
22 product conform to current good manufacturing  
23 practice, or hazard analysis and critical control  
24 point methodology, as prescribed in such regu-  
25 lations to assure that the public health is pro-



1           tected and that the tobacco product is in com-  
2           pliance with this chapter. Such regulations may  
3           provide for the testing of raw tobacco for pes-  
4           ticide chemical residues regardless of whether a  
5           tolerance for such chemical residues has been  
6           established.

7           “(B)    REQUIREMENTS.—The    Secretary  
8           shall—

9                   “(i) before promulgating any regula-  
10                  tion under subparagraph (A), afford the  
11                  Tobacco Products Scientific Advisory Com-  
12                  mittee an opportunity to submit rec-  
13                  ommendations with respect to the regula-  
14                  tion proposed to be promulgated;

15                  “(ii) before promulgating any regula-  
16                  tion under subparagraph (A), afford oppor-  
17                  tunity for an oral hearing;

18                  “(iii) provide the Tobacco Products  
19                  Scientific Advisory Committee a reasonable  
20                  time to make its recommendation with re-  
21                  spect to proposed regulations under sub-  
22                  paragraph (A);

23                  “(iv) in establishing the effective date  
24                  of a regulation promulgated under this  
25                  subsection, take into account the dif-

1           ferences in the manner in which the dif-  
2           ferent types of tobacco products have his-  
3           torically been produced, the financial re-  
4           sources of the different tobacco product  
5           manufacturers, and the state of their exist-  
6           ing manufacturing facilities, and shall pro-  
7           vide for a reasonable period of time for  
8           such manufacturers to conform to good  
9           manufacturing practices; and

10           “(v) not require any small tobacco  
11           product manufacturer to comply with a  
12           regulation under subparagraph (A) for at  
13           least 4 years following the effective date  
14           established by the Secretary for such regu-  
15           lation.

16           “(2) EXEMPTIONS; VARIANCES.—

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

24           “(i) in the case of a petition for an ex-  
25           emption from a requirement, set forth the

1 basis for the petitioner's determination  
2 that compliance with the requirement is  
3 not required to assure that the tobacco  
4 product will be in compliance with this  
5 chapter;

6 “(ii) in the case of a petition for a  
7 variance from a requirement, set forth the  
8 methods proposed to be used in, and the  
9 facilities and controls proposed to be used  
10 for, the manufacture, packing, and storage  
11 of the tobacco product in lieu of the meth-  
12 ods, facilities, and controls prescribed by  
13 the requirement; and

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

16 “(B) REFERRAL TO THE TOBACCO PROD-  
17 UCTS SCIENTIFIC ADVISORY COMMITTEE.—The  
18 Secretary may refer to the Tobacco Products  
19 Scientific Advisory Committee any petition sub-  
20 mitted under subparagraph (A). The Tobacco  
21 Products Scientific Advisory Committee shall  
22 report its recommendations to the Secretary  
23 with respect to a petition referred to it within  
24 60 days after the date of the petition's referral.  
25 Within 60 days after—

1           “(i) the date the petition was sub-  
2           mitted to the Secretary under subpara-  
3           graph (A); or

4           “(ii) the day after the petition was re-  
5           ferred to the Tobacco Products Scientific  
6           Advisory Committee,

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

9           “(C) APPROVAL.—The Secretary may ap-  
10          prove—

11          “(i) a petition for an exemption for a  
12          tobacco product from a requirement if the  
13          Secretary determines that compliance with  
14          such requirement is not required to assure  
15          that the tobacco product will be in compli-  
16          ance with this chapter; and

17          “(ii) a petition for a variance for a to-  
18          bacco product from a requirement if the  
19          Secretary determines that the methods to  
20          be used in, and the facilities and controls  
21          to be used for, the manufacture, packing,  
22          and storage of the tobacco product in lieu  
23          of the methods, facilities, and controls pre-  
24          scribed by the requirement are sufficient to

1           assure that the tobacco product will be in  
2           compliance with this chapter.

3           “(D) CONDITIONS.—An order of the Sec-  
4           retary approving a petition for a variance shall  
5           prescribe such conditions respecting the meth-  
6           ods used in, and the facilities and controls used  
7           for, the manufacture, packing, and storage of  
8           the tobacco product to be granted the variance  
9           under the petition as may be necessary to as-  
10          sure that the tobacco product will be in compli-  
11          ance with this chapter.

12          “(E) HEARING.—After the issuance of an  
13          order under subparagraph (B) respecting a pe-  
14          tition, the petitioner shall have an opportunity  
15          for an informal hearing on such order.

16          “(3) COMPLIANCE.—Compliance with require-  
17          ments under this subsection shall not be required be-  
18          fore the end of the 3-year period following the date  
19          of enactment of the Family Smoking Prevention and  
20          Tobacco Control Act.

21          “(f) RESEARCH AND DEVELOPMENT.—The Secretary  
22          may enter into contracts for research, testing, and dem-  
23          onstrations respecting tobacco products and may obtain  
24          tobacco products for research, testing, and demonstration  
25          purposes.

1 **“SEC. 907. TOBACCO PRODUCT STANDARDS.**

2 “(a) IN GENERAL.—

3 “(1) SPECIAL RULES.—

4 “(A) SPECIAL RULE FOR CIGARETTES.—

5 Beginning 3 months after the date of enact-  
6 ment of the Family Smoking Prevention and  
7 Tobacco Control Act, a cigarette or any of its  
8 component parts (including the tobacco, filter,  
9 or paper) shall not contain, as a constituent (in-  
10 cluding a smoke constituent) or additive, an ar-  
11 tificial or natural flavor (other than tobacco or  
12 menthol) or an herb or spice, including straw-  
13 berry, grape, orange, clove, cinnamon, pine-  
14 apple, vanilla, coconut, licorice, cocoa, chocolate,  
15 cherry, or coffee, that is a characterizing flavor  
16 of the tobacco product or tobacco smoke. Noth-  
17 ing in this subparagraph shall be construed to  
18 limit the Secretary’s authority to take action  
19 under this section or other sections of this Act  
20 applicable to menthol or any artificial or nat-  
21 ural flavor, herb, or spice not specified in this  
22 subparagraph.

23 “(B) ADDITIONAL SPECIAL RULE.—Begin-  
24 ning 2 years after the date of enactment of the  
25 Family Smoking Prevention and Tobacco Con-  
26 trol Act, a tobacco product manufacturer shall

1 not use tobacco, including foreign grown to-  
2 bacco, that contains a pesticide chemical res-  
3 idue that is at a level greater than is specified  
4 by any tolerance applicable under Federal law  
5 to domestically grown tobacco.

6 “(2) REVISION OF TOBACCO PRODUCT STAND-  
7 ARDS.—The Secretary may revise the tobacco prod-  
8 uct standards in paragraph (1) in accordance with  
9 subsection (c).

10 “(3) TOBACCO PRODUCT STANDARDS.—

11 “(A) IN GENERAL.—The Secretary may  
12 adopt tobacco product standards in addition to  
13 those in paragraph (1) if the Secretary finds  
14 that a tobacco product standard is appropriate  
15 for the protection of the public health.

16 “(B) DETERMINATIONS.—

17 “(i) CONSIDERATIONS.—In making a  
18 finding described in subparagraph (A), the  
19 Secretary shall consider scientific evidence  
20 concerning—

21 “(I) the risks and benefits to the  
22 population as a whole, including users  
23 and nonusers of tobacco products, of  
24 the proposed standard;

1                   “(II) the increased or decreased  
2                   likelihood that existing users of to-  
3                   bacco products will stop using such  
4                   products; and

5                   “(III) the increased or decreased  
6                   likelihood that those who do not use  
7                   tobacco products will start using such  
8                   products.

9                   “(ii)        ADDITIONAL        CONSIDER-  
10                  ATIONS.—In the event that the Secretary  
11                  makes a determination, set forth in a pro-  
12                  posed tobacco product standard in a pro-  
13                  posed rule, that it is appropriate for the  
14                  protection of public health to require the  
15                  reduction or elimination of an additive,  
16                  constituent (including a smoke constitu-  
17                  ent), or other component of a tobacco  
18                  product because the Secretary has found  
19                  that the additive, constituent, or other  
20                  component is or may be harmful, any  
21                  party objecting to the proposed standard  
22                  on the ground that the proposed standard  
23                  will not reduce or eliminate the risk of ill-  
24                  ness or injury may provide for the Sec-  
25                  retary’s consideration scientific evidence



1           that demonstrates that the proposed stand-  
2           ard will not reduce or eliminate the risk of  
3           illness or injury.

4           “(4) CONTENT OF TOBACCO PRODUCT STAND-  
5           ARDS.—A tobacco product standard established  
6           under this section for a tobacco product—

7           “(A) shall include provisions that are ap-  
8           propriate for the protection of the public health,  
9           including provisions, where appropriate—

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

11           “(ii) for the reduction or elimination  
12           of other constituents, including smoke con-  
13           stituents, or harmful components of the  
14           product; or

15           “(iii) relating to any other require-  
16           ment under subparagraph (B);

17           “(B) shall, where appropriate for the pro-  
18           tection of the public health, include—

19           “(i) provisions respecting the con-  
20           struction, components, ingredients, addi-  
21           tives, constituents, including smoke con-  
22           stituents, and properties of the tobacco  
23           product;

1           “(ii) provisions for the testing (on a  
2           sample basis or, if necessary, on an indi-  
3           vidual basis) of the tobacco product;

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

7           “(iv) provisions requiring that the re-  
8           sults of each or of certain of the tests of  
9           the tobacco product required to be made  
10          under clause (ii) show that the tobacco  
11          product is in conformity with the portions  
12          of the standard for which the test or tests  
13          were required; and

14          “(v) a provision requiring that the  
15          sale and distribution of the tobacco prod-  
16          uct be restricted but only to the extent  
17          that the sale and distribution of a tobacco  
18          product may be restricted under a regula-  
19          tion under section 906(d);

20          “(C) shall, where appropriate, require the  
21          use and prescribe the form and content of label-  
22          ing for the proper use of the tobacco product;  
23          and

24          “(D) shall require tobacco products con-  
25          taining foreign-grown tobacco to meet the same

1 standards applicable to tobacco products con-  
2 taining domestically grown tobacco.

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

11 “(6) INVOLVEMENT OF OTHER AGENCIES; IN-  
12 FORMED PERSONS.—In carrying out duties under  
13 this section, the Secretary shall endeavor to—

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

17 “(B) consult with other Federal agencies  
18 concerned with standard setting and other na-  
19 tionally or internationally recognized standard-  
20 setting entities; and

21 “(C) invite appropriate participation,  
22 through joint or other conferences, workshops,  
23 or other means, by informed persons represent-  
24 ative of scientific, professional, industry, agri-  
25 cultural, or consumer organizations who in the

1 Secretary's judgment can make a significant  
2 contribution.

3 “(b) CONSIDERATIONS BY SECRETARY.—

4 “(1) TECHNICAL ACHIEVABILITY.—The Sec-  
5 retary shall consider information submitted in con-  
6 nection with a proposed standard regarding the tech-  
7 nical achievability of compliance with such standard.

8 “(2) OTHER CONSIDERATIONS.—The Secretary  
9 shall consider all other information submitted in  
10 connection with a proposed standard, including in-  
11 formation concerning the countervailing effects of  
12 the tobacco product standard on the health of ado-  
13 lescent tobacco users, adult tobacco users, or non-  
14 tobacco users, such as the creation of a significant  
15 demand for contraband or other tobacco products  
16 that do not meet the requirements of this chapter  
17 and the significance of such demand.

18 “(c) PROPOSED STANDARDS.—

19 “(1) IN GENERAL.—The Secretary shall publish  
20 in the Federal Register a notice of proposed rule-  
21 making for the establishment, amendment, or rev-  
22 ocation of any tobacco product standard.

23 “(2) REQUIREMENTS OF NOTICE.—A notice of  
24 proposed rulemaking for the establishment or

1 amendment of a tobacco product standard for a to-  
2 bacco product shall—

3 “(A) set forth a finding with supporting  
4 justification that the tobacco product standard  
5 is appropriate for the protection of the public  
6 health;

7 “(B) invite interested persons to submit a  
8 draft or proposed tobacco product standard for  
9 consideration by the Secretary;

10 “(C) invite interested persons to submit  
11 comments on structuring the standard so that  
12 it does not advantage foreign-grown tobacco  
13 over domestically grown tobacco; and

14 “(D) invite the Secretary of Agriculture to  
15 provide any information or analysis which the  
16 Secretary of Agriculture believes is relevant to  
17 the proposed tobacco product standard.

18 “(3) FINDING.—A notice of proposed rule-  
19 making for the revocation of a tobacco product  
20 standard shall set forth a finding with supporting  
21 justification that the tobacco product standard is no  
22 longer appropriate for the protection of the public  
23 health.

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

1 “(d) PROMULGATION.—

2 “(1) IN GENERAL.—After the expiration of the  
3 period for comment on a notice of proposed rule-  
4 making published under subsection (c) respecting a  
5 tobacco product standard and after consideration of  
6 comments submitted under subsections (b) and (c)  
7 and any report from the Tobacco Products Scientific  
8 Advisory Committee, the Secretary shall—

9 “(A) if the Secretary determines that the  
10 standard would be appropriate for the protec-  
11 tion of the public health, promulgate a regula-  
12 tion establishing a tobacco product standard  
13 and publish in the Federal Register findings on  
14 the matters referred to in subsection (c); or

15 “(B) publish a notice terminating the pro-  
16 ceeding for the development of the standard to-  
17 gether with the reasons for such termination.

18 “(2) EFFECTIVE DATE.—A regulation estab-  
19 lishing a tobacco product standard shall set forth  
20 the date or dates upon which the standard shall take  
21 effect, but no such regulation may take effect before  
22 1 year after the date of its publication unless the  
23 Secretary determines that an earlier effective date is  
24 necessary for the protection of the public health.  
25 Such date or dates shall be established so as to min-

1 imize, consistent with the public health, economic  
2 loss to, and disruption or dislocation of, domestic  
3 and international trade. In establishing such effective  
4 date or dates, the Secretary shall consider information  
5 submitted in connection with a proposed  
6 product standard by interested parties, including  
7 manufacturers and tobacco growers, regarding the  
8 technical achievability of compliance with the standard,  
9 and including information concerning the existence of patents  
10 that make it impossible to comply in the timeframe envisioned  
11 in the proposed standard. If the Secretary determines, based on  
12 the Secretary's evaluation of submitted comments, that a product  
13 standard can be met only by manufacturers requiring substantial  
14 changes to the methods of farming the domestically grown tobacco  
15 used by the manufacturer, the effective date of that product  
16 standard shall be not less than 2 years after the date of publication  
17 of the final regulation establishing the standard.

21           “(3) LIMITATION ON POWER GRANTED TO THE  
22 FOOD AND DRUG ADMINISTRATION.—Because of the  
23 importance of a decision of the Secretary to issue a  
24 regulation—

1           “(A) banning all cigarettes, all smokeless  
2 tobacco products, all little cigars, all cigars  
3 other than little cigars, all pipe tobacco, or all  
4 roll-your-own tobacco products; or

5           “(B) requiring the reduction of nicotine  
6 yields of a tobacco product to zero,  
7 the Secretary is prohibited from taking such actions  
8 under this Act.

9           “(4) AMENDMENT; REVOCATION.—

10           “(A) AUTHORITY.—The Secretary, upon  
11 the Secretary’s own initiative or upon petition  
12 of an interested person, may by a regulation,  
13 promulgated in accordance with the require-  
14 ments of subsection (c) and paragraph (2),  
15 amend or revoke a tobacco product standard.

16           “(B) EFFECTIVE DATE.—The Secretary  
17 may declare a proposed amendment of a to-  
18 bacco product standard to be effective on and  
19 after its publication in the Federal Register and  
20 until the effective date of any final action taken  
21 on such amendment if the Secretary determines  
22 that making it so effective is in the public inter-  
23 est.

24           “(5) REFERRAL TO ADVISORY COMMITTEE.—



1           “(A) IN GENERAL.—The Secretary may  
2 refer a proposed regulation for the establish-  
3 ment, amendment, or revocation of a tobacco  
4 product standard to the Tobacco Products Sci-  
5 entific Advisory Committee for a report and  
6 recommendation with respect to any matter in-  
7 volved in the proposed regulation which requires  
8 the exercise of scientific judgment.

9           “(B) INITIATION OF REFERRAL.—The Sec-  
10 retary may make a referral under this para-  
11 graph—

12                   “(i) on the Secretary’s own initiative;

13                   or

14                   “(ii) upon the request of an interested  
15 person that—

16                           “(I) demonstrates good cause for  
17 the referral; and

18                           “(II) is made before the expira-  
19 tion of the period for submission of  
20 comments on the proposed regulation.

21           “(C) PROVISION OF DATA.—If a proposed  
22 regulation is referred under this paragraph to  
23 the Tobacco Products Scientific Advisory Com-  
24 mittee, the Secretary shall provide the Advisory

1           Committee with the data and information on  
2           which such proposed regulation is based.

3           “(D) REPORT AND RECOMMENDATION.—  
4           The Tobacco Products Scientific Advisory Com-  
5           mittee shall, within 60 days after the referral of  
6           a proposed regulation under this paragraph and  
7           after independent study of the data and infor-  
8           mation furnished to it by the Secretary and  
9           other data and information before it, submit to  
10          the Secretary a report and recommendation re-  
11          specting such regulation, together with all un-  
12          derlying data and information and a statement  
13          of the reason or basis for the recommendation.

14          “(E) PUBLIC AVAILABILITY.—The Sec-  
15          retary shall make a copy of each report and rec-  
16          ommendation under subparagraph (D) publicly  
17          available.

18          “(e) MENTHOL CIGARETTES.—

19                 “(1) REFERRAL; CONSIDERATIONS.—Imme-  
20                 diately upon the establishment of the Tobacco Prod-  
21                 ucts Scientific Advisory Committee under section  
22                 917(a), the Secretary shall refer to the Committee  
23                 for report and recommendation, under section  
24                 917(c)(4), the issue of the impact of the use of men-  
25                 thol in cigarettes on the public health, including

1 such use among children, African-Americans, His-  
2 panics, and other racial and ethnic minorities. In its  
3 review, the Tobacco Products Scientific Advisory  
4 Committee shall address the considerations listed in  
5 subsections (a)(3)(B)(i) and (b).

