

111TH CONGRESS
1ST SESSION

H. R. 1256

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

IN THE HOUSE OF REPRESENTATIVES

MARCH 3, 2009

Mr. WAXMAN (for himself, Mr. PLATTS, Mr. TOWNS, Mr. LYNCH, Mr. PALLONE, Mr. DINGELL, Mr. RANGEL, Mr. ABERCROMBIE, Mr. ACKERMAN, Ms. BALDWIN, Mr. BARROW, Mr. BERRY, Mr. BILBRAY, Mr. BLUMENAUER, Mrs. BONO MACK, Ms. BORDALLO, Mr. BOUCHER, Mr. BRADY of Pennsylvania, Mr. BRALEY of Iowa, Mrs. CAPPs, Mr. CARNEY, Mr. CARSON of Indiana, Mr. CASTLE, Ms. CASTOR of Florida, Mrs. CHRISTENSEN, Mr. COHEN, Mr. CONNOLLY of Virginia, Mr. CONYERS, Mr. COURTNEY, Mr. CUMMINGS, Mrs. DAHLKEMPER, Mrs. DAVIS of California, Mr. DEFazio, Ms. DEGETTE, Mr. DELAHUNT, Ms. DELAURO, Mr. DOYLE, Mr. EDWARDS of Texas, Mr. ELLISON, Mrs. EMERSON, Mr. ENGEL, Ms. ESHOO, Mr. FILNER, Mr. FRELINGHUYSEN, Mr. GONZALEZ, Mr. GENE GREEN of Texas, Mr. GRIJALVA, Mr. GUTIERREZ, Mr. HALL of New York, Ms. HARMAN, Mr. HEINRICH, Mr. HIGGINS, Mr. HIMES, Mr. HINCHEY, Ms. HIRONO, Mr. HOLT, Mr. INSLEE, Mr. ISRAEL, Ms. JACKSON-LEE of Texas, Mr. JACKSON of Illinois, Mr. KILDEE, Ms. KILROY, Mr. KIND, Mr. KIRK, Mr. LARSEN of Washington, Mr. LARSON of Connecticut, Ms. LEE of California, Mr. LEWIS of Georgia, Mr. LIPINSKI, Mr. LOBIONDO, Mr. LOEBSACK, Mrs. LOWEY, Mr. LUJÁN, Mr. MAFFEL, Mrs. MALONEY, Ms. MARKEY of Colorado, Mr. MARKEY of Massachusetts, Mr. MATHESON, Ms. MATSUI, Mrs. MCCARTHY of New York, Ms. MCCOLLUM, Mr. McDERMOTT, Mr. MCGOVERN, Mr. McMAHON, Mr. McNERNEY, Mr. MICHAUD, Mr. GEORGE MILLER of California, Mr. MITCHELL, Mr. MORAN of Virginia, Mr. MURPHY of Connecticut, Mr. NADLER of New York, Mrs. NAPOLITANO, Ms. NORTON, Mr. OBERSTAR, Mr. OLVER, Mr. PASCRELL, Ms. PINGREE of Maine, Mr. REICHERT, Mr. REYES, Mr. ROTHMAN of New Jersey, Ms. ROYBAL-ALLARD, Mr. RUSH, Mr. RYAN of Ohio, Ms. LORETTA SANCHEZ of California, Mr. SARBANES, Ms. SCHAKOWSKY, Mr. SCHIFF, Ms. SCHWARTZ, Mr. SCOTT of Virginia, Mr. SERRANO, Mr. SHERMAN, Ms. SLAUGHTER, Mr. SMITH of New Jersey, Mr. SNYDER, Mr. STARK, Ms. SUTTON, Mr. TIERNEY, Mr. TONKO, Mr. VAN HOLLEN, Ms. WATSON, Mr. WEINER, Mr. WELCH, Mr. WEXLER, Mr. WU, and Mr. YARMUTH) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in

addition to the Committee on Oversight and Government Reform, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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”.

6 (b) **TABLE OF CONTENTS.**—The table of contents of
 7 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.

TITLE IV—THRIFT SAVINGS PLAN ENHANCEMENT

- Sec. 401. Short title.
- Sec. 402. Automatic enrollments.
- Sec. 403. Qualified Roth contribution program.
- Sec. 404. Authority to establish self-directed investment window.
- Sec. 405. Reporting requirements.
- Sec. 406. Acknowledgement of risk.
- Sec. 407. Credit for unused sick leave.

1 SEC. 2. FINDINGS.

2 The Congress finds the following:

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

7 (2) A consensus exists within the scientific and
8 medical communities that tobacco products are in-
9 herently dangerous and cause cancer, heart disease,
10 and other serious adverse health effects.

11 (3) Nicotine is an addictive drug.

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

15 (5) Tobacco advertising and marketing con-
16 tribute significantly to the use of nicotine-containing
17 tobacco products by adolescents.

1 (6) Because past efforts to restrict advertising
2 and marketing of tobacco products have failed ade-
3 quately to curb tobacco use by adolescents, com-
4 prehensive restrictions on the sale, promotion, and
5 distribution of such products are needed.

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

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

15 (9) Under article I, section 8 of the Constitu-
16 tion, the Congress is vested with the responsibility
17 for regulating interstate commerce and commerce
18 with Indian tribes.

19 (10) The sale, distribution, marketing, adver-
20 tising, and use of tobacco products are activities in
21 and substantially affecting interstate commerce be-
22 cause they are sold, marketed, advertised, and dis-
23 tributed in interstate commerce on a nationwide
24 basis, and have a substantial effect on the Nation's
25 economy.

1 (11) The sale, distribution, marketing, adver-
2 tising, and use of such products substantially affect
3 interstate commerce through the health care and
4 other costs attributable to the use of tobacco prod-
5 ucts.

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

13 (13) Tobacco use is the foremost preventable
14 cause of premature death in America. It causes over
15 400,000 deaths in the United States each year, and
16 approximately 8,600,000 Americans have chronic ill-
17 nesses related to smoking.

18 (14) Reducing the use of tobacco by minors by
19 50 percent would prevent well over 10,000,000 of to-
20 day's children from becoming regular, daily smokers,
21 saving over 3,000,000 of them from premature
22 death due to tobacco-induced disease. Such a reduc-
23 tion in youth smoking would also result in approxi-
24 mately \$75,000,000,000 in savings attributable to
25 reduced health care costs.

1 (15) Advertising, marketing, and promotion of
2 tobacco products have been especially directed to at-
3 tract young persons to use tobacco products, and
4 these efforts have resulted in increased use of such
5 products by youth. Past efforts to oversee these ac-
6 tivities have not been successful in adequately pre-
7 venting such increased use.

8 (16) In 2005, the cigarette manufacturers
9 spent more than \$13,000,000,000 to attract new
10 users, retain current users, increase current con-
11 sumption, and generate favorable long-term atti-
12 tudes toward smoking and tobacco use.

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

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

20 (19) Through advertisements during and spon-
21 sorship of sporting events, tobacco has become
22 strongly associated with sports and has become por-
23 trayed as an integral part of sports and the healthy
24 lifestyle associated with rigorous sporting activity.

1 (20) Children are exposed to substantial and
2 unavoidable tobacco advertising that leads to favor-
3 able beliefs about tobacco use, plays a role in leading
4 young people to overestimate the prevalence of to-
5 bacco use, and increases the number of young people
6 who begin to use tobacco.

7 (21) The use of tobacco products in motion pic-
8 tures and other mass media glamorizes its use for
9 young people and encourages them to use tobacco
10 products.

11 (22) Tobacco advertising expands the size of
12 the tobacco market by increasing consumption of to-
13 bacco products including tobacco use by young peo-
14 ple.

15 (23) Children are more influenced by tobacco
16 marketing than adults: more than 80 percent of
17 youth smoke three heavily marketed brands, while
18 only 54 percent of adults, 26 and older, smoke these
19 same brands.

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

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

4 (26) Restrictions on advertising are necessary
5 to prevent unrestricted tobacco advertising from un-
6 dermining legislation prohibiting access to young
7 people and providing for education about tobacco
8 use.

9 (27) International experience shows that adver-
10 tising regulations that are stringent and comprehen-
11 sive have a greater impact on overall tobacco use
12 and young people's use than weaker or less com-
13 prehensive ones.

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

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

21 (30) The final regulations promulgated by the
22 Secretary of Health and Human Services in the Au-
23 gust 28, 1996, issue of the Federal Register (61
24 Fed. Reg. 44615–44618) for inclusion as part 897
25 of title 21, Code of Federal Regulations, are con-

1 sistent with the first amendment to the United
2 States Constitution and with the standards set forth
3 in the amendments made by this subtitle for the reg-
4 ulation of tobacco products by the Food and Drug
5 Administration, and the restriction on the sale and
6 distribution of, including access to and the adver-
7 tising and promotion of, tobacco products contained
8 in such regulations are substantially related to ac-
9 complishing the public health goals of this Act.

10 (31) The regulations described in paragraph
11 (30) will directly and materially advance the Federal
12 Government's substantial interest in reducing the
13 number of children and adolescents who use ciga-
14 rettes and smokeless tobacco and in preventing the
15 life-threatening health consequences associated with
16 tobacco use. An overwhelming majority of Americans
17 who use tobacco products begin using such products
18 while they are minors and become addicted to the
19 nicotine in those products before reaching the age of
20 18. Tobacco advertising and promotion play a cru-
21 cial role in the decision of these minors to begin
22 using tobacco products. Less restrictive and less
23 comprehensive approaches have not and will not be
24 effective in reducing the problems addressed by such
25 regulations. The reasonable restrictions on the ad-

1 advertising and promotion of tobacco products con-
2 tained in such regulations will lead to a significant
3 decrease in the number of minors using and becom-
4 ing addicted to those products.

5 (32) The regulations described in paragraph
6 (30) impose no more extensive restrictions on com-
7 munication by tobacco manufacturers and sellers
8 than are necessary to reduce the number of children
9 and adolescents who use cigarettes and smokeless to-
10 bacco and to prevent the life-threatening health con-
11 sequences associated with tobacco use. Such regula-
12 tions are narrowly tailored to restrict those adver-
13 tising and promotional practices which are most like-
14 ly to be seen or heard by youth and most likely to
15 entice them into tobacco use, while affording tobacco
16 manufacturers and sellers ample opportunity to con-
17 vey information about their products to adult con-
18 sumers.

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

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

1 (35) Tobacco products have been used to facili-
2 tate and finance criminal activities both domestically
3 and internationally. Illicit trade of tobacco products
4 has been linked to organized crime and terrorist
5 groups.