6 “(2) REPORT AND RECOMMENDATION.—Not  
7 later than 1 year after its establishment, the To-  
8 bacco Product Scientific Advisory Committee shall  
9 submit to the Secretary the report and recommenda-  
10 tions required pursuant to paragraph (1).

11 “(3) RULE OF CONSTRUCTION.—Nothing in  
12 this subsection shall be construed to limit the Sec-  
13 retary’s authority to take action under this section  
14 or other sections of this Act applicable to menthol.

15 **“SEC. 908. NOTIFICATION AND OTHER REMEDIES.**

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

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

22 “(2) notification under this subsection is nec-  
23 essary to eliminate the unreasonable risk of such  
24 harm and no more practicable means is available

1       under the provisions of this chapter (other than this  
2       section) to eliminate such risk,  
3 the Secretary may issue such order as may be necessary  
4 to assure that adequate notification is provided in an ap-  
5 propriate form, by the persons and means best suited  
6 under the circumstances involved, to all persons who  
7 should properly receive such notification in order to elimi-  
8 nate such risk. The Secretary may order notification by  
9 any appropriate means, including public service announce-  
10 ments. Before issuing an order under this subsection, the  
11 Secretary shall consult with the persons who are to give  
12 notice under the order.

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

20       “(c) RECALL AUTHORITY.—

21               “(1) IN GENERAL.—If the Secretary finds that  
22 there is a reasonable probability that a tobacco prod-  
23 uct contains a manufacturing or other defect not or-  
24 dinarily contained in tobacco products on the market  
25 that would cause serious, adverse health con-

1 sequences or death, the Secretary shall issue an  
2 order requiring the appropriate person (including  
3 the manufacturers, importers, distributors, or retail-  
4 ers of the tobacco product) to immediately cease dis-  
5 tribution of such tobacco product. The order shall  
6 provide the person subject to the order with an op-  
7 portunity for an informal hearing, to be held not  
8 later than 10 days after the date of the issuance of  
9 the order, on the actions required by the order and  
10 on whether the order should be amended to require  
11 a recall of such tobacco product. If, after providing  
12 an opportunity for such a hearing, the Secretary de-  
13 termines that inadequate grounds exist to support  
14 the actions required by the order, the Secretary shall  
15 vacate the order.

16 “(2) AMENDMENT OF ORDER TO REQUIRE RE-  
17 CALL.—

18 “(A) IN GENERAL.—If, after providing an  
19 opportunity for an informal hearing under  
20 paragraph (1), the Secretary determines that  
21 the order should be amended to include a recall  
22 of the tobacco product with respect to which the  
23 order was issued, the Secretary shall, except as  
24 provided in subparagraph (B), amend the order  
25 to require a recall. The Secretary shall specify

1 a timetable in which the tobacco product recall  
2 will occur and shall require periodic reports to  
3 the Secretary describing the progress of the re-  
4 call.

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

7 “(i) shall not include recall of a to-  
8 bacco product from individuals; and

9 “(ii) shall provide for notice to per-  
10 sons subject to the risks associated with  
11 the use of such tobacco product.

12 In providing the notice required by clause (ii),  
13 the Secretary may use the assistance of retail-  
14 ers and other persons who distributed such to-  
15 bacco product. If a significant number of such  
16 persons cannot be identified, the Secretary shall  
17 notify such persons under section 705(b).

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

21 **“SEC. 909. RECORDS AND REPORTS ON TOBACCO PROD-**  
22 **UCTS.**

23 “(a) IN GENERAL.—Every person who is a tobacco  
24 product manufacturer or importer of a tobacco product  
25 shall establish and maintain such records, make such re-

1 ports, and provide such information, as the Secretary may  
2 by regulation reasonably require to assure that such to-  
3 bacco product is not adulterated or misbranded and to  
4 otherwise protect public health. Regulations prescribed  
5 under the preceding sentence—

6           “(1) may require a tobacco product manufac-  
7 turer or importer to report to the Secretary when-  
8 ever the manufacturer or importer receives or other-  
9 wise becomes aware of information that reasonably  
10 suggests that one of its marketed tobacco products  
11 may have caused or contributed to a serious unex-  
12 pected adverse experience associated with the use of  
13 the product or any significant increase in the fre-  
14 quency of a serious, expected adverse product experi-  
15 ence;

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

19           “(3) shall not impose requirements unduly bur-  
20 densome to a tobacco product manufacturer or im-  
21 porter, taking into account the cost of complying  
22 with such requirements and the need for the protec-  
23 tion of the public health and the implementation of  
24 this chapter;

1           “(4) when prescribing the procedure for making  
2 requests for reports or information, shall require  
3 that each request made under such regulations for  
4 submission of a report or information to the Sec-  
5 retary state the reason or purpose for such request  
6 and identify to the fullest extent practicable such re-  
7 port or information;

8           “(5) when requiring submission of a report or  
9 information to the Secretary, shall state the reason  
10 or purpose for the submission of such report or in-  
11 formation and identify to the fullest extent prac-  
12 ticable such report or information; and

13           “(6) may not require that the identity of any  
14 patient or user be disclosed in records, reports, or  
15 information required under this subsection unless re-  
16 quired for the medical welfare of an individual, to  
17 determine risks to public health of a tobacco prod-  
18 uct, or to verify a record, report, or information sub-  
19 mitted under this chapter.

20 In prescribing regulations under this subsection, the Sec-  
21 retary shall have due regard for the professional ethics of  
22 the medical profession and the interests of patients. The  
23 prohibitions of paragraph (6) continue to apply to records,  
24 reports, and information concerning any individual who



1 has been a patient, irrespective of whether or when he  
2 ceases to be a patient.

3 “(b) REPORTS OF REMOVALS AND CORRECTIONS.—

4 “(1) IN GENERAL.—Except as provided in para-  
5 graph (2), the Secretary shall by regulation require  
6 a tobacco product manufacturer or importer of a to-  
7 bacco product to report promptly to the Secretary  
8 any corrective action taken or removal from the  
9 market of a tobacco product undertaken by such  
10 manufacturer or importer if the removal or correc-  
11 tion was undertaken—

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

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

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

22 “(2) EXCEPTION.—No report of the corrective  
23 action or removal of a tobacco product may be re-  
24 quired under paragraph (1) if a report of the correc-

1       tive action or removal is required and has been sub-  
2       mitted under subsection (a).

3       **“SEC. 910. APPLICATION FOR REVIEW OF CERTAIN TO-**  
4               **BACCO PRODUCTS.**

5       “(a) IN GENERAL.—

6               “(1) NEW TOBACCO PRODUCT DEFINED.—For  
7       purposes of this section the term ‘new tobacco prod-  
8       uct’ means—

9               “(A) any tobacco product (including those  
10       products in test markets) that was not commer-  
11       cially marketed in the United States as of Feb-  
12       ruary 15, 2007; or

13              “(B) any modification (including a change  
14       in design, any component, any part, or any con-  
15       stituent, including a smoke constituent, or in  
16       the content, delivery or form of nicotine, or any  
17       other additive or ingredient) of a tobacco prod-  
18       uct where the modified product was commer-  
19       cially marketed in the United States after Feb-  
20       ruary 15, 2007.

21       “(2) PREMARKET REVIEW REQUIRED.—

22              “(A) NEW PRODUCTS.—An order under  
23       subsection (c)(1)(A)(i) for a new tobacco prod-  
24       uct is required unless—

1           “(i) the manufacturer has submitted a  
2           report under section 905(j); and the Sec-  
3           retary has issued an order that the tobacco  
4           product—

5                   “(I) is substantially equivalent to  
6                   a tobacco product commercially mar-  
7                   keted (other than for test marketing)  
8                   in the United States as of February  
9                   15, 2007; and

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

12           “(ii) the tobacco product is exempt  
13           from the requirements of section 905(j)  
14           pursuant to a regulation issued under sec-  
15           tion 905(j)(3).

16           “(B) APPLICATION TO CERTAIN POST-FEB-  
17           RUARY 15, 2007, PRODUCTS.—Subparagraph (A)  
18           shall not apply to a tobacco product—

19                   “(i) that was first introduced or deliv-  
20                   ered for introduction into interstate com-  
21                   merce for commercial distribution in the  
22                   United States after February 15, 2007,  
23                   and prior to the date that is 21 months  
24                   after the date of enactment of the Family

1 Smoking Prevention and Tobacco Control  
2 Act; and

3 “(ii) for which a report was submitted  
4 under section 905(j) within such 21-month  
5 period,

6 except that subparagraph (A) shall apply to the  
7 tobacco product if the Secretary issues an order  
8 that the tobacco product is not substantially  
9 equivalent.

10 “(3) SUBSTANTIALLY EQUIVALENT DEFINED.—

11 “(A) IN GENERAL.—In this section and  
12 section 905(j), the term ‘substantially equiva-  
13 lent’ or ‘substantial equivalence’ means, with  
14 respect to the tobacco product being compared  
15 to the predicate tobacco product, that the Sec-  
16 retary by order has found that the tobacco  
17 product—

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

20 “(ii) has different characteristics and  
21 the information submitted contains infor-  
22 mation, including clinical data if deemed  
23 necessary by the Secretary, that dem-  
24 onstrates that it is not appropriate to reg-  
25 ulate the product under this section be-

1           cause the product does not raise different  
2           questions of public health.

3           “(B) CHARACTERISTICS.—In subpara-  
4           graph (A), the term ‘characteristics’ means the  
5           materials, ingredients, design, composition,  
6           heating source, or other features of a tobacco  
7           product.

8           “(C) LIMITATION.—A tobacco product may  
9           not be found to be substantially equivalent to a  
10          predicate tobacco product that has been re-  
11          moved from the market at the initiative of the  
12          Secretary or that has been determined by a ju-  
13          dicial order to be misbranded or adulterated.

14          “(4) HEALTH INFORMATION.—

15                 “(A) SUMMARY.—As part of a submission  
16                 under section 905(j) respecting a tobacco prod-  
17                 uct, the person required to file a premarket no-  
18                 tification under such section shall provide an  
19                 adequate summary of any health information  
20                 related to the tobacco product or state that  
21                 such information will be made available upon  
22                 request by any person.

23                 “(B) REQUIRED INFORMATION.—Any sum-  
24                 mary under subparagraph (A) respecting a to-  
25                 bacco product shall contain detailed information

1           regarding data concerning adverse health ef-  
2           fects and shall be made available to the public  
3           by the Secretary within 30 days of the issuance  
4           of a determination that such tobacco product is  
5           substantially equivalent to another tobacco  
6           product.

7           “(b) APPLICATION.—

8                 “(1) CONTENTS.—An application under this  
9           section shall contain—

10                     “(A) full reports of all information, pub-  
11                     lished or known to, or which should reasonably  
12                     be known to, the applicant, concerning inves-  
13                     tigations which have been made to show the  
14                     health risks of such tobacco product and wheth-  
15                     er such tobacco product presents less risk than  
16                     other tobacco products;

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

21                     “(C) a full description of the methods used  
22                     in, and the facilities and controls used for, the  
23                     manufacture, processing, and, when relevant,  
24                     packing and installation of, such tobacco prod-  
25                     uct;

1           “(D) an identifying reference to any to-  
2           bacco product standard under section 907  
3           which would be applicable to any aspect of such  
4           tobacco product, and either adequate informa-  
5           tion to show that such aspect of such tobacco  
6           product fully meets such tobacco product stand-  
7           ard or adequate information to justify any devi-  
8           ation from such standard;

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

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

14          “(G) such other information relevant to  
15          the subject matter of the application as the Sec-  
16          retary may require.

17          “(2) REFERRAL TO TOBACCO PRODUCTS SCI-  
18          ENTIFIC ADVISORY COMMITTEE.—Upon receipt of an  
19          application meeting the requirements set forth in  
20          paragraph (1), the Secretary—

21                 “(A) may, on the Secretary’s own initia-  
22                 tive; or

23                 “(B) may, upon the request of an appli-  
24                 cant,

1 refer such application to the Tobacco Products Sci-  
2 entific Advisory Committee for reference and for  
3 submission (within such period as the Secretary may  
4 establish) of a report and recommendation respect-  
5 ing the application, together with all underlying data  
6 and the reasons or basis for the recommendation.

7 “(c) ACTION ON APPLICATION.—

8 “(1) DEADLINE.—

9 “(A) IN GENERAL.—As promptly as pos-  
10 sible, but in no event later than 180 days after  
11 the receipt of an application under subsection  
12 (b), the Secretary, after considering the report  
13 and recommendation submitted under sub-  
14 section (b)(2), shall—

15 “(i) issue an order that the new prod-  
16 uct may be introduced or delivered for in-  
17 troduction into interstate commerce if the  
18 Secretary finds that none of the grounds  
19 specified in paragraph (2) of this sub-  
20 section applies; or

21 “(ii) issue an order that the new prod-  
22 uct may not be introduced or delivered for  
23 introduction into interstate commerce if  
24 the Secretary finds (and sets forth the  
25 basis for such finding as part of or accom-



1           panying such denial) that 1 or more  
2           grounds for denial specified in paragraph  
3           (2) of this subsection apply.

4           “(B) RESTRICTIONS ON SALE AND DIS-  
5           TRIBUTION.—An order under subparagraph  
6           (A)(i) may require that the sale and distribu-  
7           tion of the tobacco product be restricted but  
8           only to the extent that the sale and distribution  
9           of a tobacco product may be restricted under a  
10          regulation under section 906(d).

11          “(2) DENIAL OF APPLICATION.—The Secretary  
12          shall deny an application submitted under subsection  
13          (b) if, upon the basis of the information submitted  
14          to the Secretary as part of the application and any  
15          other information before the Secretary with respect  
16          to such tobacco product, the Secretary finds that—

17                 “(A) there is a lack of a showing that per-  
18                 mitting such tobacco product to be marketed  
19                 would be appropriate for the protection of the  
20                 public health;

21                 “(B) the methods used in, or the facilities  
22                 or controls used for, the manufacture, proc-  
23                 essing, or packing of such tobacco product do  
24                 not conform to the requirements of section  
25                 906(e);

1           “(C) based on a fair evaluation of all mate-  
2           rial facts, the proposed labeling is false or mis-  
3           leading in any particular; or

4           “(D) such tobacco product is not shown to  
5           conform in all respects to a tobacco product  
6           standard in effect under section 907, and there  
7           is a lack of adequate information to justify the  
8           deviation from such standard.

9           “(3) DENIAL INFORMATION.—Any denial of an  
10          application shall, insofar as the Secretary determines  
11          to be practicable, be accompanied by a statement in-  
12          forming the applicant of the measures required to  
13          remove such application from deniable form (which  
14          measures may include further research by the appli-  
15          cant in accordance with 1 or more protocols pre-  
16          scribed by the Secretary).

17          “(4) BASIS FOR FINDING.—For purposes of  
18          this section, the finding as to whether the marketing  
19          of a tobacco product for which an application has  
20          been submitted is appropriate for the protection of  
21          the public health shall be determined with respect to  
22          the risks and benefits to the population as a whole,  
23          including users and nonusers of the tobacco product,  
24          and taking into account—

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

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

7           “(5) BASIS FOR ACTION.—

8           “(A) INVESTIGATIONS.—For purposes of  
9 paragraph (2)(A), whether permitting a tobacco  
10 product to be marketed would be appropriate  
11 for the protection of the public health shall,  
12 when appropriate, be determined on the basis of  
13 well-controlled investigations, which may in-  
14 clude 1 or more clinical investigations by ex-  
15 perts qualified by training and experience to  
16 evaluate the tobacco product.

17           “(B) OTHER EVIDENCE.—If the Secretary  
18 determines that there exists valid scientific evi-  
19 dence (other than evidence derived from inves-  
20 tigation described in subparagraph (A)) which  
21 is sufficient to evaluate the tobacco product, the  
22 Secretary may authorize that the determination  
23 for purposes of paragraph (2)(A) be made on  
24 the basis of such evidence.

25           “(d) WITHDRAWAL AND TEMPORARY SUSPENSION.—

1           “(1) IN GENERAL.—The Secretary shall, upon  
2           obtaining, where appropriate, advice on scientific  
3           matters from the Tobacco Products Scientific Advi-  
4           sory Committee, and after due notice and oppor-  
5           tunity for informal hearing for a tobacco product for  
6           which an order was issued under subsection  
7           (c)(1)(A)(i), issue an order withdrawing the order if  
8           the Secretary finds—

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

12                  “(B) that the application contained or was  
13                  accompanied by an untrue statement of a mate-  
14                  rial fact;

15                  “(C) that the applicant—

16                          “(i) has failed to establish a system  
17                          for maintaining records, or has repeatedly  
18                          or deliberately failed to maintain records  
19                          or to make reports, required by an applica-  
20                          ble regulation under section 909;

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

24                          “(iii) has not complied with the re-  
25                          quirements of section 905;

1           “(D) on the basis of new information be-  
2 fore the Secretary with respect to such tobacco  
3 product, evaluated together with the evidence  
4 before the Secretary when the application was  
5 reviewed, that the methods used in, or the fa-  
6 cilities and controls used for, the manufacture,  
7 processing, packing, or installation of such to-  
8 bacco product do not conform with the require-  
9 ments of section 906(e) and were not brought  
10 into conformity with such requirements within a  
11 reasonable time after receipt of written notice  
12 from the Secretary of nonconformity;

13           “(E) on the basis of new information be-  
14 fore the Secretary, evaluated together with the  
15 evidence before the Secretary when the applica-  
16 tion was reviewed, that the labeling of such to-  
17 bacco product, based on a fair evaluation of all  
18 material facts, is false or misleading in any par-  
19 ticular and was not corrected within a reason-  
20 able time after receipt of written notice from  
21 the Secretary of such fact; or

22           “(F) on the basis of new information be-  
23 fore the Secretary, evaluated together with the  
24 evidence before the Secretary when such order  
25 was issued, that such tobacco product is not

1 shown to conform in all respects to a tobacco  
2 product standard which is in effect under sec-  
3 tion 907, compliance with which was a condi-  
4 tion to the issuance of an order relating to the  
5 application, and that there is a lack of adequate  
6 information to justify the deviation from such  
7 standard.