6 (36) It is essential that the Food and Drug Ad-
7 ministration review products sold or distributed for
8 use to reduce risks or exposures associated with to-
9 bacco products and that it be empowered to review
10 any advertising and labeling for such products. It is
11 also essential that manufacturers, prior to marketing
12 such products, be required to demonstrate that such
13 products will meet a series of rigorous criteria, and
14 will benefit the health of the population as a whole,
15 taking into account both users of tobacco products
16 and persons who do not currently use tobacco prod-
17 ucts.

18 (37) Unless tobacco products that purport to
19 reduce the risks to the public of tobacco use actually
20 reduce such risks, those products can cause substan-
21 tial harm to the public health to the extent that the
22 individuals, who would otherwise not consume to-
23 bacco products or would consume such products less,
24 use tobacco products purporting to reduce risk.
25 Those who use products sold or distributed as modi-

1 fied risk products that do not in fact reduce risk,
2 rather than quitting or reducing their use of tobacco
3 products, have a substantially increased likelihood of
4 suffering disability and premature death. The costs
5 to society of the widespread use of products sold or
6 distributed as modified risk products that do not in
7 fact reduce risk or that increase risk include thou-
8 sands of unnecessary deaths and injuries and huge
9 costs to our health care system.

10 (38) As the National Cancer Institute has
11 found, many smokers mistakenly believe that “low
12 tar” and “light” cigarettes cause fewer health prob-
13 lems than other cigarettes. As the National Cancer
14 Institute has also found, mistaken beliefs about the
15 health consequences of smoking “low tar” and
16 “light” cigarettes can reduce the motivation to quit
17 smoking entirely and thereby lead to disease and
18 death.

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

24 (40) The dangers of products sold or distrib-
25 uted as modified risk tobacco products that do not

1 in fact reduce risk are so high that there is a com-
2 pelling governmental interest in ensuring that state-
3 ments about modified risk tobacco products are com-
4 plete, accurate, and relate to the overall disease risk
5 of the product.

6 (41) As the Federal Trade Commission has
7 found, consumers have misinterpreted advertise-
8 ments in which one product is claimed to be less
9 harmful than a comparable product, even in the
10 presence of disclosures and advisories intended to
11 provide clarification.

12 (42) Permitting manufacturers to make unsub-
13 substantiated statements concerning modified risk to-
14 bacco products, whether express or implied, even if
15 accompanied by disclaimers would be detrimental to
16 the public health.

17 (43) The only way to effectively protect the
18 public health from the dangers of unsubstantiated
19 modified risk tobacco products is to empower the
20 Food and Drug Administration to require that prod-
21 ucts that tobacco manufacturers sold or distributed
22 for risk reduction be reviewed in advance of mar-
23 keting, and to require that the evidence relied on to
24 support claims be fully verified.

1 (44) The Food and Drug Administration is a
2 regulatory agency with the scientific expertise to
3 identify harmful substances in products to which
4 consumers are exposed, to design standards to limit
5 exposure to those substances, to evaluate scientific
6 studies supporting claims about the safety of prod-
7 ucts, and to evaluate the impact of labels, labeling,
8 and advertising on consumer behavior in order to re-
9 duce the risk of harm and promote understanding of
10 the impact of the product on health. In connection
11 with its mandate to promote health and reduce the
12 risk of harm, the Food and Drug Administration
13 routinely makes decisions about whether and how
14 products may be marketed in the United States.

15 (45) The Federal Trade Commission was cre-
16 ated to protect consumers from unfair or deceptive
17 acts or practices, and to regulate unfair methods of
18 competition. Its focus is on those marketplace prac-
19 tices that deceive or mislead consumers, and those
20 that give some competitors an unfair advantage. Its
21 mission is to regulate activities in the marketplace.
22 Neither the Federal Trade Commission nor any
23 other Federal agency except the Food and Drug Ad-
24 ministration possesses the scientific expertise needed

1 to implement effectively all provisions of the Family
2 Smoking Prevention and Tobacco Control Act.

3 (46) If manufacturers state or imply in commu-
4 nications directed to consumers through the media
5 or through a label, labeling, or advertising, that a to-
6 bacco product is approved or inspected by the Food
7 and Drug Administration or complies with Food and
8 Drug Administration standards, consumers are like-
9 ly to be confused and misled. Depending upon the
10 particular language used and its context, such a
11 statement could result in consumers being misled
12 into believing that the product is endorsed by the
13 Food and Drug Administration for use or in con-
14 sumers being misled about the harmfulness of the
15 product because of such regulation, inspection, ap-
16 proval, or compliance.

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

22 (48) In August 2006 a United States district
23 court judge found that the major United States cig-
24 arette companies dramatically increased their adver-
25 tising and promotional spending in ways that en-

1 courage youth to start smoking subsequent to the
2 signing of the Master Settlement Agreement in
3 1998. *USA v. Philip Morris, USA, Inc., et al.* (Civil
4 Action No. 99–2496 (GK), August 17, 2006).

5 (49) In August 2006 a United States district
6 court judge found that the major United States cig-
7 arette companies have designed their cigarettes to
8 precisely control nicotine delivery levels and provide
9 doses of nicotine sufficient to create and sustain ad-
10 diction while also concealing much of their nicotine-
11 related research. *USA v. Philip Morris, USA, Inc.,*
12 *et al.* (Civil Action No. 99–2496 (GK), August 17,
13 2006).