8 “(2) APPEAL.—The holder of an application  
9 subject to an order issued under paragraph (1) with-  
10 drawing an order issued pursuant to subsection  
11 (c)(1)(A)(i) may, by petition filed on or before the  
12 30th day after the date upon which such holder re-  
13 ceives notice of such withdrawal, obtain review there-  
14 of in accordance with section 912.

15 “(3) TEMPORARY SUSPENSION.—If, after pro-  
16 viding an opportunity for an informal hearing, the  
17 Secretary determines there is reasonable probability  
18 that the continuation of distribution of a tobacco  
19 product under an order would cause serious, adverse  
20 health consequences or death, that is greater than  
21 ordinarily caused by tobacco products on the market,  
22 the Secretary shall by order temporarily suspend the  
23 authority of the manufacturer to market the prod-  
24 uct. If the Secretary issues such an order, the Sec-

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

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

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

7             “(2) by mailing the order by registered mail or  
8 certified mail addressed to the applicant at the ap-  
9 plicant’s last known address in the records of the  
10 Secretary.

11       “(f) RECORDS.—

12             “(1) ADDITIONAL INFORMATION.—In the case  
13 of any tobacco product for which an order issued  
14 pursuant to subsection (c)(1)(A)(i) for an applica-  
15 tion filed under subsection (b) is in effect, the appli-  
16 cant shall establish and maintain such records, and  
17 make such reports to the Secretary, as the Secretary  
18 may by regulation, or by order with respect to such  
19 application, prescribe on the basis of a finding that  
20 such records and reports are necessary in order to  
21 enable the Secretary to determine, or facilitate a de-  
22 termination of, whether there is or may be grounds  
23 for withdrawing or temporarily suspending such  
24 order.

1           “(2) ACCESS TO RECORDS.—Each person re-  
 2           quired under this section to maintain records, and  
 3           each person in charge of custody thereof, shall, upon  
 4           request of an officer or employee designated by the  
 5           Secretary, permit such officer or employee at all rea-  
 6           sonable times to have access to and copy and verify  
 7           such records.

8           “(g) INVESTIGATIONAL TOBACCO PRODUCT EXEMP-  
 9           TION FOR INVESTIGATIONAL USE.—The Secretary may  
 10          exempt tobacco products intended for investigational use  
 11          from the provisions of this chapter under such conditions  
 12          as the Secretary may by regulation prescribe.

13          **“SEC. 911. MODIFIED RISK TOBACCO PRODUCTS.**

14          “(a) IN GENERAL.—No person may introduce or de-  
 15          liver for introduction into interstate commerce any modi-  
 16          fied risk tobacco product unless an order issued pursuant  
 17          to subsection (g) is effective with respect to such product.

18          “(b) DEFINITIONS.—In this section:

19                 “(1) MODIFIED RISK TOBACCO PRODUCT.—The  
 20                 term ‘modified risk tobacco product’ means any to-  
 21                 bacco product that is sold or distributed for use to  
 22                 reduce harm or the risk of tobacco-related disease  
 23                 associated with commercially marketed tobacco prod-  
 24                 ucts.

25                 “(2) SOLD OR DISTRIBUTED.—



1           “(A) IN GENERAL.—With respect to a to-  
2           bacco product, the term ‘sold or distributed for  
3           use to reduce harm or the risk of tobacco-re-  
4           lated disease associated with commercially mar-  
5           keted tobacco products’ means a tobacco prod-  
6           uct—

7                   “(i) the label, labeling, or advertising  
8                   of which represents explicitly or implicitly  
9                   that—

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

15                           “(II) the tobacco product or its  
16                           smoke contains a reduced level of a  
17                           substance or presents a reduced expo-  
18                           sure to a substance; or

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

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

1           “(iii) the tobacco product manufac-  
2           turer of which has taken any action di-  
3           rected to consumers through the media or  
4           otherwise, other than by means of the to-  
5           bacco product’s label, labeling, or adver-  
6           tising, after the date of enactment of the  
7           Family Smoking Prevention and Tobacco  
8           Control Act, respecting the product that  
9           would be reasonably expected to result in  
10          consumers believing that the tobacco prod-  
11          uct or its smoke may present a lower risk  
12          of disease or is less harmful than one or  
13          more commercially marketed tobacco prod-  
14          ucts, or presents a reduced exposure to, or  
15          does not contain or is free of, a substance  
16          or substances.

17          “(B) LIMITATION.—No tobacco product  
18          shall be considered to be ‘sold or distributed for  
19          use to reduce harm or the risk of tobacco-re-  
20          lated disease associated with commercially mar-  
21          keted tobacco products’, except as described in  
22          subparagraph (A).

23          “(C) SMOKELESS TOBACCO PRODUCT.—No  
24          smokeless tobacco product shall be considered  
25          to be ‘sold or distributed for use to reduce harm

1 or the risk of tobacco-related disease associated  
2 with commercially marketed tobacco products’  
3 solely because its label, labeling, or advertising  
4 uses the following phrases to describe such  
5 product and its use: ‘smokeless tobacco’,  
6 ‘smokeless tobacco product’, ‘not consumed by  
7 smoking’, ‘does not produce smoke’,  
8 ‘smokefree’, ‘smoke-free’, ‘without smoke’, ‘no  
9 smoke’, or ‘not smoke’.

10 “(3) EFFECTIVE DATE.—The provisions of  
11 paragraph (2)(A)(ii) shall take effect 12 months  
12 after the date of enactment of the Family Smoking  
13 Prevention and Tobacco Control Act for those prod-  
14 ucts whose label, labeling, or advertising contains  
15 the terms described in such paragraph on such date  
16 of enactment. The effective date shall be with re-  
17 spect to the date of manufacture, provided that, in  
18 any case, beginning 30 days after such effective  
19 date, a manufacturer shall not introduce into the do-  
20 mestic commerce of the United States any product,  
21 irrespective of the date of manufacture, that is not  
22 in conformance with paragraph (2)(A)(ii).

23 “(c) TOBACCO DEPENDENCE PRODUCTS.—A product  
24 that is intended to be used for the treatment of tobacco  
25 dependence, including smoking cessation, is not a modified

1 risk tobacco product under this section if it has been ap-  
2 proved as a drug or device by the Food and Drug Adminis-  
3 tration and is subject to the requirements of chapter V.

4 “(d) FILING.—Any person may file with the Sec-  
5 retary an application for a modified risk tobacco product.

6 Such application shall include—

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

9 “(2) the conditions for using the product;

10 “(3) the formulation of the product;

11 “(4) sample product labels and labeling;

12 “(5) all documents (including underlying sci-  
13 entific information) relating to research findings  
14 conducted, supported, or possessed by the tobacco  
15 product manufacturer relating to the effect of the  
16 product on tobacco-related diseases and health-re-  
17 lated conditions, including information both favor-  
18 able and unfavorable to the ability of the product to  
19 reduce risk or exposure and relating to human  
20 health;

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

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

1       “(e) PUBLIC AVAILABILITY.—The Secretary shall  
2 make the application described in subsection (d) publicly  
3 available (except matters in the application which are  
4 trade secrets or otherwise confidential, commercial infor-  
5 mation) and shall request comments by interested persons  
6 on the information contained in the application and on the  
7 label, labeling, and advertising accompanying such appli-  
8 cation.

9       “(f) ADVISORY COMMITTEE.—

10           “(1) IN GENERAL.—The Secretary shall refer to  
11 the Tobacco Products Scientific Advisory Committee  
12 any application submitted under this section.

13           “(2) RECOMMENDATIONS.—Not later than 60  
14 days after the date an application is referred to the  
15 Tobacco Products Scientific Advisory Committee  
16 under paragraph (1), the Advisory Committee shall  
17 report its recommendations on the application to the  
18 Secretary.

19       “(g) MARKETING.—

20           “(1) MODIFIED RISK PRODUCTS.—Except as  
21 provided in paragraph (2), the Secretary shall, with  
22 respect to an application submitted under this sec-  
23 tion, issue an order that a modified risk product  
24 may be commercially marketed only if the Secretary  
25 determines that the applicant has demonstrated that

1 such product, as it is actually used by consumers,  
2 will—

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

6 “(B) benefit the health of the population  
7 as a whole taking into account both users of to-  
8 bacco products and persons who do not cur-  
9 rently use tobacco products.

10 “(2) SPECIAL RULE FOR CERTAIN PRODUCTS.—

11 “(A) IN GENERAL.—The Secretary may  
12 issue an order that a tobacco product may be  
13 introduced or delivered for introduction into  
14 interstate commerce, pursuant to an application  
15 under this section, with respect to a tobacco  
16 product that may not be commercially marketed  
17 under paragraph (1) if the Secretary makes the  
18 findings required under this paragraph and de-  
19 termines that the applicant has demonstrated  
20 that—

21 “(i) such order would be appropriate  
22 to promote the public health;

23 “(ii) any aspect of the label, labeling,  
24 and advertising for such product that  
25 would cause the tobacco product to be a

1 modified risk tobacco product under sub-  
2 section (b) is limited to an explicit or im-  
3 plicit representation that such tobacco  
4 product or its smoke does not contain or is  
5 free of a substance or contains a reduced  
6 level of a substance, or presents a reduced  
7 exposure to a substance in tobacco smoke;

8 “(iii) scientific evidence is not avail-  
9 able and, using the best available scientific  
10 methods, cannot be made available without  
11 conducting long-term epidemiological stud-  
12 ies for an application to meet the stand-  
13 ards set forth in paragraph (1); and

14 “(iv) the scientific evidence that is  
15 available without conducting long-term epi-  
16 demiological studies demonstrates that a  
17 measurable and substantial reduction in  
18 morbidity or mortality among individual  
19 tobacco users is reasonably likely in subse-  
20 quent studies.

21 “(B) ADDITIONAL FINDINGS REQUIRED.—

22 To issue an order under subparagraph (A) the  
23 Secretary must also find that the applicant has  
24 demonstrated that—

1           “(i) the magnitude of the overall re-  
2           ductions in exposure to the substance or  
3           substances which are the subject of the ap-  
4           plication is substantial, such substance or  
5           substances are harmful, and the product as  
6           actually used exposes consumers to the  
7           specified reduced level of the substance or  
8           substances;

9           “(ii) the product as actually used by  
10          consumers will not expose them to higher  
11          levels of other harmful substances com-  
12          pared to the similar types of tobacco prod-  
13          ucts then on the market unless such in-  
14          creases are minimal and the reasonably  
15          likely overall impact of use of the product  
16          remains a substantial and measurable re-  
17          duction in overall morbidity and mortality  
18          among individual tobacco users;

19          “(iii) testing of actual consumer per-  
20          ception shows that, as the applicant pro-  
21          poses to label and market the product, con-  
22          sumers will not be misled into believing  
23          that the product—

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



1           “(II) presents or has been dem-  
2           onstrated to present less of a risk of  
3           disease than 1 or more other commer-  
4           cially marketed tobacco products; and

5           “(iv) issuance of an order with respect  
6           to the application is expected to benefit the  
7           health of the population as a whole taking  
8           into account both users of tobacco prod-  
9           ucts and persons who do not currently use  
10          tobacco products.

11          “(C) CONDITIONS OF MARKETING.—

12           “(i) IN GENERAL.—Applications sub-  
13          ject to an order under this paragraph shall  
14          be limited to a term of not more than 5  
15          years, but may be renewed upon a finding  
16          by the Secretary that the requirements of  
17          this paragraph continue to be satisfied  
18          based on the filing of a new application.

19           “(ii) AGREEMENTS BY APPLICANT.—  
20          An order under this paragraph shall be  
21          conditioned on the applicant’s agreement  
22          to conduct postmarket surveillance and  
23          studies and to submit to the Secretary the  
24          results of such surveillance and studies to  
25          determine the impact of the order on con-

1           sumer perception, behavior, and health and  
2           to enable the Secretary to review the accu-  
3           racy of the determinations upon which the  
4           order was based in accordance with a pro-  
5           tocol approved by the Secretary.

6           “(iii) ANNUAL SUBMISSION.—The re-  
7           sults of such postmarket surveillance and  
8           studies described in clause (ii) shall be  
9           submitted annually.

10          “(3) BASIS.—The determinations under para-  
11          graphs (1) and (2) shall be based on—

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

14           “(B) scientific evidence and other informa-  
15           tion that is made available to the Secretary.

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

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

23           “(B) the increased or decreased likelihood  
24           that existing users of tobacco products who  
25           would otherwise stop using such products will

1 switch to the tobacco product that is the subject  
2 of the application;

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

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

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

15 “(h) ADDITIONAL CONDITIONS FOR MARKETING.—

16 “(1) MODIFIED RISK PRODUCTS.—The Sec-  
17 retary shall require for the marketing of a product  
18 under this section that any advertising or labeling  
19 concerning modified risk products enable the public  
20 to comprehend the information concerning modified  
21 risk and to understand the relative significance of  
22 such information in the context of total health and  
23 in relation to all of the diseases and health-related  
24 conditions associated with the use of tobacco prod-  
25 ucts.

1 “(2) COMPARATIVE CLAIMS.—

2 “(A) IN GENERAL.—The Secretary may re-  
3 quire for the marketing of a product under this  
4 subsection that a claim comparing a tobacco  
5 product to 1 or more other commercially mar-  
6 keted tobacco products shall compare the to-  
7 bacco product to a commercially marketed to-  
8 bacco product that is representative of that type  
9 of tobacco product on the market (for example  
10 the average value of the top 3 brands of an es-  
11 tablished regular tobacco product).

12 “(B) QUANTITATIVE COMPARISONS.—The  
13 Secretary may also require, for purposes of sub-  
14 paragraph (A), that the percent (or fraction) of  
15 change and identity of the reference tobacco  
16 product and a quantitative comparison of the  
17 amount of the substance claimed to be reduced  
18 shall be stated in immediate proximity to the  
19 most prominent claim.

20 “(3) LABEL DISCLOSURE.—

21 “(A) IN GENERAL.—The Secretary may re-  
22 quire the disclosure on the label of other sub-  
23 stances in the tobacco product, or substances  
24 that may be produced by the consumption of  
25 that tobacco product, that may affect a disease

1 or health-related condition or may increase the  
2 risk of other diseases or health-related condi-  
3 tions associated with the use of tobacco prod-  
4 ucts.

5 “(B) CONDITIONS OF USE.—If the condi-  
6 tions of use of the tobacco product may affect  
7 the risk of the product to human health, the  
8 Secretary may require the labeling of conditions  
9 of use.

10 “(4) TIME.—An order issued under subsection  
11 (g)(1) shall be effective for a specified period of  
12 time.

13 “(5) ADVERTISING.—The Secretary may re-  
14 quire, with respect to a product for which an appli-  
15 cant obtained an order under subsection (g)(1), that  
16 the product comply with requirements relating to ad-  
17 vertising and promotion of the tobacco product.

18 “(i) POSTMARKET SURVEILLANCE AND STUDIES.—

19 “(1) IN GENERAL.—The Secretary shall re-  
20 quire, with respect to a product for which an appli-  
21 cant obtained an order under subsection (g)(1), that  
22 the applicant conduct postmarket surveillance and  
23 studies for such a tobacco product to determine the  
24 impact of the order issuance on consumer percep-  
25 tion, behavior, and health, to enable the Secretary to

1 review the accuracy of the determinations upon  
2 which the order was based, and to provide informa-  
3 tion that the Secretary determines is otherwise nec-  
4 essary regarding the use or health risks involving  
5 the tobacco product. The results of postmarket sur-  
6 veillance and studies shall be submitted to the Sec-  
7 retary on an annual basis.

8 “(2) SURVEILLANCE PROTOCOL.—Each appli-  
9 cant required to conduct a surveillance of a tobacco  
10 product under paragraph (1) shall, within 30 days  
11 after receiving notice that the applicant is required  
12 to conduct such surveillance, submit, for the ap-  
13 proval of the Secretary, a protocol for the required  
14 surveillance. The Secretary, within 60 days of the  
15 receipt of such protocol, shall determine if the prin-  
16 cipal investigator proposed to be used in the surveil-  
17 lance has sufficient qualifications and experience to  
18 conduct such surveillance and if such protocol will  
19 result in collection of the data or other information  
20 designated by the Secretary as necessary to protect  
21 the public health.

22 “(j) WITHDRAWAL OF AUTHORIZATION.—The Sec-  
23 retary, after an opportunity for an informal hearing, shall  
24 withdraw an order under subsection (g) if the Secretary  
25 determines that—

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

6           “(2) the application failed to include material  
7           information or included any untrue statement of ma-  
8           terial fact;

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

12                 “(A) a tobacco product standard is estab-  
13                 lished pursuant to section 907;

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

18                 “(C) any postmarket surveillance or stud-  
19                 ies reveal that the order is no longer consistent  
20                 with the protection of the public health;

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

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

1       “(k) CHAPTER IV OR V.—A product for which the  
2 Secretary has issued an order pursuant to subsection (g)  
3 shall not be subject to chapter IV or V.

4       “(l) IMPLEMENTING REGULATIONS OR GUIDANCE.—

5           “(1) SCIENTIFIC EVIDENCE.—Not later than 2  
6 years after the date of enactment of the Family  
7 Smoking Prevention and Tobacco Control Act, the  
8 Secretary shall issue regulations or guidance (or any  
9 combination thereof) on the scientific evidence re-  
10 quired for assessment and ongoing review of modi-  
11 fied risk tobacco products. Such regulations or guid-  
12 ance shall—

13           “(A) to the extent that adequate scientific  
14 evidence exists, establish minimum standards  
15 for scientific studies needed prior to issuing an  
16 order under subsection (g) to show that a sub-  
17 stantial reduction in morbidity or mortality  
18 among individual tobacco users occurs for prod-  
19 ucts described in subsection (g)(1) or is reason-  
20 ably likely for products described in subsection  
21 (g)(2);

22           “(B) include validated biomarkers, inter-  
23 mediate clinical endpoints, and other feasible  
24 outcome measures, as appropriate;



1           “(C) establish minimum standards for  
2 postmarket studies, that shall include regular  
3 and long-term assessments of health outcomes  
4 and mortality, intermediate clinical endpoints,  
5 consumer perception of harm reduction, and the  
6 impact on quitting behavior and new use of to-  
7 bacco products, as appropriate;

8           “(D) establish minimum standards for re-  
9 quired postmarket surveillance, including ongo-  
10 ing assessments of consumer perception;

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

15           “(F) establish a reasonable timetable for  
16 the Secretary to review an application under  
17 this section.

18           “(2) CONSULTATION.—The regulations or guid-  
19 ance issued under paragraph (1) shall be developed  
20 in consultation with the Institute of Medicine, and  
21 with the input of other appropriate scientific and  
22 medical experts, on the design and conduct of such  
23 studies and surveillance.

24           “(3) REVISION.—The regulations or guidance  
25 under paragraph (1) shall be revised on a regular

1 basis as new scientific information becomes avail-  
2 able.

3 “(4) NEW TOBACCO PRODUCTS.—Not later  
4 than 2 years after the date of enactment of the  
5 Family Smoking Prevention and Tobacco Control  
6 Act, the Secretary shall issue a regulation or guid-  
7 ance that permits the filing of a single application  
8 for any tobacco product that is a new tobacco prod-  
9 uct under section 910 and which the applicant seeks  
10 to commercially market under this section.

11 “(m) DISTRIBUTORS.—Except as provided in this  
12 section, no distributor may take any action, after the date  
13 of enactment of the Family Smoking Prevention and To-  
14 bacco Control Act, with respect to a tobacco product that  
15 would reasonably be expected to result in consumers be-  
16 lieving that the tobacco product or its smoke may present  
17 a lower risk of disease or is less harmful than one or more  
18 commercially marketed tobacco products, or presents a re-  
19 duced exposure to, or does not contain or is free of, a sub-  
20 stance or substances.

21 **“SEC. 912. JUDICIAL REVIEW.**

22 “(a) RIGHT TO REVIEW.—

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

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

4           “(B) a denial of an application under sec-  
5           tion 910(c),

6           any person adversely affected by such regulation or  
7           denial may file a petition for judicial review of such  
8           regulation or denial with the United States Court of  
9           Appeals for the District of Columbia or for the cir-  
10          cuit in which such person resides or has their prin-  
11          cipal place of business.

12          “(2) REQUIREMENTS.—

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

17           “(B) RECORD OF PROCEEDINGS.—On re-  
18           ceipt of a petition under subparagraph (A), the  
19           Secretary shall file in the court in which such  
20           petition was filed—

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

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

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

3           “(i) all notices and other matter pub-  
4 lished in the Federal Register with respect  
5 to the regulation or order reviewed;

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

9           “(iii) proceedings of any panel or ad-  
10 visory committee with respect to such reg-  
11 ulation or order;

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

14           “(v) any other information identified  
15 by the Secretary, in the administrative pro-  
16 ceeding held with respect to such regula-  
17 tion or order, as being relevant to such  
18 regulation or order.

19           “(b) STANDARD OF REVIEW.—Upon the filing of the  
20 petition under subsection (a) for judicial review of a regu-  
21 lation or order, the court shall have jurisdiction to review  
22 the regulation or order in accordance with chapter 7 of  
23 title 5, United States Code, and to grant appropriate re-  
24 lief, including interim relief, as provided for in such chap-  
25 ter. A regulation or denial described in subsection (a) shall

1 be reviewed in accordance with section 706(2)(A) of title  
2 5, United States Code.

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

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

12 “(e) REGULATIONS AND ORDERS MUST RECITE  
13 BASIS IN RECORD.—To facilitate judicial review, a regula-  
14 tion or order issued under section 906, 907, 908, 909,  
15 910, or 916 shall contain a statement of the reasons for  
16 the issuance of such regulation or order in the record of  
17 the proceedings held in connection with its issuance.

18 **“SEC. 913. EQUAL TREATMENT OF RETAIL OUTLETS.**

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

1 **“SEC. 914. JURISDICTION OF AND COORDINATION WITH**  
2 **THE FEDERAL TRADE COMMISSION.**

3 “(a) JURISDICTION.—

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

10 “(2) ENFORCEMENT.—Any advertising that vio-  
11 lates this chapter or a provision of the regulations  
12 referred to in section 102 of the Family Smoking  
13 Prevention and Tobacco Control Act, is an unfair or  
14 deceptive act or practice under section 5(a) of the  
15 Federal Trade Commission Act and shall be consid-  
16 ered a violation of a rule promulgated under section  
17 18 of that Act.

18 “(b) COORDINATION.—With respect to the require-  
19 ments of section 4 of the Federal Cigarette Labeling and  
20 Advertising Act and section 3 of the Comprehensive  
21 Smokeless Tobacco Health Education Act of 1986—

22 “(1) the Chairman of the Federal Trade Com-  
23 mission shall coordinate with the Secretary con-  
24 cerning the enforcement of such Act as such enforce-  
25 ment relates to unfair or deceptive acts or practices

1 in the advertising of cigarettes or smokeless tobacco;  
2 and

3 “(2) the Secretary shall consult with the Chair-  
4 man of such Commission in revising the label state-  
5 ments and requirements under such sections.

6 **“SEC. 915. REGULATION REQUIREMENT.**

7 “(a) TESTING, REPORTING, AND DISCLOSURE.—Not  
8 later than 36 months after the date of enactment of the  
9 Family Smoking Prevention and Tobacco Control Act, the  
10 Secretary shall promulgate regulations under this Act that  
11 meet the requirements of subsection (b).

12 “(b) CONTENTS OF RULES.—The regulations pro-  
13 mulgated under subsection (a)—

14 “(1) shall require testing and reporting of to-  
15 bacco product constituents, ingredients, and addi-  
16 tives, including smoke constituents, by brand and  
17 subbrand that the Secretary determines should be  
18 tested to protect the public health, provided that, for  
19 purposes of the testing requirements of this para-  
20 graph, tobacco products manufactured and sold by a  
21 single tobacco product manufacturer that are iden-  
22 tical in all respects except the labels, packaging de-  
23 sign, logo, trade dress, trademark, brand name, or  
24 any combination thereof, shall be considered as a  
25 single brand; and

1           “(2) may require that tobacco product manu-  
2           facturers, packagers, or importers make disclosures  
3           relating to the results of the testing of tar and nico-  
4           tine through labels or advertising or other appro-  
5           priate means, and make disclosures regarding the  
6           results of the testing of other constituents, including  
7           smoke constituents, ingredients, or additives, that  
8           the Secretary determines should be disclosed to the  
9           public to protect the public health and will not mis-  
10          lead consumers about the risk of tobacco-related dis-  
11          ease.

12          “(c) **AUTHORITY.**—The Secretary shall have the au-  
13          thority under this chapter to conduct or to require the  
14          testing, reporting, or disclosure of tobacco product con-  
15          stituents, including smoke constituents.

16          “(d) **SMALL TOBACCO PRODUCT MANUFACTUR-**  
17          **ERS.**—

18                 “(1) **FIRST COMPLIANCE DATE.**—The initial  
19                 regulations promulgated under subsection (a) shall  
20                 not impose requirements on small tobacco product  
21                 manufacturers before the later of—

22                         “(A) the end of the 2-year period following  
23                         the final promulgation of such regulations; and

24                         “(B) the initial date set by the Secretary  
25                         for compliance with such regulations by manu-



1           facturers that are not small tobacco product  
2           manufacturers.

3           “(2) TESTING AND REPORTING INITIAL COM-  
4           PLIANCE PERIOD.—

5                   “(A) 4-YEAR PERIOD.—The initial regula-  
6           tions promulgated under subsection (a) shall  
7           give each small tobacco product manufacturer a  
8           4-year period over which to conduct testing and  
9           reporting for all of its tobacco products. Subject  
10          to paragraph (1), the end of the first year of  
11          such 4-year period shall coincide with the initial  
12          date of compliance under this section set by the  
13          Secretary with respect to manufacturers that  
14          are not small tobacco product manufacturers or  
15          the end of the 2-year period following the final  
16          promulgation of such regulations, as described  
17          in paragraph (1)(A). A small tobacco product  
18          manufacturer shall be required—

19                   “(i) to conduct such testing and re-  
20                  porting for 25 percent of its tobacco prod-  
21                  ucts during each year of such 4-year pe-  
22                  riod; and

23                   “(ii) to conduct such testing and re-  
24                  porting for its largest-selling tobacco prod-  
25                  ucts (as determined by the Secretary) be-

1           fore its other tobacco products, or in such  
2           other order of priority as determined by  
3           the Secretary.

4           “(B) CASE-BY-CASE DELAY.—Notwith-  
5           standing subparagraph (A), the Secretary may,  
6           on a case-by-case basis, delay the date by which  
7           an individual small tobacco product manufac-  
8           turer must conduct testing and reporting for its  
9           tobacco products under this section based upon  
10          a showing of undue hardship to such manufac-  
11          turer. Notwithstanding the preceding sentence,  
12          the Secretary shall not extend the deadline for  
13          a small tobacco product manufacturer to con-  
14          duct testing and reporting for all of its tobacco  
15          products beyond a total of 5 years after the ini-  
16          tial date of compliance under this section set by  
17          the Secretary with respect to manufacturers  
18          that are not small tobacco product manufactur-  
19          ers.

20          “(3) SUBSEQUENT AND ADDITIONAL TESTING  
21          AND REPORTING.—The regulations promulgated  
22          under subsection (a) shall provide that, with respect  
23          to any subsequent or additional testing and report-  
24          ing of tobacco products required under this section,  
25          such testing and reporting by a small tobacco prod-

1       uct manufacturer shall be conducted in accordance  
2       with the timeframes described in paragraph (2)(A),  
3       except that, in the case of a new product, or if there  
4       has been a modification described in section  
5       910(a)(1)(B) of any product of a small tobacco  
6       product manufacturer since the last testing and re-  
7       porting required under this section, the Secretary  
8       shall require that any subsequent or additional test-  
9       ing and reporting be conducted in accordance with  
10      the same timeframe applicable to manufacturers  
11      that are not small tobacco product manufacturers.

12           “(4) JOINT LABORATORY TESTING SERVICES.—  
13      The Secretary shall allow any 2 or more small to-  
14      bacco product manufacturers to join together to pur-  
15      chase laboratory testing services required by this  
16      section on a group basis in order to ensure that such  
17      manufacturers receive access to, and fair pricing of,  
18      such testing services.

19           “(e) EXTENSIONS FOR LIMITED LABORATORY CA-  
20      PACITY.—

21           “(1) IN GENERAL.—The regulations promul-  
22      gated under subsection (a) shall provide that a small  
23      tobacco product manufacturer shall not be consid-  
24      ered to be in violation of this section before the

1 deadline applicable under paragraphs (3) and (4),  
2 if—

3 “(A) the tobacco products of such manu-  
4 facturer are in compliance with all other re-  
5 quirements of this chapter; and

6 “(B) the conditions described in paragraph  
7 (2) are met.

8 “(2) CONDITIONS.—Notwithstanding the re-  
9 quirements of this section, the Secretary may delay  
10 the date by which a small tobacco product manufac-  
11 turer must be in compliance with the testing and re-  
12 porting required by this section until such time as  
13 the testing is reported if, not later than 90 days be-  
14 fore the deadline for reporting in accordance with  
15 this section, a small tobacco product manufacturer  
16 provides evidence to the Secretary demonstrating  
17 that—

18 “(A) the manufacturer has submitted the  
19 required products for testing to a laboratory  
20 and has done so sufficiently in advance of the  
21 deadline to create a reasonable expectation of  
22 completion by the deadline;

23 “(B) the products currently are awaiting  
24 testing by the laboratory; and

1           “(C) neither that laboratory nor any other  
2           laboratory is able to complete testing by the  
3           deadline at customary, nonexpedited testing  
4           fees.

5           “(3) EXTENSION.—The Secretary, taking into  
6           account the laboratory testing capacity that is avail-  
7           able to tobacco product manufacturers, shall review  
8           and verify the evidence submitted by a small tobacco  
9           product manufacturer in accordance with paragraph  
10          (2). If the Secretary finds that the conditions de-  
11          scribed in such paragraph are met, the Secretary  
12          shall notify the small tobacco product manufacturer  
13          that the manufacturer shall not be considered to be  
14          in violation of the testing and reporting require-  
15          ments of this section until the testing is reported or  
16          until 1 year after the reporting deadline has passed,  
17          whichever occurs sooner. If, however, the Secretary  
18          has not made a finding before the reporting dead-  
19          line, the manufacturer shall not be considered to be  
20          in violation of such requirements until the Secretary  
21          finds that the conditions described in paragraph (2)  
22          have not been met, or until 1 year after the report-  
23          ing deadline, whichever occurs sooner.

24          “(4) ADDITIONAL EXTENSION.—In addition to  
25          the time that may be provided under paragraph (3),

1 the Secretary may provide further extensions of  
2 time, in increments of no more than 1 year, for re-  
3 quired testing and reporting to occur if the Sec-  
4 retary determines, based on evidence properly and  
5 timely submitted by a small tobacco product manu-  
6 facturer in accordance with paragraph (2), that a  
7 lack of available laboratory capacity prevents the  
8 manufacturer from completing the required testing  
9 during the period described in paragraph (3).

10 “(f) **RULE OF CONSTRUCTION.**—Nothing in sub-  
11 section (d) or (e) shall be construed to authorize the exten-  
12 sion of any deadline, or to otherwise affect any timeframe,  
13 under any provision of this Act or the Family Smoking  
14 Prevention and Tobacco Control Act other than this sec-  
15 tion.

16 **“SEC. 916. PRESERVATION OF STATE AND LOCAL AUTHOR-**  
17 **ITY.**

18 “(a) **IN GENERAL.**—

19 “(1) **PRESERVATION.**—Except as provided in  
20 paragraph (2)(A), nothing in this chapter, or rules  
21 promulgated under this chapter, shall be construed  
22 to limit the authority of a Federal agency (including  
23 the Armed Forces), a State or political subdivision  
24 of a State, or the government of an Indian tribe to  
25 enact, adopt, promulgate, and enforce any law, rule,

1 regulation, or other measure with respect to tobacco  
2 products that is in addition to, or more stringent  
3 than, requirements established under this chapter,  
4 including a law, rule, regulation, or other measure  
5 relating to or prohibiting the sale, distribution, pos-  
6 session, exposure to, access to, advertising and pro-  
7 motion of, or use of tobacco products by individuals  
8 of any age, information reporting to the State, or  
9 measures relating to fire safety standards for to-  
10 bacco products. No provision of this chapter shall  
11 limit or otherwise affect any State, tribal, or local  
12 taxation of tobacco products.

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

15 “(A) IN GENERAL.—No State or political  
16 subdivision of a State may establish or continue  
17 in effect with respect to a tobacco product any  
18 requirement which is different from, or in addi-  
19 tion to, any requirement under the provisions of  
20 this chapter relating to tobacco product stand-  
21 ards, premarket review, adulteration, mis-  
22 branding, labeling, registration, good manufac-  
23 turing standards, or modified risk tobacco prod-  
24 ucts.

1           “(B) EXCEPTION.—Subparagraph (A)  
 2           does not apply to requirements relating to the  
 3           sale, distribution, possession, information re-  
 4           porting to the State, exposure to, access to, the  
 5           advertising and promotion of, or use of, tobacco  
 6           products by individuals of any age, or relating  
 7           to fire safety standards for tobacco products.  
 8           Information disclosed to a State under subpara-  
 9           graph (A) that is exempt from disclosure under  
 10          section 552(b)(4) of title 5, United States Code,  
 11          shall be treated as a trade secret and confiden-  
 12          tial information by the State.

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

18          **“SEC. 917. TOBACCO PRODUCTS SCIENTIFIC ADVISORY**  
 19   **COMMITTEE.**

20          “(a) ESTABLISHMENT.—Not later than 6 months  
 21          after the date of enactment of the Family Smoking Pre-  
 22          vention and Tobacco Control Act, the Secretary shall es-  
 23          tablish a 12-member advisory committee, to be known as  
 24          the Tobacco Products Scientific Advisory Committee (in  
 25          this section referred to as the ‘Advisory Committee’).



1 “(b) MEMBERSHIP.—

2 “(1) IN GENERAL.—

3 “(A) MEMBERS.—The Secretary shall ap-  
4 point as members of the Tobacco Products Sci-  
5 entific Advisory Committee individuals who are  
6 technically qualified by training and experience  
7 in medicine, medical ethics, science, or tech-  
8 nology involving the manufacture, evaluation, or  
9 use of tobacco products, who are of appro-  
10 priately diversified professional backgrounds.

11 The committee shall be composed of—

12 “(i) 7 individuals who are physicians,  
13 dentists, scientists, or health care profes-  
14 sionals practicing in the area of oncology,  
15 pulmonology, cardiology, toxicology, phar-  
16 macology, addiction, or any other relevant  
17 specialty;

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

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

23 “(iv) 1 individual as a representative  
24 of the interests of the tobacco manufac-  
25 turing industry;

1           “(v) 1 individual as a representative  
2           of the interests of the small business to-  
3           bacco manufacturing industry, which posi-  
4           tion may be filled on a rotating, sequential  
5           basis by representatives of different small  
6           business tobacco manufacturers based on  
7           areas of expertise relevant to the topics  
8           being considered by the Advisory Com-  
9           mittee; and

10           “(vi) 1 individual as a representative  
11           of the interests of the tobacco growers.

12           “(B) NONVOTING MEMBERS.—The mem-  
13           bers of the committee appointed under clauses  
14           (iv), (v), and (vi) of subparagraph (A) shall  
15           serve as consultants to those described in  
16           clauses (i) through (iii) of subparagraph (A)  
17           and shall be nonvoting representatives.