14 **SEC. 3. PURPOSE.**

15 The purposes of this Act are—

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

23 (2) to ensure that the Food and Drug Adminis-
24 tration has the authority to address issues of par-
25 ticular concern to public health officials, especially

1 the use of tobacco by young people and dependence
2 on tobacco;

3 (3) to authorize the Food and Drug Adminis-
4 tration to set national standards controlling the
5 manufacture of tobacco products and the identity,
6 public disclosure, and amount of ingredients used in
7 such products;

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

12 (5) to vest the Food and Drug Administration
13 with the authority to regulate the levels of tar, nico-
14 tine, and other harmful components of tobacco prod-
15 ucts;

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

22 (7) to continue to permit the sale of tobacco
23 products to adults in conjunction with measures to
24 ensure that they are not sold or accessible to under-
25 age purchasers;

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

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

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

8 **SEC. 4. SCOPE AND EFFECT.**

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

11 (1) establish a precedent with regard to any
12 other industry, situation, circumstance, or legal ac-
13 tion; or

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

17 (b) AGRICULTURAL ACTIVITIES.—The provisions of
18 this Act (or an amendment made by this Act) which au-
19 thorize the Secretary to take certain actions with regard
20 to tobacco and tobacco products shall not be construed to
21 affect any authority of the Secretary of Agriculture under
22 existing law regarding the growing, cultivation, or curing
23 of raw tobacco.

24 (c) REVENUE ACTIVITIES.—The provisions of this
25 Act (or an amendment made by this Act) which authorize

1 the Secretary to take certain actions with regard to to-
2 bacco products shall not be construed to affect any author-
3 ity of the Secretary of the Treasury under chapter 52 of
4 the Internal Revenue Code of 1986.

5 **SEC. 5. SEVERABILITY.**

6 If any provision of this Act, the amendments made
7 by this Act, or the application of any provision of this Act
8 to any person or circumstance is held to be invalid, the
9 remainder of this Act, the amendments made by this Act,
10 and the application of the provisions of this Act to any
11 other person or circumstance shall not be affected and
12 shall continue to be enforced to the fullest extent possible.

13 **TITLE I—AUTHORITY OF THE**
14 **FOOD AND DRUG ADMINIS-**
15 **TRATION**

16 **SEC. 101. AMENDMENT OF FEDERAL FOOD, DRUG, AND**
17 **COSMETIC ACT.**

18 (a) DEFINITION OF TOBACCO PRODUCTS.—Section
19 201 of the Federal Food, Drug, and Cosmetic Act (21
20 U.S.C. 321) is amended by adding at the end the fol-
21 lowing:

22 “(rr)(1) The term ‘tobacco product’ means any prod-
23 uct made or derived from tobacco that is intended for
24 human consumption, including any component, part, or
25 accessory of a tobacco product (except for raw materials

1 other than tobacco used in manufacturing a component,
2 part, or accessory of a tobacco product).

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

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

9 “(4) A tobacco product shall not be marketed in com-
10 bination with any other article or product regulated under
11 this Act (including a drug, biologic, food, cosmetic, med-
12 ical device, or a dietary supplement).”.

13 (b) FDA AUTHORITY OVER TOBACCO PRODUCTS.—
14 The Federal Food, Drug, and Cosmetic Act (21 U.S.C.
15 301 et seq.) is amended—

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

17 (2) by redesignating sections 901 through 910
18 as sections 1001 through 1010; and

19 (3) by inserting after chapter VIII the fol-
20 lowing:

21 **“CHAPTER IX—TOBACCO PRODUCTS**

22 **“SEC. 900. DEFINITIONS.**

23 “In this chapter:

24 “(1) ADDITIVE.—The term ‘additive’ means
25 any substance the intended use of which results or

1 may reasonably be expected to result, directly or in-
2 directly, in its becoming a component or otherwise
3 affecting the characteristic of any tobacco product
4 (including any substances intended for use as a fla-
5 voring or coloring or in producing, manufacturing,
6 packing, processing, preparing, treating, packaging,
7 transporting, or holding), except that such term does
8 not include tobacco or a pesticide chemical residue
9 in or on raw tobacco or a pesticide chemical.

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

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

17 “(A) means a product that—

18 “(i) is a tobacco product; and

19 “(ii) meets the definition of the term
20 ‘cigarette’ in section 3(1) of the Federal
21 Cigarette Labeling and Advertising Act;
22 and

23 “(B) includes tobacco, in any form, that is
24 functional in the product, which, because of its
25 appearance, the type of tobacco used in the

1 filler, or its packaging and labeling, is likely to
2 be offered to, or purchased by, consumers as a
3 cigarette or as roll-your-own tobacco.

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

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

13 “(6) COUNTERFEIT TOBACCO PRODUCT.—The
14 term ‘counterfeit tobacco product’ means a tobacco
15 product (or the container or labeling of such a prod-
16 uct) that, without authorization, bears the trade-
17 mark, trade name, or other identifying mark, im-
18 print, or device, or any likeness thereof, of a tobacco
19 product listed in a registration under section
20 905(i)(1).