18           “(C) CONFLICTS OF INTEREST.—No mem-  
19           bers of the committee, other than members ap-  
20           pointed pursuant to clauses (iv), (v), and (vi) of  
21           subparagraph (A) shall, during the member’s  
22           tenure on the committee or for the 18-month  
23           period prior to becoming such a member, re-  
24           ceive any salary, grants, or other payments or  
25           support from any business that manufactures,

1 distributes, markets, or sells cigarettes or other  
2 tobacco products.

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

9 “(3) CHAIRPERSON.—The Secretary shall des-  
10 ignate 1 of the members appointed under clauses (i),  
11 (ii), and (iii) of paragraph (1)(A) to serve as chair-  
12 person.

13 “(c) DUTIES.—The Tobacco Products Scientific Ad-  
14 visory Committee shall provide advice, information, and  
15 recommendations to the Secretary—

16 “(1) as provided in this chapter;

17 “(2) on the effects of the alteration of the nico-  
18 tine yields from tobacco products;

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

22 “(4) on its review of other safety, dependence,  
23 or health issues relating to tobacco products as re-  
24 quested by the Secretary.

25 “(d) COMPENSATION; SUPPORT; FACA.—

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

17           “(2) ADMINISTRATIVE SUPPORT.—The Sec-  
18 retary shall furnish the Advisory Committee clerical  
19 and other assistance.

20           “(3) NONAPPLICATION OF FACA.—Section 14 of  
21 the Federal Advisory Committee Act does not apply  
22 to the Advisory Committee.

23           “(e) PROCEEDINGS OF ADVISORY PANELS AND COM-  
24 MITTEES.—The Advisory Committee shall make and  
25 maintain a transcript of any proceeding of the panel or

1 committee. Each such panel and committee shall delete  
2 from any transcript made under this subsection informa-  
3 tion which is exempt from disclosure under section 552(b)  
4 of title 5, United States Code.

5 **“SEC. 918. DRUG PRODUCTS USED TO TREAT TOBACCO DE-**  
6 **PENDENCE.**

7 “(a) IN GENERAL.—The Secretary shall—

8 “(1) at the request of the applicant, consider  
9 designating products for smoking cessation, includ-  
10 ing nicotine replacement products as fast track re-  
11 search and approval products within the meaning of  
12 section 506;

13 “(2) consider approving the extended use of nic-  
14 otine replacement products (such as nicotine patch-  
15 es, nicotine gum, and nicotine lozenges) for the  
16 treatment of tobacco dependence; and

17 “(3) review and consider the evidence for addi-  
18 tional indications for nicotine replacement products,  
19 such as for craving relief or relapse prevention.

20 “(b) REPORT ON INNOVATIVE PRODUCTS.—

21 “(1) IN GENERAL.—Not later than 3 years  
22 after the date of enactment of the Family Smoking  
23 Prevention and Tobacco Control Act, the Secretary,  
24 after consultation with recognized scientific, medical,  
25 and public health experts (including both Federal

1 agencies and nongovernmental entities, the Institute  
2 of Medicine of the National Academy of Sciences,  
3 and the Society for Research on Nicotine and To-  
4 bacco), shall submit to the Congress a report that  
5 examines how best to regulate, promote, and encour-  
6 age the development of innovative products and  
7 treatments (including nicotine-based and non-nico-  
8 tine-based products and treatments) to better  
9 achieve, in a manner that best protects and pro-  
10 motes the public health—

11 “(A) total abstinence from tobacco use;

12 “(B) reductions in consumption of tobacco;

13 and

14 “(C) reductions in the harm associated  
15 with continued tobacco use.

16 “(2) RECOMMENDATIONS.—The report under  
17 paragraph (1) shall include the recommendations of  
18 the Secretary on how the Food and Drug Adminis-  
19 tration should coordinate and facilitate the exchange  
20 of information on such innovative products and  
21 treatments among relevant offices and centers within  
22 the Administration and within the National Insti-  
23 tutes of Health, the Centers for Disease Control and  
24 Prevention, and other relevant agencies.

1 **“SEC. 919. USER FEES.**

2       “(a) ESTABLISHMENT OF QUARTERLY FEE.—Begin-  
3 ning on the date of enactment of the Family Smoking Pre-  
4 vention and Tobacco Control Act, the Secretary shall in  
5 accordance with this section assess user fees on, and col-  
6 lect such fees from, each manufacturer and importer of  
7 tobacco products subject to this chapter. The fees shall  
8 be assessed and collected with respect to each quarter of  
9 each fiscal year, and the total amount assessed and col-  
10 lected for a fiscal year shall be the amount specified in  
11 subsection (b)(1) for such year, subject to subsection (c).

12       “(b) ASSESSMENT OF USER FEE.—

13               “(1) AMOUNT OF ASSESSMENT.—The total  
14 amount of user fees authorized to be assessed and  
15 collected under subsection (a) for a fiscal year is the  
16 following, as applicable to the fiscal year involved:

17                       “(A) For fiscal year 2009, \$85,000,000  
18                       (subject to subsection (e)).

19                       “(B) For fiscal year 2010, \$235,000,000.

20                       “(C) For fiscal year 2011, \$450,000,000.

21                       “(D) For fiscal year 2012, \$477,000,000.

22                       “(E) For fiscal year 2013, \$505,000,000.

23                       “(F) For fiscal year 2014, \$534,000,000.

24                       “(G) For fiscal year 2015, \$566,000,000.

25                       “(H) For fiscal year 2016, \$599,000,000.

26                       “(I) For fiscal year 2017, \$635,000,000.

1           “(J) For fiscal year 2018, \$672,000,000.

2           “(K) For fiscal year 2019 and each subse-  
3           quent fiscal year, \$712,000,000.

4           “(2) ALLOCATIONS OF ASSESSMENT BY CLASS  
5           OF TOBACCO PRODUCTS.—

6           “(A) IN GENERAL.—The total user fees as-  
7           sessed and collected under subsection (a) each  
8           fiscal year with respect to each class of tobacco  
9           products shall be an amount that is equal to  
10          the applicable percentage of each class for the  
11          fiscal year multiplied by the amount specified in  
12          paragraph (1) for the fiscal year.

13          “(B) APPLICABLE PERCENTAGE.—

14                 “(i) IN GENERAL.—For purposes of  
15                 subparagraph (A), the applicable percent-  
16                 age for a fiscal year for each of the fol-  
17                 lowing classes of tobacco products shall be  
18                 determined in accordance with clause (ii):

19                         “(I) Cigarettes.

20                         “(II) Cigars, including small ci-  
21                         gars and cigars other than small ci-  
22                         gars.

23                         “(III) Snuff.

24                         “(IV) Chewing tobacco.

25                         “(V) Pipe tobacco.



1 “(VI) Roll-your-own tobacco.

2 “(ii) ALLOCATIONS.—The applicable  
3 percentage of each class of tobacco product  
4 described in clause (i) for a fiscal year  
5 shall be the percentage determined under  
6 section 625(c) of Public Law 108–357 for  
7 each such class of product for such fiscal  
8 year.

9 “(iii) REQUIREMENT OF REGULA-  
10 TIONS.—Notwithstanding clause (ii), no  
11 user fees shall be assessed on a class of to-  
12 bacco products unless such class of tobacco  
13 products is listed in section 901(b) or is  
14 deemed by the Secretary in a regulation  
15 under section 901(b) to be subject to this  
16 chapter.

17 “(iv) REALLOCATIONS.—In the case  
18 of a class of tobacco products that is not  
19 listed in section 901(b) or deemed by the  
20 Secretary in a regulation under section  
21 901(b) to be subject to this chapter, the  
22 amount of user fees that would otherwise  
23 be assessed to such class of tobacco prod-  
24 ucts shall be reallocated to the classes of  
25 tobacco products that are subject to this

1 chapter in the same manner and based on  
2 the same relative percentages otherwise de-  
3 termined under clause (ii).

4 “(3) DETERMINATION OF USER FEE BY COM-  
5 PANY.—

6 “(A) IN GENERAL.—The total user fee to  
7 be paid by each manufacturer or importer of a  
8 particular class of tobacco products shall be de-  
9 termined for each quarter by multiplying—

10 “(i) such manufacturer’s or importer’s  
11 percentage share as determined under  
12 paragraph (4); by

13 “(ii) the portion of the user fee  
14 amount for the current quarter to be as-  
15 sessed on all manufacturers and importers  
16 of such class of tobacco products as deter-  
17 mined under paragraph (2).

18 “(B) NO FEE IN EXCESS OF PERCENTAGE  
19 SHARE.—No manufacturer or importer of to-  
20 bacco products shall be required to pay a user  
21 fee in excess of the percentage share of such  
22 manufacturer or importer.

23 “(4) ALLOCATION OF ASSESSMENT WITHIN  
24 EACH CLASS OF TOBACCO PRODUCT.—The percent-  
25 age share of each manufacturer or importer of a

1 particular class of tobacco products of the total user  
2 fee to be paid by all manufacturers or importers of  
3 that class of tobacco products shall be the percent-  
4 age determined for purposes of allocations under  
5 subsections (e) through (h) of section 625 of Public  
6 Law 108–357.

7 “(5) ALLOCATION FOR CIGARS.—Notwith-  
8 standing paragraph (4), if a user fee assessment is  
9 imposed on cigars, the percentage share of each  
10 manufacturer or importer of cigars shall be based on  
11 the excise taxes paid by such manufacturer or im-  
12 porter during the prior fiscal year.

13 “(6) TIMING OF ASSESSMENT.—The Secretary  
14 shall notify each manufacturer and importer of to-  
15 bacco products subject to this section of the amount  
16 of the quarterly assessment imposed on such manu-  
17 facturer or importer under this subsection for each  
18 quarter of each fiscal year. Such notifications shall  
19 occur not later than 30 days prior to the end of the  
20 quarter for which such assessment is made, and pay-  
21 ments of all assessments shall be made by the last  
22 day of the quarter involved.

23 “(7) MEMORANDUM OF UNDERSTANDING.—

24 “(A) IN GENERAL.—The Secretary shall  
25 request the appropriate Federal agency to enter

1 into a memorandum of understanding that pro-  
2 vides for the regular and timely transfer from  
3 the head of such agency to the Secretary of the  
4 information described in paragraphs (2)(B)(ii)  
5 and (4) and all necessary information regarding  
6 all tobacco product manufacturers and import-  
7 ers required to pay user fees. The Secretary  
8 shall maintain all disclosure restrictions estab-  
9 lished by the head of such agency regarding the  
10 information provided under the memorandum of  
11 understanding.

12 “(B) ASSURANCES.—Beginning not later  
13 than fiscal year 2015, and for each subsequent  
14 fiscal year, the Secretary shall ensure that the  
15 Food and Drug Administration is able to deter-  
16 mine the applicable percentages described in  
17 paragraph (2) and the percentage shares de-  
18 scribed in paragraph (4). The Secretary may  
19 carry out this subparagraph by entering into a  
20 contract with the head of the Federal agency  
21 referred to in subparagraph (A) to continue to  
22 provide the necessary information.

23 “(c) CREDITING AND AVAILABILITY OF FEES.—

24 “(1) IN GENERAL.—Fees authorized under sub-  
25 section (a) shall be collected and available for obliga-

1 tion only to the extent and in the amount provided  
2 in advance in appropriations Acts. Such fees are au-  
3 thorized to remain available until expended. Such  
4 sums as may be necessary may be transferred from  
5 the Food and Drug Administration salaries and ex-  
6 penses appropriation account without fiscal year lim-  
7 itation to such appropriation account for salaries  
8 and expenses with such fiscal year limitation.

9 “(2) AVAILABILITY.—

10 “(A) IN GENERAL.—Fees appropriated  
11 under paragraph (3) are available only for the  
12 purpose of paying the costs of the activities of  
13 the Food and Drug Administration related to  
14 the regulation of tobacco products under this  
15 chapter and the Family Smoking Prevention  
16 and Tobacco Control Act. No fees collected  
17 under subsection (a) may be used for any other  
18 costs.

19 “(B) PROHIBITION AGAINST USE OF  
20 OTHER FUNDS.—

21 “(i) IN GENERAL.—Except as pro-  
22 vided in clause (ii), fees collected under  
23 subsection (a) are the only funds author-  
24 ized to be made available for the purpose  
25 described in subparagraph (A).

1           “(ii) STARTUP COSTS.—Clause (i)  
2           does not apply until the date on which the  
3           Secretary has collected fees under sub-  
4           section (a) for 2 fiscal year quarters. Any  
5           amounts provided to pay the costs de-  
6           scribed in subparagraph (A) prior to the  
7           date described in the previous sentence  
8           shall be reimbursed through fees collected  
9           under subsection (a).

10           “(3) AUTHORIZATION OF APPROPRIATIONS.—  
11           For fiscal year 2009 and each subsequent fiscal  
12           year, there is authorized to be appropriated for fees  
13           under this section an amount equal to the amount  
14           specified in subsection (b)(1) for the fiscal year.

15           “(d) COLLECTION OF UNPAID FEES.—In any case  
16           where the Secretary does not receive payment of a fee as-  
17           sessed under subsection (a) within 30 days after it is due,  
18           such fee shall be treated as a claim of the United States  
19           Government subject to subchapter II of chapter 37 of title  
20           31, United States Code.

21           “(e) APPLICABILITY TO FISCAL YEAR 2009.—If the  
22           date of enactment of the Family Smoking Prevention and  
23           Tobacco Control Act occurs during fiscal year 2009, the  
24           following applies, subject to subsection (c):

1           “(1) The Secretary shall determine the fees  
2 that would apply for a single quarter of such fiscal  
3 year according to the application of subsection (b) to  
4 the amount specified in paragraph (1)(A) of such  
5 subsection (referred to in this subsection as the  
6 ‘quarterly fee amounts’).

7           “(2) For the quarter in which such date of en-  
8 actment occurs, the amount of fees assessed shall be  
9 a pro rata amount, determined according to the  
10 number of days remaining in the quarter (including  
11 such date of enactment) and according to the daily  
12 equivalent of the quarterly fee amounts. Fees as-  
13 sessed under the preceding sentence shall not be col-  
14 lected until the next quarter.

15           “(3) For the quarter following the quarter to  
16 which paragraph (2) applies, the full quarterly fee  
17 amounts shall be assessed and collected, in addition  
18 to collection of the pro rata fees assessed under  
19 paragraph (2).”.

20           (c) CONFORMING AMENDMENT.—Section 9(1) of the  
21 Comprehensive Smokeless Tobacco Health Education Act  
22 of 1986 (15 U.S.C. 4408(i)) is amended to read as follows:

23           “(1) The term ‘smokeless tobacco’ has the  
24 meaning given such term by section 900(18) of the  
25 Federal Food, Drug, and Cosmetic Act.”.

1 **SEC. 102. FINAL RULE.**

2 (a) CIGARETTES AND SMOKELESS TOBACCO.—

3 (1) IN GENERAL.—On the first day of publica-  
4 tion of the Federal Register that is 180 days or  
5 more after the date of enactment of this Act, the  
6 Secretary of Health and Human Services shall pub-  
7 lish in the Federal Register a final rule regarding  
8 cigarettes and smokeless tobacco, which—

9 (A) is deemed to be issued under chapter  
10 9 of the Federal Food, Drug, and Cosmetic  
11 Act, as added by section 101 of this Act; and

12 (B) shall be deemed to be in compliance  
13 with all applicable provisions of chapter 5 of  
14 title 5, United States Code, and all other provi-  
15 sions of law relating to rulemaking procedures.

16 (2) CONTENTS OF RULE.—Except as provided  
17 in this subsection, the final rule published under  
18 paragraph (1), shall be identical in its provisions to  
19 part 897 of the regulations promulgated by the Sec-  
20 retary of Health and Human Services in the August  
21 28, 1996, issue of the Federal Register (61 Fed.  
22 Reg. 44615–44618). Such rule shall—

23 (A) provide for the designation of jurisdic-  
24 tional authority that is in accordance with this  
25 subsection in accordance with this Act and the  
26 amendments made by this Act;



1 (B) strike Subpart C—Labels and section  
2 897.32(c);

3 (C) strike paragraphs (a), (b), and (i) of  
4 section 897.3 and insert definitions of the terms  
5 “cigarette”, “cigarette tobacco”, and “smoke-  
6 less tobacco” as defined in section 900 of the  
7 Federal Food, Drug, and Cosmetic Act;

8 (D) insert “or roll-your-own paper” in sec-  
9 tion 897.34(a) after “other than cigarettes or  
10 smokeless tobacco”;

11 (E) include such modifications to section  
12 897.30(b), if any, that the Secretary determines  
13 are appropriate in light of governing First  
14 Amendment case law, including the decision of  
15 the Supreme Court of the United States in  
16 *Lorillard Tobacco Co. v. Reilly* (533 U.S. 525  
17 (2201));

18 (F) become effective on the date that is 1  
19 year after the date of enactment of this Act;  
20 and

21 (G) amend paragraph (d) of section 897.16  
22 to read as follows:

23 “(d)(1) Except as provided in subparagraph (2), no  
24 manufacturer, distributor, or retailer may distribute or  
25 cause to be distributed any free samples of cigarettes,

1 smokeless tobacco, or other tobacco products (as such  
2 term is defined in section 201 of the Federal Food, Drug,  
3 and Cosmetic Act).

4 “(2)(A) Subparagraph (1) does not prohibit a manu-  
5 facturer, distributor, or retailer from distributing or caus-  
6 ing to be distributed free samples of smokeless tobacco  
7 in a qualified adult-only facility.

8 “(B) This subparagraph does not affect the authority  
9 of a State or local government to prohibit or otherwise  
10 restrict the distribution of free samples of smokeless to-  
11 bacco.

12 “(C) For purposes of this paragraph, the term ‘quali-  
13 fied adult-only facility’ means a facility or restricted area  
14 that—

15 “(i) requires each person present to provide to  
16 a law enforcement officer (whether on or off duty)  
17 or to a security guard licensed by a governmental  
18 entity government-issued identification showing a  
19 photograph and at least the minimum age estab-  
20 lished by applicable law for the purchase of smoke-  
21 less tobacco;

22 “(ii) does not sell, serve, or distribute alcohol;

23 “(iii) is not located adjacent to or immediately  
24 across from (in any direction) a space that is used

1 primarily for youth-oriented marketing, promotional,  
2 or other activities;

3 “(iv) is a temporary structure constructed, des-  
4 ignated, and operated as a distinct enclosed area for  
5 the purpose of distributing free samples of smokeless  
6 tobacco in accordance with this subparagraph;

7 “(v) is enclosed by a barrier that—

8 “(I) is constructed of, or covered with, an  
9 opaque material (except for entrances and  
10 exits);

11 “(II) extends from no more than 12 inches  
12 above the ground or floor (which area at the  
13 bottom of the barrier must be covered with ma-  
14 terial that restricts visibility but may allow air-  
15 flow) to at least 8 feet above the ground or  
16 floor (or to the ceiling); and

17 “(III) prevents persons outside the quali-  
18 fied adult-only facility from seeing into the  
19 qualified adult-only facility, unless they make  
20 unreasonable efforts to do so; and

21 “(vi) does not display on its exterior—

22 “(I) any tobacco product advertising;

23 “(II) a brand name other than in conjunc-  
24 tion with words for an area or enclosure to  
25 identify an adult-only facility; or

1           “(III) any combination of words that  
2           would imply to a reasonable observer that the  
3           manufacturer, distributor, or retailer has a  
4           sponsorship that would violate section  
5           897.34(c).

6           “(D) Distribution of samples of smokeless tobacco  
7           under this subparagraph permitted to be taken out of the  
8           qualified adult-only facility shall be limited to 1 package  
9           per adult consumer containing no more than 0.53 ounces  
10          (15 grams) of smokeless tobacco. If such package of  
11          smokeless tobacco contains individual portions of smoke-  
12          less tobacco, the individual portions of smokeless tobacco  
13          shall not exceed 8 individual portions and the collective  
14          weight of such individual portions shall not exceed 0.53  
15          ounces (15 grams). Any manufacturer, distributor, or re-  
16          tailer who distributes or causes to be distributed free sam-  
17          ples also shall take reasonable steps to ensure that the  
18          above amounts are limited to one such package per adult  
19          consumer per day.

20          “(3) Notwithstanding subparagraph (2), no manufac-  
21          turer, distributor, or retailer may distribute or cause to  
22          be distributed any free samples of smokeless tobacco—

23                 “(A) to a sports team or entertainment group;  
24                 or

1           “(B) at any football, basketball, baseball, soc-  
2           cer, or hockey event or any other sporting or enter-  
3           tainment event determined by the Secretary to be  
4           covered by this subparagraph.

5           “(4) The Secretary shall implement a program to en-  
6           sure compliance with this paragraph and submit a report  
7           to the Congress on such compliance not later than 18  
8           months after the date of enactment of the Family Smok-  
9           ing Prevention and Tobacco Control Act.

10          “(5) Nothing in this paragraph shall be construed to  
11          authorize any person to distribute or cause to be distrib-  
12          uted any sample of a tobacco product to any individual  
13          who has not attained the minimum age established by ap-  
14          plicable law for the purchase of such product.”.

15                 (3) AMENDMENTS TO RULE.—Prior to making  
16          amendments to the rule published under paragraph  
17          (1), the Secretary shall promulgate a proposed rule  
18          in accordance with chapter 5 of title 5, United  
19          States Code.

20                 (4) RULE OF CONSTRUCTION.—Except as pro-  
21          vided in paragraph (3), nothing in this section shall  
22          be construed to limit the authority of the Secretary  
23          to amend, in accordance with chapter 5 of title 5,  
24          United States Code, the regulation promulgated pur-  
25          suant to this section, including the provisions of

1 such regulation relating to distribution of free sam-  
2 ples.

3 (5) ENFORCEMENT OF RETAIL SALE PROVI-  
4 SIONS.—The Secretary of Health and Human Serv-  
5 ices shall ensure that the provisions of this Act, the  
6 amendments made by this Act, and the imple-  
7 menting regulations (including such provisions,  
8 amendments, and regulations relating to the retail  
9 sale of tobacco products) are enforced with respect  
10 to the United States and Indian tribes.

11 (6) QUALIFIED ADULT-ONLY FACILITY.—A  
12 qualified adult-only facility (as such term is defined  
13 in section 897.16(d) of the final rule published  
14 under paragraph (1)) that is also a retailer and that  
15 commits a violation as a retailer shall not be subject  
16 to the limitations in section 103(q) and shall be sub-  
17 ject to penalties applicable to a qualified adult-only  
18 facility.

19 (7) CONGRESSIONAL REVIEW PROVISIONS.—  
20 Section 801 of title 5, United States Code, shall not  
21 apply to the final rule published under paragraph  
22 (1).

23 (b) LIMITATION ON ADVISORY OPINIONS.—As of the  
24 date of enactment of this Act, the following documents  
25 issued by the Food and Drug Administration shall not

1 constitute advisory opinions under section 10.85(d)(1) of  
2 title 21, Code of Federal Regulations, except as they apply  
3 to tobacco products, and shall not be cited by the Sec-  
4 retary of Health and Human Services or the Food and  
5 Drug Administration as binding precedent:

6 (1) The preamble to the proposed rule in the  
7 document titled “Regulations Restricting the Sale  
8 and Distribution of Cigarettes and Smokeless To-  
9 bacco Products to Protect Children and Adoles-  
10 cents” (60 Fed. Reg. 41314–41372 (August 11,  
11 1995)).

12 (2) The document titled “Nicotine in Cigarettes  
13 and Smokeless Tobacco Products is a Drug and  
14 These Products Are Nicotine Delivery Devices  
15 Under the Federal Food, Drug, and Cosmetic Act”  
16 (60 Fed. Reg. 41453–41787 (August 11, 1995)).

17 (3) The preamble to the final rule in the docu-  
18 ment titled “Regulations Restricting the Sale and  
19 Distribution of Cigarettes and Smokeless Tobacco to  
20 Protect Children and Adolescents” (61 Fed. Reg.  
21 44396–44615 (August 28, 1996)).

22 (4) The document titled “Nicotine in Cigarettes  
23 and Smokeless Tobacco is a Drug and These Prod-  
24 ucts are Nicotine Delivery Devices Under the Fed-  
25 eral Food, Drug, and Cosmetic Act; Jurisdictional

1 Determination” (61 Fed. Reg. 44619–45318 (Au-  
2 gust 28, 1996)).

3 **SEC. 103. CONFORMING AND OTHER AMENDMENTS TO GEN-  
4 ERAL PROVISIONS.**

5 (a) AMENDMENT OF FEDERAL FOOD, DRUG, AND  
6 COSMETIC ACT.—Except as otherwise expressly provided,  
7 whenever in this section an amendment is expressed in  
8 terms of an amendment to, or repeal of, a section or other  
9 provision, the reference is to a section or other provision  
10 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
11 301 et seq.).

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

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

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

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

20 (4) in subsection (e)—

21 (A) by striking the period after “572(i)”;

22 and

23 (B) by striking “or 761 or the refusal to  
24 permit access to” and inserting “761, 909, or  
25 920 or the refusal to permit access to”;



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

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

5           (7) in subsection (j)—

6                 (A) by striking the period after “573”; and

7                 (B) by striking “708, or 721” and insert-  
8 ing “708, 721, 904, 905, 906, 907, 908, 909,  
9 or 920(b)”;

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

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

14          “(p) The failure to register in accordance with section  
15 510 or 905, the failure to provide any information re-  
16 quired by section 510(j), 510(k), 905(i), or 905(j), or the  
17 failure to provide a notice required by section 510(j)(2)  
18 or 905(i)(3).”;

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

21          “(q)(1) The failure or refusal—

22                 “(A) to comply with any requirement prescribed  
23 under section 518, 520(g), 903(b), 907, 908, or 916;

1           “(B) to furnish any notification or other mate-  
2           rial or information required by or under section 519,  
3           520(g), 904, 909, or 920; or

4           “(C) to comply with a requirement under sec-  
5           tion 522 or 913.”;

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

8           (12) in subsection (r), by inserting “or tobacco  
9           product” after the term “device” each time that  
10          such term appears; and

11          (13) by adding at the end the following:

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

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

17          “(qq)(1) Forging, counterfeiting, simulating, or false-  
18          ly representing, or without proper authority using any  
19          mark, stamp (including tax stamp), tag, label, or other  
20          identification device upon any tobacco product or con-  
21          tainer or labeling thereof so as to render such tobacco  
22          product a counterfeit tobacco product.

23          “(2) Making, selling, disposing of, or keeping in pos-  
24          session, control, or custody, or concealing any punch, die,  
25          plate, stone, or other item that is designed to print, im-

1 print, or reproduce the trademark, trade name, or other  
2 identifying mark, imprint, or device of another or any like-  
3 ness of any of the foregoing upon any tobacco product or  
4 container or labeling thereof so as to render such tobacco  
5 product a counterfeit tobacco product.

6 “(3) The doing of any act that causes a tobacco prod-  
7 uct to be a counterfeit tobacco product, or the sale or dis-  
8 pensing, or the holding for sale or dispensing, of a coun-  
9 terfeit tobacco product.

10 “(rr) The charitable distribution of tobacco products.

11 “(ss) The failure of a manufacturer or distributor to  
12 notify the Attorney General and the Secretary of the  
13 Treasury of their knowledge of tobacco products used in  
14 illicit trade.

15 “(tt) With respect to a tobacco product, any state-  
16 ment or representation, express or implied, directed to  
17 consumers through the media or through the label, label-  
18 ing, or advertising that is false or would reasonably be  
19 expected to mislead consumers into believing that the  
20 product is approved by the Food and Drug Administra-  
21 tion, or that the Food and Drug Administration deems  
22 the product to be safe for use by consumers, or that the  
23 product is endorsed by the Food and Drug Administration  
24 for use by consumers, or that is false or would reasonably  
25 be expected to mislead consumers regarding the harmful-

1 ness of the product because of the Food and Drug Admin-  
2 istration’s regulation or inspection of it or because of its  
3 compliance with regulatory requirements set by the Food  
4 and Drug Administration.”.

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

7 (1) in paragraph (1)(A), by inserting “or to-  
8 bacco products” after the term “devices” each place  
9 such term appears;

10 (2) in paragraph (5)—

11 (A) in subparagraph (A)—

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

16 (ii) by striking “penalty” the second  
17 time it appears and inserting “penalty, or  
18 upon whom a no-tobacco-sale order is to be  
19 imposed,”;

20 (B) in subparagraph (B)—

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

24 (ii) by adding at the end the fol-  
25 lowing: “A no-tobacco-sale order perma-

1           nently prohibiting an individual retail out-  
2           let from selling tobacco products shall in-  
3           clude provisions that allow the outlet, after  
4           a specified period of time, to request that  
5           the Secretary compromise, modify, or ter-  
6           minate the order.”; and

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

8           “(D) The Secretary may compromise, modify, or ter-  
9           minate, with or without conditions, any no-tobacco-sale  
10          order.”;

11          (3) in paragraph (6)—

12           (A) by inserting “or the imposition of a  
13           no-tobacco-sale order” after the term “penalty”  
14           each place such term appears; and

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

18          (4) by adding at the end the following:

19          “(8) If the Secretary finds that a person has com-  
20          mitted repeated violations of restrictions promulgated  
21          under section 906(d) at a particular retail outlet then the  
22          Secretary may impose a no-tobacco-sale order on that per-  
23          son prohibiting the sale of tobacco products in that outlet.  
24          A no-tobacco-sale order may be imposed with a civil pen-  
25          alty under paragraph (1). Prior to the entry of a no-sale

1 order under this paragraph, a person shall be entitled to  
2 a hearing pursuant to the procedures established through  
3 regulations of the Food and Drug Administration for as-  
4 sessing civil money penalties, including at a retailer's re-  
5 quest a hearing by telephone, or at the nearest regional  
6 or field office of the Food and Drug Administration, or  
7 at a Federal, State, or county facility within 100 miles  
8 from the location of the retail outlet, if such a facility is  
9 available.”.

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

12 (1) in subsection (a)(2)—

13 (A) by striking “and” before “(D)”; and

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

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

19 (3) in subsection (g)(1), by inserting “or to-  
20 bacco product” after the term “device” each place  
21 such term appears; and

22 (4) in subsection (g)(2)(A), by inserting “or to-  
23 bacco product” after “device”.

1 (e) SECTION 505.—Section 505(n)(2) (21 U.S.C.  
2 355(n)(2)) is amended by striking “section 904” and in-  
3 serting “section 1004”.

4 (f) SECTION 523.—Section 523(b)(2)(D) (21 U.S.C.  
5 360m(b)(2)(D)) is amended by striking “section 903(g)”  
6 and inserting “section 1003(g)”.

7 (g) SECTION 702.—Section 702(a)(1) (U.S.C.  
8 372(a)(1)) is amended—

9 (1) by striking “(a)(1)” and inserting  
10 “(a)(1)(A)”; and

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

12 “(B)(i) For a tobacco product, to the extent feasible,  
13 the Secretary shall contract with the States in accordance  
14 with this paragraph to carry out inspections of retailers  
15 within that State in connection with the enforcement of  
16 this Act.

17 “(ii) The Secretary shall not enter into any contract  
18 under clause (i) with the government of any of the several  
19 States to exercise enforcement authority under this Act  
20 on Indian country without the express written consent of  
21 the Indian tribe involved.”.

22 (h) SECTION 703.—Section 703 (21 U.S.C. 373) is  
23 amended—

24 (1) by inserting “tobacco product,” after the  
25 term “device,” each place such term appears; and

1           (2) by inserting “tobacco products,” after the  
2 term “devices,” each place such term appears.

3           (i) SECTION 704.—Section 704 (21 U.S.C. 374) is  
4 amended—

5           (1) in subsection (a)(1)—

6               (A) by striking “devices, or cosmetics”  
7 each place it appears and inserting “devices, to-  
8 bacco products, or cosmetics”;

9               (B) by striking “or restricted devices” each  
10 place it appears and inserting “restricted de-  
11 vices, or tobacco products”; and

12               (C) by striking “and devices and subject  
13 to” and all that follows through “other drugs or  
14 devices” and inserting “devices, and tobacco  
15 products and subject to reporting and inspec-  
16 tion under regulations lawfully issued pursuant  
17 to section 505 (i) or (k), section 519, section  
18 520(g), or chapter IX and data relating to  
19 other drugs, devices, or tobacco products”;

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

22           (3) in subsection (g)(13), by striking “section  
23 903(g)” and inserting “section 1003(g)”.



1 (j) SECTION 705.—Section 705(b) (21 U.S.C.  
2 375(b)) is amended by inserting “tobacco products,” after  
3 “devices,”.

4 (k) SECTION 709.—Section 709 (21 U.S.C. 379a) is  
5 amended by inserting “tobacco product,” after “device,”.

6 (l) SECTION 801.—Section 801 (21 U.S.C. 381) is  
7 amended—

8 (1) in subsection (a)—

9 (A) by inserting “tobacco products,” after  
10 the term “devices,”;

11 (B) by inserting “or section 905(h)” after  
12 “section 510”; and

13 (C) by striking the term “drugs or de-  
14 vices” each time such term appears and insert-  
15 ing “drugs, devices, or tobacco products”;

16 (2) in subsection (e)(1)—

17 (A) by inserting “tobacco product” after  
18 “drug, device,”; and

19 (B) by inserting “, and a tobacco product  
20 intended for export shall not be deemed to be  
21 in violation of section 906(e), 907, 911, or  
22 920(a),” before “if it—”; and

23 (3) by adding at the end the following:

24 “(p)(1) Not later than 36 months after the date of  
25 enactment of the Family Smoking Prevention and To-

1   tobacco Control Act, and annually thereafter, the Secretary  
2 shall submit to the Committee on Health, Education,  
3 Labor, and Pensions of the Senate and the Committee on  
4 Energy and Commerce of the House of Representatives,  
5 a report regarding—

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

10           “(B) the public health implications of such ex-  
11       ports, including any evidence of a negative public  
12       health impact; and

13           “(C) recommendations or assessments of policy  
14       alternatives available to Congress and the executive  
15       branch to reduce any negative public health impact  
16       caused by such exports.

17       “(2) The Secretary is authorized to establish appro-  
18       priate information disclosure requirements to carry out  
19       this subsection.”.

20       (m) SECTION 1003.—Section 1003(d)(2)(C) (as re-  
21       designated by section 101(b)) is amended—

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

23           (2) inserting “, and tobacco products” after  
24       “devices”.

1           (n) SECTION 1009.—Section 1009(b) (as redesign-  
2 nated by section 101(b)) is amended by striking “section  
3 908” and inserting “section 1008”.

4           (o) SECTION 409 OF THE FEDERAL MEAT INSPEC-  
5 TION ACT.—Section 409(a) of the Federal Meat Inspec-  
6 tion Act (21 U.S.C. 679(a)) is amended by striking “sec-  
7 tion 902(b)” and inserting “section 1002(b)”.

8           (p) RULE OF CONSTRUCTION.—Nothing in this sec-  
9 tion is intended or shall be construed to expand, contract,  
10 or otherwise modify or amend the existing limitations on  
11 State government authority over tribal restricted fee or  
12 trust lands.