21 “(7) DISTRIBUTOR.—The term ‘distributor’ as
22 regards a tobacco product means any person who
23 furthers the distribution of a tobacco product,
24 whether domestic or imported, at any point from the
25 original place of manufacture to the person who sells

1 or distributes the product to individuals for personal
2 consumption. Common carriers are not considered
3 distributors for purposes of this chapter.

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

10 “(9) INDIAN COUNTRY.—The term ‘Indian
11 country’ has the meaning given such term in section
12 1151 of title 18, United States Code.

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

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

19 “(A) is a tobacco product; and

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

23 “(12) NICOTINE.—The term ‘nicotine’ means
24 the chemical substance named 3-(1-Methyl-2-

1 pyrrolidiny] pyridine or C[10]H[14]N[2], including
2 any salt or complex of nicotine.

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

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

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

19 “(16) SMALL TOBACCO PRODUCT MANUFAC-
20 Turer.—The term ‘small tobacco product manufac-
21 turer’ means a tobacco product manufacturer that
22 employs fewer than 350 employees. For purposes of
23 determining the number of employees of a manufac-
24 turer under the preceding sentence, the employees of
25 a manufacturer are deemed to include the employees

1 of each entity that controls, is controlled by, or is
2 under common control with such manufacturer.

3 “(17) SMOKE CONSTITUENT.—The term ‘smoke
4 constituent’ means any chemical or chemical com-
5 pound in mainstream or sidestream tobacco smoke
6 that either transfers from any component of the cig-
7 arette to the smoke or that is formed by the combus-
8 tion or heating of tobacco, additives, or other compo-
9 nent of the tobacco product.

10 “(18) SMOKELESS TOBACCO.—The term
11 ‘smokeless tobacco’ means any tobacco product that
12 consists of cut, ground, powdered, or leaf tobacco
13 and that is intended to be placed in the oral or nasal
14 cavity.

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

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

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

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

25 “(21) TOBACCO WAREHOUSE.—

1 “(A) Subject to subparagraphs (B) and
2 (C), the term ‘tobacco warehouse’ includes any
3 person—

4 “(i) who—

5 “(I) removes foreign material
6 from tobacco leaf through nothing
7 other than a mechanical process;

8 “(II) humidifies tobacco leaf with
9 nothing other than potable water in
10 the form of steam or mist; or

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

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

15 “(iii) who provides to any manufac-
16 turer to whom the person sells tobacco all
17 information related to the person’s actions
18 described in clause (i) that is necessary for
19 compliance with this Act.

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

22 “(i) reconstitutes tobacco leaf;

23 “(ii) is a manufacturer, distributor, or
24 retailer of a tobacco product; or

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

4 “(C) The definition of the term ‘tobacco
5 warehouse’ in subparagraph (A) shall not apply
6 to the extent to which the Secretary determines,
7 through rulemaking, that regulation under this
8 chapter of the actions described in such sub-
9 paragraph is appropriate for the protection of
10 the public health.

11 “(22) UNITED STATES.—The term ‘United
12 States’ means the 50 States of the United States of
13 America and the District of Columbia, the Common-
14 wealth of Puerto Rico, Guam, the Virgin Islands,
15 American Samoa, Wake Island, Midway Islands,
16 Kingman Reef, Johnston Atoll, the Northern Mar-
17 iana Islands, and any other trust territory or posses-
18 sion of the United States.

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

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

1 “(b) APPLICABILITY.—This chapter shall apply to all
2 cigarettes, cigarette tobacco, roll-your-own tobacco, and
3 smokeless tobacco and to any other tobacco products that
4 the Secretary by regulation deems to be subject to this
5 chapter.

6 “(c) SCOPE.—

7 “(1) IN GENERAL.—Nothing in this chapter, or
8 any policy issued or regulation promulgated there-
9 under, or in sections 101(a), 102, or 103 of title I,
10 title II, or title III of the Family Smoking Preven-
11 tion and Tobacco Control Act, shall be construed to
12 affect, expand, or limit the Secretary’s authority
13 over (including the authority to determine whether
14 products may be regulated), or the regulation of,
15 products under this Act that are not tobacco prod-
16 ucts under chapter V or any other chapter.

17 “(2) LIMITATION OF AUTHORITY.—

18 “(A) IN GENERAL.—The provisions of this
19 chapter shall not apply to tobacco leaf that is
20 not in the possession of a manufacturer of to-
21 bacco products, or to the producers of tobacco
22 leaf, including tobacco growers, tobacco ware-
23 houses, and tobacco grower cooperatives, nor
24 shall any employee of the Food and Drug Ad-
25 ministration have any authority to enter onto a

1 farm owned by a producer of tobacco leaf with-
2 out the written consent of such producer.

3 “(B) EXCEPTION.—Notwithstanding sub-
4 paragraph (A), if a producer of tobacco leaf is
5 also a tobacco product manufacturer or con-
6 trolled by a tobacco product manufacturer, the
7 producer shall be subject to this chapter in the
8 producer’s capacity as a manufacturer. The ex-
9 ception in this subparagraph shall not apply to
10 a producer of tobacco leaf who grows tobacco
11 under a contract with a tobacco product manu-
12 facturer and who is not otherwise engaged in
13 the manufacturing process.

14 “(C) RULE OF CONSTRUCTION.—Nothing
15 in this chapter shall be construed to grant the
16 Secretary authority to promulgate regulations
17 on any matter that involves the production of
18 tobacco leaf or a producer thereof, other than
19 activities by a manufacturer affecting produc-
20 tion.

21 “(d) RULEMAKING PROCEDURES.—Each rulemaking
22 under this chapter shall be in accordance with chapter 5
23 of title 5, United States Code. This subsection shall not
24 be construed to affect the rulemaking provisions of section

1 102(a) of the Family Smoking Prevention and Tobacco
2 Control Act.

3 “(e) CENTER FOR TOBACCO PRODUCTS.—Not later
4 than 90 days after the date of enactment of the Family
5 Smoking Prevention and Tobacco Control Act, the Sec-
6 retary shall establish within the Food and Drug Adminis-
7 tration the Center for Tobacco Products, which shall re-
8 port to the Commissioner of Food and Drugs in the same
9 manner as the other agency centers within the Food and
10 Drug Administration. The Center shall be responsible for
11 the implementation of this chapter and related matters as-
12 signed by the Commissioner.

13 “(f) OFFICE TO ASSIST SMALL TOBACCO PRODUCT
14 MANUFACTURERS.—The Secretary shall establish within
15 the Food and Drug Administration an identifiable office
16 to provide technical and other nonfinancial assistance to
17 small tobacco product manufacturers to assist them in
18 complying with the requirements of this Act.

19 “(g) CONSULTATION PRIOR TO RULEMAKING.—Prior
20 to promulgating rules under this chapter, the Secretary
21 shall endeavor to consult with other Federal agencies as
22 appropriate.

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

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

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

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

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

13 “(4) the manufacturer or importer of the to-
14 bacco product fails to pay a user fee assessed to
15 such manufacturer or importer pursuant to section
16 919 by the date specified in section 919 or by the
17 30th day after final agency action on a resolution of
18 any dispute as to the amount of such fee;

19 “(5) it is, or purports to be or is represented
20 as, a tobacco product which is subject to a tobacco
21 product standard established under section 907 un-
22 less such tobacco product is in all respects in con-
23 formity with such standard;

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

4 “(B) it is in violation of an order under section
5 910(c)(1)(A);

6 “(7) the methods used in, or the facilities or
7 controls used for, its manufacture, packing, or stor-
8 age are not in conformity with applicable require-
9 ments under section 906(e)(1) or an applicable con-
10 dition prescribed by an order under section
11 906(e)(2); or

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

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

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

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

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

20 “(A) the name and place of business of the
21 tobacco product manufacturer, packer, or dis-
22 tributor;

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

1 “(C) an accurate statement of the percent-
2 age of the tobacco used in the product that is
3 domestically grown tobacco and the percentage
4 that is foreign grown tobacco; and

5 “(D) the statement required under section
6 920(a),
7 except that under subparagraph (B) reasonable vari-
8 ations shall be permitted, and exemptions as to
9 small packages shall be established, by regulations
10 prescribed by the Secretary;

11 “(3) if any word, statement, or other informa-
12 tion required by or under authority of this chapter
13 to appear on the label or labeling is not prominently
14 placed thereon with such conspicuousness (as com-
15 pared with other words, statements, or designs in
16 the labeling) and in such terms as to render it likely
17 to be read and understood by the ordinary individual
18 under customary conditions of purchase and use;

19 “(4) if it has an established name, unless its
20 label bears, to the exclusion of any other nonpropri-
21 etary name, its established name prominently print-
22 ed in type as required by the Secretary by regula-
23 tion;

24 “(5) if the Secretary has issued regulations re-
25 quiring that its labeling bear adequate directions for

1 use, or adequate warnings against use by children,
2 that are necessary for the protection of users unless
3 its labeling conforms in all respects to such regula-
4 tions;

5 “(6) if it was manufactured, prepared, propa-
6 gated, compounded, or processed in an establishment
7 not duly registered under section 905(b), 905(c),
8 905(d), or 905(h), if it was not included in a list re-
9 quired by section 905(i), if a notice or other infor-
10 mation respecting it was not provided as required by
11 such section or section 905(j), or if it does not bear
12 such symbols from the uniform system for identifica-
13 tion of tobacco products prescribed under section
14 905(e) as the Secretary by regulation requires;

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

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

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

21 “(8) unless, in the case of any tobacco product
22 distributed or offered for sale in any State, the man-
23 ufacturer, packer, or distributor thereof includes in
24 all advertisements and other descriptive printed mat-
25 ter issued or caused to be issued by the manufac-

1 turer, packer, or distributor with respect to that to-
2 bacco product—

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

6 “(B) a brief statement of—

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

10 “(ii) in the case of specific tobacco
11 products made subject to a finding by the
12 Secretary after notice and opportunity for
13 comment that such action is appropriate to
14 protect the public health, a full description
15 of the components of such tobacco product
16 or the formula showing quantitatively each
17 ingredient of such tobacco product to the
18 extent required in regulations which shall
19 be issued by the Secretary after an oppor-
20 tunity for a hearing;

21 “(9) if it is a tobacco product subject to a to-
22 bacco product standard established under section
23 907, unless it bears such labeling as may be pre-
24 scribed in such tobacco product standard; or

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

1 “(1) Not later than 6 months after the date of
2 enactment of the Family Smoking Prevention and
3 Tobacco Control Act, a listing of all ingredients, in-
4 cluding tobacco, substances, compounds, and addi-
5 tives that are, as of such date, added by the manu-
6 facturer to the tobacco, paper, filter, or other part
7 of each tobacco product by brand and by quantity in
8 each brand and subbrand.