13           (q) GUIDANCE AND EFFECTIVE DATES.—

14                 (1) IN GENERAL.—The Secretary of Health and  
15 Human Services shall issue guidance—

16                     (A) defining the term “repeated violation”,  
17 as used in section 303(f)(8) of the Federal  
18 Food, Drug, and Cosmetic Act (21 U.S.C.  
19 333(f)(8)) as amended by subsection (c), as in-  
20 cluding at least 5 violations of particular re-  
21 quirements over a 36-month period at a par-  
22 ticular retail outlet that constitute a repeated  
23 violation and providing for civil penalties in ac-  
24 cordance with paragraph (2);

1           (B) providing for timely and effective no-  
2           tice by certified or registered mail or personal  
3           delivery to the retailer of each alleged violation  
4           at a particular retail outlet prior to conducting  
5           a followup compliance check, such notice to be  
6           sent to the location specified on the retailer's  
7           registration or to the retailer's registered agent  
8           if the retailer has provided such agent informa-  
9           tion to the Food and Drug Administration prior  
10          to the violation;

11          (C) providing for a hearing pursuant to the  
12          procedures established through regulations of  
13          the Food and Drug Administration for assess-  
14          ing civil money penalties, including at a retail-  
15          er's request a hearing by telephone or at the  
16          nearest regional or field office of the Food and  
17          Drug Administration, and providing for an ex-  
18          pedited procedure for the administrative appeal  
19          of an alleged violation;

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

1 (E) establishing that civil money penalties  
2 for multiple violations shall increase from one  
3 violation to the next violation pursuant to para-  
4 graph (2) within the time periods provided for  
5 in such paragraph;

6 (F) providing that good faith reliance on  
7 the presentation of a false government-issued  
8 photographic identification that contains a date  
9 of birth does not constitute a violation of any  
10 minimum age requirement for the sale of to-  
11 bacco products if the retailer has taken effective  
12 steps to prevent such violations, including—

13 (i) adopting and enforcing a written  
14 policy against sales to minors;

15 (ii) informing its employees of all ap-  
16 plicable laws;

17 (iii) establishing disciplinary sanctions  
18 for employee noncompliance; and

19 (iv) requiring its employees to verify  
20 age by way of photographic identification  
21 or electronic scanning device; and

22 (G) providing for the Secretary, in deter-  
23 mining whether to impose a no-tobacco-sale  
24 order and in determining whether to com-  
25 promise, modify, or terminate such an order, to

1 consider whether the retailer has taken effective  
2 steps to prevent violations of the minimum age  
3 requirements for the sale of tobacco products,  
4 including the steps listed in subparagraph (F).

5 (2) PENALTIES FOR VIOLATIONS.—

6 (A) IN GENERAL.—The amount of the civil  
7 penalty to be applied for violations of restric-  
8 tions promulgated under section 906(d), as de-  
9 scribed in paragraph (1), shall be as follows:

10 (i) With respect to a retailer with an  
11 approved training program, the amount of  
12 the civil penalty shall not exceed—

13 (I) in the case of the first viola-  
14 tion, \$0.00 together with the issuance  
15 of a warning letter to the retailer;

16 (II) in the case of a second viola-  
17 tion within a 12-month period, \$250;

18 (III) in the case of a third viola-  
19 tion within a 24-month period, \$500;

20 (IV) in the case of a fourth viola-  
21 tion within a 24-month period,  
22 \$2,000;

23 (V) in the case of a fifth violation  
24 within a 36-month period, \$5,000;  
25 and

1 (VI) in the case of a sixth or sub-  
2 sequent violation within a 48-month  
3 period, \$10,000 as determined by the  
4 Secretary on a case-by-case basis.

5 (ii) With respect to a retailer that  
6 does not have an approved training pro-  
7 gram, the amount of the civil penalty shall  
8 not exceed—

9 (I) in the case of the first viola-  
10 tion, \$250;

11 (II) in the case of a second viola-  
12 tion within a 12-month period, \$500;

13 (III) in the case of a third viola-  
14 tion within a 24-month period,  
15 \$1,000;

16 (IV) in the case of a fourth viola-  
17 tion within a 24-month period,  
18 \$2,000;

19 (V) in the case of a fifth violation  
20 within a 36-month period, \$5,000;  
21 and

22 (VI) in the case of a sixth or sub-  
23 sequent violation within a 48-month  
24 period, \$10,000 as determined by the  
25 Secretary on a case-by-case basis.

1 (B) TRAINING PROGRAM.—For purposes of  
2 subparagraph (A), the term “approved training  
3 program” means a training program that com-  
4 plies with standards developed by the Food and  
5 Drug Administration for such programs.

6 (C) CONSIDERATION OF STATE PEN-  
7 ALTIES.—The Secretary shall coordinate with  
8 the States in enforcing the provisions of this  
9 Act and, for purposes of mitigating a civil pen-  
10 alty to be applied for a violation by a retailer  
11 of any restriction promulgated under section  
12 906(d), shall consider the amount of any pen-  
13 alties paid by the retailer to a State for the  
14 same violation.

15 (3) GENERAL EFFECTIVE DATE.—The amend-  
16 ments made by paragraphs (2), (3), and (4) of sub-  
17 section (c) shall take effect upon the issuance of  
18 guidance described in paragraph (1) of this sub-  
19 section.

20 (4) SPECIAL EFFECTIVE DATE.—The amend-  
21 ment made by subsection (c)(1) shall take effect on  
22 the date of enactment of this Act.

23 (5) PACKAGE LABEL REQUIREMENTS.—The  
24 package label requirements of paragraphs (2), (3),  
25 and (4) of section 903(a) of the Federal Food,



1 Drug, and Cosmetic Act (as amended by this Act)  
2 shall take effect on the date that is 12 months after  
3 the date of enactment of this Act. The effective date  
4 shall be with respect to the date of manufacture,  
5 provided that, in any case, beginning 30 days after  
6 such effective date, a manufacturer shall not intro-  
7 duce into the domestic commerce of the United  
8 States any product, irrespective of the date of manu-  
9 facture, that is not in conformance with section  
10 903(a) (2), (3), and (4) and section 920(a) of the  
11 Federal Food, Drug, and Cosmetic Act.

12 (6) ADVERTISING REQUIREMENTS.—The adver-  
13 tising requirements of section 903(a)(8) of the Fed-  
14 eral Food, Drug, and Cosmetic Act (as amended by  
15 this Act) shall take effect on the date that is 12  
16 months after the date of enactment of this Act.

17 **SEC. 104. STUDY ON RAISING THE MINIMUM AGE TO PUR-**  
18 **CHASE TOBACCO PRODUCTS.**

19 The Secretary of Health and Human Services shall—

20 (1) convene an expert panel to conduct a study  
21 on the public health implications of raising the min-  
22 imum age to purchase tobacco products; and

23 (2) not later than 5 years after the date of en-  
24 actment of this Act, submit a report to the Congress  
25 on the results of such study.

1 **SEC. 105. ENFORCEMENT ACTION PLAN FOR ADVERTISING**  
2 **AND PROMOTION RESTRICTIONS.**

3 (a) ACTION PLAN.—

4 (1) DEVELOPMENT.—Not later than 6 months  
5 after the date of enactment of this Act, the Sec-  
6 retary of Health and Human Services (in this sec-  
7 tion referred to as the “Secretary”) shall develop  
8 and publish an action plan to enforce restrictions  
9 adopted pursuant to section 906 of the Federal  
10 Food, Drug, and Cosmetic Act, as added by section  
11 101(b) of this Act, or pursuant to section 102(a) of  
12 this Act, on promotion and advertising of menthol  
13 and other cigarettes to youth.

14 (2) CONSULTATION.—The action plan required  
15 by paragraph (1) shall be developed in consultation  
16 with public health organizations and other stake-  
17 holders with demonstrated expertise and experience  
18 in serving minority communities.

19 (3) PRIORITY.—The action plan required by  
20 paragraph (1) shall include provisions designed to  
21 ensure enforcement of the restrictions described in  
22 paragraph (1) in minority communities.

23 (b) STATE AND LOCAL ACTIVITIES.—

24 (1) INFORMATION ON AUTHORITY.—Not later  
25 than 3 months after the date of enactment of this  
26 Act, the Secretary shall inform State, local, and trib-

1 al governments of the authority provided to such en-  
 2 tities under section 5(c) of the Federal Cigarette La-  
 3 beling and Advertising Act, as added by section 203  
 4 of this Act, or preserved by such entities under sec-  
 5 tion 916 of the Federal Food, Drug, and Cosmetic  
 6 Act, as added by section 101(b) of this Act.

7 (2) COMMUNITY ASSISTANCE.—At the request  
 8 of communities seeking assistance to prevent under-  
 9 age tobacco use, the Secretary shall provide such as-  
 10 sistance, including assistance with strategies to ad-  
 11 dress the prevention of underage tobacco use in com-  
 12 munities with a disproportionate use of menthol  
 13 cigarettes by minors.

14 **TITLE II—TOBACCO PRODUCT**  
 15 **WARNINGS; CONSTITUENT**  
 16 **AND SMOKE CONSTITUENT**  
 17 **DISCLOSURE**

18 **SEC. 201. CIGARETTE LABEL AND ADVERTISING WARNINGS.**

19 (a) AMENDMENT.—Section 4 of the Federal Ciga-  
 20 rette Labeling and Advertising Act (15 U.S.C. 1333) is  
 21 amended to read as follows:

22 **“SEC. 4. LABELING.**

23 **“(a) LABEL REQUIREMENTS.—**

24 **“(1) IN GENERAL.—**It shall be unlawful for any  
 25 person to manufacture, package, sell, offer to sell,

1 distribute, or import for sale or distribution within  
2 the United States any cigarettes the package of  
3 which fails to bear, in accordance with the require-  
4 ments of this section, one of the following labels:

5 “WARNING: Cigarettes are addictive.

6 “WARNING: Tobacco smoke can harm  
7 your children.

8 “WARNING: Cigarettes cause fatal lung  
9 disease.

10 “WARNING: Cigarettes cause cancer.

11 “WARNING: Cigarettes cause strokes and  
12 heart disease.

13 “WARNING: Smoking during pregnancy  
14 can harm your baby.

15 “WARNING: Smoking can kill you.

16 “WARNING: Tobacco smoke causes fatal  
17 lung disease in nonsmokers.

18 “WARNING: Quitting smoking now great-  
19 ly reduces serious risks to your health.

20 “(2) PLACEMENT; TYPOGRAPHY; ETC.—Each  
21 label statement required by paragraph (1) shall be  
22 located in the upper portion of the front and rear  
23 panels of the package, directly on the package un-  
24 derneath the cellophane or other clear wrapping.  
25 Each label statement shall comprise the top 50 per-

1 cent of the front and rear panels of the package.  
2 The word ‘WARNING’ shall appear in capital letters  
3 and all text shall be in conspicuous and legible 17-  
4 point type, unless the text of the label statement  
5 would occupy more than 70 percent of such area, in  
6 which case the text may be in a smaller conspicuous  
7 and legible type size, provided that at least 60 per-  
8 cent of such area is occupied by required text. The  
9 text shall be black on a white background, or white  
10 on a black background, in a manner that contrasts,  
11 by typography, layout, or color, with all other print-  
12 ed material on the package, in an alternating fash-  
13 ion under the plan submitted under subsection (c).

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

20 “(4) APPLICABILITY TO RETAILERS.—A retailer  
21 of cigarettes shall not be in violation of this sub-  
22 section for packaging that—

23 “(A) contains a warning label;

1           “(B) is supplied to the retailer by a  
2           license- or permit-holding tobacco product man-  
3           ufacturer, importer, or distributor; and

4           “(C) is not altered by the retailer in a way  
5           that is material to the requirements of this sub-  
6           section.

7           “(b) ADVERTISING REQUIREMENTS.—

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

15          “(2) TYPOGRAPHY, ETC.—Each label statement  
16          required by subsection (a) in cigarette advertising  
17          shall comply with the standards set forth in this  
18          paragraph. For press and poster advertisements,  
19          each such statement and (where applicable) any re-  
20          quired statement relating to tar, nicotine, or other  
21          constituent (including a smoke constituent) yield  
22          shall comprise at least 20 percent of the area of the  
23          advertisement and shall appear in a conspicuous and  
24          prominent format and location at the top of each ad-  
25          vertisement within the trim area. The Secretary may

1       revise the required type sizes in such area in such  
2       manner as the Secretary determines appropriate.  
3       The word ‘WARNING’ shall appear in capital let-  
4       ters, and each label statement shall appear in con-  
5       spicuous and legible type. The text of the label state-  
6       ment shall be black if the background is white and  
7       white if the background is black, under the plan sub-  
8       mitted under subsection (c). The label statements  
9       shall be enclosed by a rectangular border that is the  
10      same color as the letters of the statements and that  
11      is the width of the first downstroke of the capital  
12      ‘W’ of the word ‘WARNING’ in the label state-  
13      ments. The text of such label statements shall be in  
14      a typeface pro rata to the following requirements:  
15      45-point type for a whole-page broadsheet newspaper  
16      advertisement; 39-point type for a half-page  
17      broadsheet newspaper advertisement; 39-point type  
18      for a whole-page tabloid newspaper advertisement;  
19      27-point type for a half-page tabloid newspaper ad-  
20      vertisement; 31.5-point type for a double page  
21      spread magazine or whole-page magazine advertise-  
22      ment; 22.5-point type for a 28 centimeter by 3 col-  
23      umn advertisement; and 15-point type for a 20 cen-  
24      timeter by 2 column advertisement. The label state-  
25      ments shall be in English, except that—

1           “(A) in the case of an advertisement that  
2           appears in a newspaper, magazine, periodical,  
3           or other publication that is not in English, the  
4           statements shall appear in the predominant lan-  
5           guage of the publication; and

6           “(B) in the case of any other advertise-  
7           ment that is not in English, the statements  
8           shall appear in the same language as that prin-  
9           cipally used in the advertisement.

10          “(3) MATCHBOOKS.—Notwithstanding para-  
11          graph (2), for matchbooks (defined as containing not  
12          more than 20 matches) customarily given away with  
13          the purchase of tobacco products, each label state-  
14          ment required by subsection (a) may be printed on  
15          the inside cover of the matchbook.

16          “(4) ADJUSTMENT BY SECRETARY.—The Sec-  
17          retary may, through a rulemaking under section 553  
18          of title 5, United States Code, adjust the format and  
19          type sizes for the label statements required by this  
20          section; the text, format, and type sizes of any re-  
21          quired tar, nicotine yield, or other constituent (in-  
22          cluding smoke constituent) disclosures; or the text,  
23          format, and type sizes for any other disclosures re-  
24          quired under the Federal Food, Drug, and Cosmetic  
25          Act. The text of any such label statements or dislo-



1       sures shall be required to appear only within the 20  
2       percent area of cigarette advertisements provided by  
3       paragraph (2). The Secretary shall promulgate regu-  
4       lations which provide for adjustments in the format  
5       and type sizes of any text required to appear in such  
6       area to ensure that the total text required to appear  
7       by law will fit within such area.

8       “(c) MARKETING REQUIREMENTS.—

9               “(1) RANDOM DISPLAY.—The label statements  
10       specified in subsection (a)(1) shall be randomly dis-  
11       played in each 12-month period, in as equal a num-  
12       ber of times as is possible on each brand of the  
13       product and be randomly distributed in all areas of  
14       the United States in which the product is marketed  
15       in accordance with a plan submitted by the tobacco  
16       product manufacturer, importer, distributor, or re-  
17       tailer and approved by the Secretary.

18               “(2) ROTATION.—The label statements speci-  
19       fied in subsection (a)(1) shall be rotated quarterly in  
20       alternating sequence in advertisements for each  
21       brand of cigarettes in accordance with a plan sub-  
22       mitted by the tobacco product manufacturer, im-  
23       porter, distributor, or retailer to, and approved by,  
24       the Secretary.

1           “(3) REVIEW.—The Secretary shall review each  
2 plan submitted under paragraph (2) and approve it  
3 if the plan—

4           “(A) will provide for the equal distribution  
5 and display on packaging and the rotation re-  
6 quired in advertising under this subsection; and

7           “(B) assures that all of the labels required  
8 under this section will be displayed by the to-  
9 bacco product manufacturer, importer, dis-  
10 tributor, or retailer at the same time.

11           “(4) APPLICABILITY TO RETAILERS.—This sub-  
12 section and subsection (b) apply to a retailer only if  
13 that retailer is responsible for or directs the label  
14 statements required under this section except that  
15 this paragraph shall not relieve a retailer of liability  
16 if the retailer displays, in a location open to the pub-  
17 lic, an advertisement that does not contain a warn-  
18 ing label or has been altered by the retailer in a way  
19 that is material to the requirements of this sub-  
20 section and subsection (b).”.

21           (b) EFFECTIVE DATE.—The amendment made by  
22 subsection (a) shall take effect 12 months after the date  
23 of enactment of this Act. Such effective date shall be with  
24 respect to the date of manufacture, provided that, in any  
25 case, beginning 30 days after such effective date, a manu-

1    factorer shall not introduce into the domestic commerce  
2    of the United States any product, irrespective of the date  
3    of manufacture, that is not in conformance with section  
4    4 of the Federal Cigarette Labeling and Advertising Act  
5    (15 U.S.C. 1333), as amended by subsection (a).

6    **SEC. 202. AUTHORITY TO REVISE CIGARETTE WARNING**  
7                                   **LABEL STATEMENTS.**

8           (a) **PREEMPTION.**—Section 5(a) of the Federal Ciga-  
9    rette Labeling and Advertising Act (15 U.S.C. 1334(a))  
10   is amended by striking “No” and inserting “Except to the  
11   extent the Secretary requires additional or different state-  
12   ments on any cigarette package by a regulation, by an  
13   order, by a standard, by an authorization to market a  
14   product, or by a condition of marketing a product, pursu-  
15   ant to the Family Smoking Prevention and Tobacco Con-  
16   trol Act (and the amendments made by that Act), or as  
17   required under section 903(a)(2) or section 920(a) of the  
18   Federal Food, Drug, and Cosmetic Act, no”.

19           (b) **CHANGE IN REQUIRED STATEMENTS.**—Section 4  
20   of the Federal Cigarette Labeling and Advertising Act (15  
21   U.S.C. 1333), as amended by section 201, is further  
22   amended by adding at the end the following:

23           “(d) **CHANGE IN REQUIRED STATEMENTS.**—The  
24   Secretary through a rulemaking conducted under section  
25   553 of title 5, United States Code—

1           “(1) shall issue regulations within 24 months of  
2           the date of enactment of the Family Smoking Pre-  
3           vention and Tobacco Control Act that require color  
4           graphics depicting the negative health consequences  
5           of smoking to accompany label requirements; and

6           “(2) may thereafter adjust the format, type  
7           size, color graphics, and text of any of the label re-  
8           quirements, or establish the format, type size, and  
9           text of any other disclosures required under the Fed-  
10          eral Food, Drug, and Cosmetic Act, if the Secretary  
11          finds that such a change would promote greater pub-  
12          lic understanding of the risks associated with the  
13          use of tobacco products.”.