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

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

1 reporting information under this paragraph, where ap-
2 plicable.

3 “(4) Beginning 6 months after the date of en-
4 actment of the Family Smoking Prevention and To-
5 bacco Control Act, all documents developed after
6 such date of enactment that relate to health, toxi-
7 cological, behavioral, or physiologic effects of current
8 or future tobacco products, their constituents (in-
9 cluding smoke constituents), ingredients, compo-
10 nents, and additives.

11 “(b) DATA SUBMISSION.—At the request of the Sec-
12 retary, each tobacco product manufacturer or importer of
13 tobacco products, or agents thereof, shall submit the fol-
14 lowing:

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

23 “(2) Any or all documents (including under-
24 lying scientific information) relating to research ac-
25 tivities, and research findings, conducted, supported,

1 or possessed by the manufacturer (or agents thereof)
2 that relate to the issue of whether a reduction in
3 risk to health from tobacco products can occur upon
4 the employment of technology available or known to
5 the manufacturer.

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

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

15 “(c) TIME FOR SUBMISSION.—

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

23 “(2) DISCLOSURE OF ADDITIVE.—If at any
24 time a tobacco product manufacturer adds to its to-
25 bacco products a new tobacco additive or increases

1 the quantity of an existing tobacco additive, the
2 manufacturer shall, except as provided in paragraph
3 (3), at least 90 days prior to such action so advise
4 the Secretary in writing.

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

14 “(d) DATA LIST.—

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

23 “(2) CONSUMER RESEARCH.—The Secretary
24 shall conduct periodic consumer research to ensure
25 that the list published under paragraph (1) is not

1 misleading to lay persons. Not later than 5 years
2 after the date of enactment of the Family Smoking
3 Prevention and Tobacco Control Act, the Secretary
4 shall submit to the appropriate committees of Con-
5 gress a report on the results of such research, to-
6 gether with recommendations on whether such publi-
7 cation should be continued or modified.

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

19 **“SEC. 905. ANNUAL REGISTRATION.**

20 “(a) DEFINITIONS.—In this section:

21 “(1) MANUFACTURE, PREPARATION,
22 COMPOUNDING, OR PROCESSING.—The term
23 ‘manufacture, preparation, compounding, or proc-
24 essing’ shall include repackaging or otherwise chang-
25 ing the container, wrapper, or labeling of any to-

1 bacco product package in furtherance of the dis-
2 tribution of the tobacco product from the original
3 place of manufacture to the person who makes final
4 delivery or sale to the ultimate consumer or user.

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

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

22 “(c) REGISTRATION BY NEW OWNERS AND OPERA-
23 TORS.—Every person upon first engaging in the manufac-
24 ture, preparation, compounding, or processing of a tobacco
25 product or tobacco products in any establishment owned

1 or operated in any State by that person shall immediately
2 register with the Secretary that person's name, place of
3 business, and such establishment.

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

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

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

21 “(g) BIENNIAL INSPECTION OF REGISTERED ESTAB-
22 LISHMENTS.—Every establishment registered with the
23 Secretary under this section shall be subject to inspection
24 under section 704 or subsection (h), and every such estab-
25 lishment engaged in the manufacture, compounding, or

1 processing of a tobacco product or tobacco products shall
2 be so inspected by 1 or more officers or employees duly
3 designated by the Secretary at least once in the 2-year
4 period beginning with the date of registration of such es-
5 tablishment under this section and at least once in every
6 successive 2-year period thereafter.

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

23 “(i) REGISTRATION INFORMATION.—

24 “(1) PRODUCT LIST.—Every person who reg-
25 isters with the Secretary under subsection (b), (c),

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

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

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

1 good cause, a copy of all advertisements for a
2 particular tobacco product; and

3 “(C) if the registrant filing a list has de-
4 termined that a tobacco product contained in
5 such list is not subject to a tobacco product
6 standard established under section 907, a brief
7 statement of the basis upon which the reg-
8 istrant made such determination if the Sec-
9 retary requests such a statement with respect
10 to that particular tobacco product.

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

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

24 “(A) A list of each tobacco product intro-
25 duced by the registrant for commercial distribu-

1 tion which has not been included in any list
2 previously filed by that person with the Sec-
3 retary under this subparagraph or paragraph
4 (1). A list under this subparagraph shall list a
5 tobacco product by its established name and
6 shall be accompanied by the other information
7 required by paragraph (1).

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

17 “(C) If since the date the registrant re-
18 ported under subparagraph (B) a notice of dis-
19 continuance that person has resumed the manu-
20 facture, preparation, compounding, or proc-
21 essing for commercial distribution of the to-
22 bacco product with respect to which such notice
23 of discontinuance was reported, notice of such
24 resumption, the date of such resumption, the
25 identity of such tobacco product by established

1 name, and other information required by para-
2 graph (1), unless the registrant has previously
3 reported such resumption to the Secretary
4 under this subparagraph.