14 **SEC. 203. STATE REGULATION OF CIGARETTE ADVER-**  
15 **TISING AND PROMOTION.**

16          Section 5 of the Federal Cigarette Labeling and Ad-  
17          vertising Act (15 U.S.C. 1334) is amended by adding at  
18          the end the following:

19          “(c) EXCEPTION.—Notwithstanding subsection (b), a  
20          State or locality may enact statutes and promulgate regu-  
21          lations, based on smoking and health, that take effect  
22          after the effective date of the Family Smoking Prevention  
23          and Tobacco Control Act, imposing specific bans or re-  
24          strictions on the time, place, and manner, but not content,  
25          of the advertising or promotion of any cigarettes.”.

1 **SEC. 204. SMOKELESS TOBACCO LABELS AND ADVERTISING**  
2 **WARNINGS.**

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

6 **“SEC. 3. SMOKELESS TOBACCO WARNING.**

7 “(a) GENERAL RULE.—

8 “(1) It shall be unlawful for any person to man-  
9 ufacture, package, sell, offer to sell, distribute, or  
10 import for sale or distribution within the United  
11 States any smokeless tobacco product unless the  
12 product package bears, in accordance with the re-  
13 quirements of this Act, one of the following labels:

14 “WARNING: This product can cause  
15 mouth cancer.

16 “WARNING: This product can cause gum  
17 disease and tooth loss.

18 “WARNING: This product is not a safe al-  
19 ternative to cigarettes.

20 “WARNING: Smokeless tobacco is addict-  
21 ive.

22 “(2) Each label statement required by para-  
23 graph (1) shall be—

24 “(A) located on the 2 principal display  
25 panels of the package, and each label statement

1 shall comprise at least 30 percent of each such  
2 display panel; and

3 “(B) in 17-point conspicuous and legible  
4 type and in black text on a white background,  
5 or white text on a black background, in a man-  
6 ner that contrasts by typography, layout, or  
7 color, with all other printed material on the  
8 package, in an alternating fashion under the  
9 plan submitted under subsection (b)(3), except  
10 that if the text of a label statement would oc-  
11 cupy more than 70 percent of the area specified  
12 by subparagraph (A), such text may appear in  
13 a smaller type size, so long as at least 60 per-  
14 cent of such warning area is occupied by the  
15 label statement.

16 “(3) The label statements required by para-  
17 graph (1) shall be introduced by each tobacco prod-  
18 uct manufacturer, packager, importer, distributor, or  
19 retailer of smokeless tobacco products concurrently  
20 into the distribution chain of such products.

21 “(4) The provisions of this subsection do not  
22 apply to a tobacco product manufacturer or dis-  
23 tributor of any smokeless tobacco product that does  
24 not manufacture, package, or import smokeless to-

1       bacco products for sale or distribution within the  
2       United States.

3           “(5) A retailer of smokeless tobacco products  
4       shall not be in violation of this subsection for pack-  
5       aging that—

6           “(A) contains a warning label;

7           “(B) is supplied to the retailer by a  
8       license- or permit-holding tobacco product man-  
9       ufacturer, importer, or distributor; and

10          “(C) is not altered by the retailer in a way  
11       that is material to the requirements of this sub-  
12       section.

13       “(b) REQUIRED LABELS.—

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

21           “(2)(A) Each label statement required by sub-  
22       section (a) in smokeless tobacco advertising shall  
23       comply with the standards set forth in this para-  
24       graph.

1           “(B) For press and poster advertisements, each  
2 such statement and (where applicable) any required  
3 statement relating to tar, nicotine, or other con-  
4 stituent yield shall comprise at least 20 percent of  
5 the area of the advertisement.

6           “(C) The word ‘WARNING’ shall appear in  
7 capital letters, and each label statement shall appear  
8 in conspicuous and legible type.

9           “(D) The text of the label statement shall be  
10 black on a white background, or white on a black  
11 background, in an alternating fashion under the  
12 plan submitted under paragraph (3).

13           “(E) The label statements shall be enclosed by  
14 a rectangular border that is the same color as the  
15 letters of the statements and that is the width of the  
16 first downstroke of the capital ‘W’ of the word  
17 ‘WARNING’ in the label statements.

18           “(F) The text of such label statements shall be  
19 in a typeface pro rata to the following requirements:  
20 45-point type for a whole-page broadsheet newspaper  
21 advertisement; 39-point type for a half-page  
22 broadsheet newspaper advertisement; 39-point type  
23 for a whole-page tabloid newspaper advertisement;  
24 27-point type for a half-page tabloid newspaper ad-  
25 vertisement; 31.5-point type for a double page



1 spread magazine or whole-page magazine advertise-  
2 ment; 22.5-point type for a 28 centimeter by 3 col-  
3 umn advertisement; and 15-point type for a 20 cen-  
4 timeter by 2 column advertisement.

5 “(G) The label statements shall be in English,  
6 except that—

7 “(i) in the case of an advertisement that  
8 appears in a newspaper, magazine, periodical,  
9 or other publication that is not in English, the  
10 statements shall appear in the predominant lan-  
11 guage of the publication; and

12 “(ii) in the case of any other advertisement  
13 that is not in English, the statements shall ap-  
14 pear in the same language as that principally  
15 used in the advertisement.

16 “(3)(A) The label statements specified in sub-  
17 section (a)(1) shall be randomly displayed in each  
18 12-month period, in as equal a number of times as  
19 is possible on each brand of the product and be ran-  
20 domly distributed in all areas of the United States  
21 in which the product is marketed in accordance with  
22 a plan submitted by the tobacco product manufac-  
23 turer, importer, distributor, or retailer and approved  
24 by the Secretary.

1           “(B) The label statements specified in sub-  
2           section (a)(1) shall be rotated quarterly in alter-  
3           nating sequence in advertisements for each brand of  
4           smokeless tobacco product in accordance with a plan  
5           submitted by the tobacco product manufacturer, im-  
6           porter, distributor, or retailer to, and approved by,  
7           the Secretary.

8           “(C) The Secretary shall review each plan sub-  
9           mitted under subparagraphs (A) and (B) and ap-  
10          prove it if the plan—

11                 “(i) will provide for the equal distribution  
12                 and display on packaging and the rotation re-  
13                 quired in advertising under this subsection; and

14                 “(ii) assures that all of the labels required  
15                 under this section will be displayed by the to-  
16                 bacco product manufacturer, importer, dis-  
17                 tributor, or retailer at the same time.

18          “(D) This paragraph applies to a retailer only  
19          if that retailer is responsible for or directs the label  
20          statements under this section, unless the retailer dis-  
21          plays, in a location open to the public, an advertise-  
22          ment that does not contain a warning label or has  
23          been altered by the retailer in a way that is material  
24          to the requirements of this subsection.

1           “(4) The Secretary may, through a rulemaking  
2           under section 553 of title 5, United States Code, ad-  
3           just the format and type sizes for the label state-  
4           ments required by this section; the text, format, and  
5           type sizes of any required tar, nicotine yield, or  
6           other constituent disclosures; or the text, format,  
7           and type sizes for any other disclosures required  
8           under the Federal Food, Drug, and Cosmetic Act.  
9           The text of any such label statements or disclosures  
10          shall be required to appear only within the 20 per-  
11          cent area of advertisements provided by paragraph  
12          (2). The Secretary shall promulgate regulations  
13          which provide for adjustments in the format and  
14          type sizes of any text required to appear in such  
15          area to ensure that the total text required to appear  
16          by law will fit within such area.

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

21          (b) EFFECTIVE DATE.—The amendment made by  
22          subsection (a) shall take effect 12 months after the date  
23          of enactment of this Act. Such effective date shall be with  
24          respect to the date of manufacture, provided that, in any  
25          case, beginning 30 days after such effective date, a manu-

1   factorer shall not introduce into the domestic commerce  
2   of the United States any product, irrespective of the date  
3   of manufacture, that is not in conformance with section  
4   3 of the Comprehensive Smokeless Tobacco Health Edu-  
5   cation Act of 1986 (15 U.S.C. 4402), as amended by sub-  
6   section (a).

7   **SEC. 205. AUTHORITY TO REVISE SMOKELESS TOBACCO**  
8                   **PRODUCT WARNING LABEL STATEMENTS.**

9           (a) IN GENERAL.—Section 3 of the Comprehensive  
10   Smokeless Tobacco Health Education Act of 1986 (15  
11   U.S.C. 4402), as amended by section 204, is further  
12   amended by adding at the end the following:

13           “(d) AUTHORITY TO REVISE WARNING LABEL  
14   STATEMENTS.—The Secretary may, by a rulemaking con-  
15   ducted under section 553 of title 5, United States Code,  
16   adjust the format, type size, and text of any of the label  
17   requirements, require color graphics to accompany the  
18   text, increase the required label area from 30 percent up  
19   to 50 percent of the front and rear panels of the package,  
20   or establish the format, type size, and text of any other  
21   disclosures required under the Federal Food, Drug, and  
22   Cosmetic Act, if the Secretary finds that such a change  
23   would promote greater public understanding of the risks  
24   associated with the use of smokeless tobacco products.”.

1 (b) PREEMPTION.—Section 7(a) of the Comprehen-  
 2 sive Smokeless Tobacco Health Education Act of 1986 (15  
 3 U.S.C. 4406(a)) is amended by striking “No” and insert-  
 4 ing “Except as provided in the Family Smoking Preven-  
 5 tion and Tobacco Control Act (and the amendments made  
 6 by that Act), no”.

7 **SEC. 206. TAR, NICOTINE, AND OTHER SMOKE CON-**  
 8 **STITUENT DISCLOSURE TO THE PUBLIC.**

9 Section 4 of the Federal Cigarette Labeling and Ad-  
 10 vertising Act (15 U.S.C. 1333), as amended by sections  
 11 201 and 202, is further amended by adding at the end  
 12 the following:

13 “(e) TAR, NICOTINE, AND OTHER SMOKE CON-  
 14 STITUENT DISCLOSURE.—

15 “(1) IN GENERAL.—The Secretary shall, by a  
 16 rulemaking conducted under section 553 of title 5,  
 17 United States Code, determine (in the Secretary’s  
 18 sole discretion) whether cigarette and other tobacco  
 19 product manufacturers shall be required to include  
 20 in the area of each cigarette advertisement specified  
 21 by subsection (b) of this section, or on the package  
 22 label, or both, the tar and nicotine yields of the ad-  
 23 vertised or packaged brand. Any such disclosure  
 24 shall be in accordance with the methodology estab-  
 25 lished under such regulations, shall conform to the

1 type size requirements of subsection (b) of this sec-  
2 tion, and shall appear within the area specified in  
3 subsection (b) of this section.

4 “(2) RESOLUTION OF DIFFERENCES.—Any dif-  
5 ferences between the requirements established by the  
6 Secretary under paragraph (1) and tar and nicotine  
7 yield reporting requirements established by the Fed-  
8 eral Trade Commission shall be resolved by a memo-  
9 randum of understanding between the Secretary and  
10 the Federal Trade Commission.

11 “(3) CIGARETTE AND OTHER TOBACCO PROD-  
12 UCT CONSTITUENTS.—In addition to the disclosures  
13 required by paragraph (1), the Secretary may, under  
14 a rulemaking conducted under section 553 of title 5,  
15 United States Code, prescribe disclosure require-  
16 ments regarding the level of any cigarette or other  
17 tobacco product constituent including any smoke  
18 constituent. Any such disclosure may be required if  
19 the Secretary determines that disclosure would be of  
20 benefit to the public health, or otherwise would in-  
21 crease consumer awareness of the health con-  
22 sequences of the use of tobacco products, except that  
23 no such prescribed disclosure shall be required on  
24 the face of any cigarette package or advertisement.  
25 Nothing in this section shall prohibit the Secretary

1 from requiring such prescribed disclosure through a  
 2 cigarette or other tobacco product package or adver-  
 3 tisement insert, or by any other means under the  
 4 Federal Food, Drug, and Cosmetic Act.

5 “(4) RETAILERS.—This subsection applies to a  
 6 retailer only if that retailer is responsible for or di-  
 7 rects the label statements required under this sec-  
 8 tion.”.

9 **TITLE III—PREVENTION OF IL-**  
 10 **LICIT TRADE IN TOBACCO**  
 11 **PRODUCTS**

12 **SEC. 301. LABELING, RECORDKEEPING, RECORDS INSPEC-**  
 13 **TION.**

14 Chapter IX of the Federal Food, Drug, and Cosmetic  
 15 Act, as added by section 101, is further amended by add-  
 16 ing at the end the following:

17 **“SEC. 920. LABELING, RECORDKEEPING, RECORDS INSPEC-**  
 18 **TION.**

19 “(a) ORIGIN LABELING.—

20 “(1) REQUIREMENT.—Beginning 1 year after  
 21 the date of enactment of the Family Smoking Pre-  
 22 vention and Tobacco Control Act, the label, pack-  
 23 aging, and shipping containers of tobacco products  
 24 for introduction or delivery for introduction into  
 25 interstate commerce in the United States shall bear

1 the statement ‘sale only allowed in the United  
2 States’.

3 “(2) EFFECTIVE DATE.—The effective date  
4 specified in paragraph (1) shall be with respect to  
5 the date of manufacture, provided that, in any case,  
6 beginning 30 days after such effective date, a manu-  
7 facturer shall not introduce into the domestic com-  
8 merce of the United States any product, irrespective  
9 of the date of manufacture, that is not in conform-  
10 ance with such paragraph.

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

13 “(1) IN GENERAL.—The Secretary shall pro-  
14 mulgate regulations regarding the establishment and  
15 maintenance of records by any person who manufac-  
16 tures, processes, transports, distributes, receives,  
17 packages, holds, exports, or imports tobacco prod-  
18 ucts.

19 “(2) INSPECTION.—In promulgating the regula-  
20 tions described in paragraph (1), the Secretary shall  
21 consider which records are needed for inspection to  
22 monitor the movement of tobacco products from the  
23 point of manufacture through distribution to retail  
24 outlets to assist in investigating potential illicit



1 trade, smuggling, or counterfeiting of tobacco prod-  
2 ucts.

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

7 “(4) SIZE OF BUSINESS.—The Secretary shall  
8 take into account the size of a business in promul-  
9 gating regulations under this section.

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

14 “(c) RECORDS INSPECTION.—If the Secretary has a  
15 reasonable belief that a tobacco product is part of an illicit  
16 trade or smuggling or is a counterfeit product, each person  
17 who manufactures, processes, transports, distributes, re-  
18 ceives, holds, packages, exports, or imports tobacco prod-  
19 ucts shall, at the request of an officer or employee duly  
20 designated by the Secretary, permit such officer or em-  
21 ployee, at reasonable times and within reasonable limits  
22 and in a reasonable manner, upon the presentation of ap-  
23 propriate credentials and a written notice to such person,  
24 to have access to and copy all records (including financial  
25 records) relating to such article that are needed to assist

1 the Secretary in investigating potential illicit trade, smug-  
2 gling, or counterfeiting of tobacco products. The Secretary  
3 shall not authorize an officer or employee of the govern-  
4 ment of any of the several States to exercise authority  
5 under the preceding sentence on Indian country without  
6 the express written consent of the Indian tribe involved.

7 “(d) KNOWLEDGE OF ILLEGAL TRANSACTION.—

8 “(1) NOTIFICATION.—If the manufacturer or  
9 distributor of a tobacco product has knowledge  
10 which reasonably supports the conclusion that a to-  
11 bacco product manufactured or distributed by such  
12 manufacturer or distributor that has left the control  
13 of such person may be or has been—

14 “(A) imported, exported, distributed, or of-  
15 fered for sale in interstate commerce by a per-  
16 son without paying duties or taxes required by  
17 law; or

18 “(B) imported, exported, distributed, or di-  
19 verted for possible illicit marketing,

20 the manufacturer or distributor shall promptly no-  
21 tify the Attorney General and the Secretary of the  
22 Treasury of such knowledge.

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

1           “(A) the actual knowledge that the manu-  
2           facturer or distributor had; or

3           “(B) the knowledge which a reasonable  
4           person would have had under like circumstances  
5           or which would have been obtained upon the ex-  
6           ercise of due care.

7           “(e) CONSULTATION.—In carrying out this section,  
8           the Secretary shall consult with the Attorney General of  
9           the United States and the Secretary of the Treasury, as  
10          appropriate.”.

11       **SEC. 302. STUDY AND REPORT.**

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

15               (1) collect data on cross-border trade in tobacco  
16          products, including illicit trade and trade of counter-  
17          feit tobacco products and make recommendations on  
18          the monitoring of such trade;

19               (2) collect data on cross-border advertising (any  
20          advertising intended to be broadcast, transmitted, or  
21          distributed from the United States to another coun-  
22          try) of tobacco products and make recommendations  
23          on how to prevent or eliminate, and what tech-  
24          nologies could help facilitate the elimination of,  
25          cross-border advertising; and

1           (3) collect data on the health effects (particu-  
2           larly with respect to individuals under 18 years of  
3           age) resulting from cross-border trade in tobacco  
4           products, including the health effects resulting  
5           from—

6                   (A) the illicit trade of tobacco products  
7                   and the trade of counterfeit tobacco products;  
8                   and

9                   (B) the differing tax rates applicable to to-  
10                  bacco products.

11          (b) REPORT.—Not later than 18 months after the  
12 date of enactment of this Act, the Comptroller General  
13 of the United States shall submit to the Committee on  
14 Health, Education, Labor, and Pensions of the Senate and  
15 the Committee on Energy and Commerce of the House  
16 of Representatives a report on the study described in sub-  
17 section (a).

18          (c) DEFINITION.—In this section:

19                  (1) The term “cross-border trade” means trade  
20                  across a border of the United States, a State or Ter-  
21                  ritory, or Indian country.

22                  (2) The term “Indian country” has the mean-  
23                  ing given to such term in section 1151 of title 18,  
24                  United States Code.

1           (3) The terms “State” and “Territory” have  
2           the meanings given to those terms in section 201 of  
3           the Federal Food, Drug, and Cosmetic Act (21  
4           U.S.C. 321).

○