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

8 “(j) REPORT PRECEDING INTRODUCTION OF CER-
9 TAIN SUBSTANTIALLY EQUIVALENT PRODUCTS INTO
10 INTERSTATE COMMERCE.—

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

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

24 “(i) the tobacco product is substan-
25 tially equivalent, within the meaning of

1 section 910, to a tobacco product commer-
2 cially marketed (other than for test mar-
3 keting) in the United States as of Feb-
4 ruary 15, 2007, or to a tobacco product
5 that the Secretary has previously deter-
6 mined, pursuant to subsection (a)(3) of
7 section 910, is substantially equivalent and
8 that is in compliance with the require-
9 ments of this Act; or

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

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

21 “(2) APPLICATION TO CERTAIN POST-FEB-
22 RUARY 15, 2007, PRODUCTS.—A report under this
23 subsection for a tobacco product that was first intro-
24 duced or delivered for introduction into interstate
25 commerce for commercial distribution in the United

1 States after February 15, 2007, and prior to the
2 date that is 21 months after the date of enactment
3 of the Family Smoking Prevention and Tobacco
4 Control Act shall be submitted to the Secretary not
5 later than 21 months after such date of enactment.

6 “(3) EXEMPTIONS.—

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

16 “(i) such modification would be a
17 minor modification of a tobacco product
18 that can be sold under this Act;

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

24 “(iii) an exemption is otherwise appro-
25 priate.

1 “(B) REGULATIONS.—Not later than 15
2 months after the date of enactment of the Fam-
3 ily Smoking Prevention and Tobacco Control
4 Act, the Secretary shall issue regulations to im-
5 plement this paragraph.

6 **“SEC. 906. GENERAL PROVISIONS RESPECTING CONTROL**
7 **OF TOBACCO PRODUCTS.**

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

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

1 be made in connection with rulemaking under any such
2 section shall set forth—

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

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

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

25 “(d) RESTRICTIONS.—

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

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

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

23 No such regulation may require that the sale or dis-
24 tribution of a tobacco product be limited to the writ-

1 ten or oral authorization of a practitioner licensed
2 by law to prescribe medical products.

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

8 “(3) LIMITATIONS.—

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

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

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

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

1 treatment of matchbooks is not appropriate for
2 the protection of the public health, the Sec-
3 retary may determine by regulation that match-
4 books shall not be considered adult-written pub-
5 lications.

6 “(4) REMOTE SALES.—

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

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

21 “(ii) within 2 years after such date of
22 enactment, issue regulations to address the
23 promotion and marketing of tobacco prod-
24 ucts that are sold or distributed through
25 means other than a direct, face-to-face ex-

1 change between a retailer and a consumer
2 in order to protect individuals who have
3 not attained the minimum age established
4 by applicable law for the purchase of such
5 products.

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

10 “(e) GOOD MANUFACTURING PRACTICE REQUIRE-
11 MENTS.—

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

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

1 point methodology, as prescribed in such regu-
2 lations to assure that the public health is pro-
3 tected and that the tobacco product is in com-
4 pliance with this chapter. Such regulations may
5 provide for the testing of raw tobacco for pes-
6 ticide chemical residues regardless of whether a
7 tolerance for such chemical residues has been
8 established.

9 “(B) REQUIREMENTS.—The Secretary
10 shall—

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

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

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

1 “(iv) in establishing the effective date
2 of a regulation promulgated under this
3 subsection, take into account the dif-
4 ferences in the manner in which the dif-
5 ferent types of tobacco products have his-
6 torically been produced, the financial re-
7 sources of the different tobacco product
8 manufacturers, and the state of their exist-
9 ing manufacturing facilities, and shall pro-
10 vide for a reasonable period of time for
11 such manufacturers to conform to good
12 manufacturing practices; and

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

19 “(2) EXEMPTIONS; VARIANCES.—

20 “(A) PETITION.—Any person subject to
21 any requirement prescribed under paragraph
22 (1) may petition the Secretary for a permanent
23 or temporary exemption or variance from such
24 requirement. Such a petition shall be submitted

1 to the Secretary in such form and manner as
2 the Secretary shall prescribe and shall—

3 “(i) in the case of a petition for an ex-
4 emption from a requirement, set forth the
5 basis for the petitioner’s determination
6 that compliance with the requirement is
7 not required to assure that the tobacco
8 product will be in compliance with this
9 chapter;

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

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

20 “(B) REFERRAL TO THE TOBACCO PROD-
21 UCTS SCIENTIFIC ADVISORY COMMITTEE.—The
22 Secretary may refer to the Tobacco Products
23 Scientific Advisory Committee any petition sub-
24 mitted under subparagraph (A). The Tobacco
25 Products Scientific Advisory Committee shall

1 report its recommendations to the Secretary
2 with respect to a petition referred to it within
3 60 days after the date of the petition's referral.

4 Within 60 days after—

5 “(i) the date the petition was sub-
6 mitted to the Secretary under subpara-
7 graph (A); or

8 “(ii) the day after the petition was re-
9 ferred to the Tobacco Products Scientific
10 Advisory Committee,

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

13 “(C) APPROVAL.—The Secretary may ap-
14 prove—

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

21 “(ii) a petition for a variance for a to-
22 bacco product from a requirement if the
23 Secretary determines that the methods to
24 be used in, and the facilities and controls
25 to be used for, the manufacture, packing,

1 and storage of the tobacco product in lieu
2 of the methods, facilities, and controls pre-
3 scribed by the requirement are sufficient to
4 assure that the tobacco product will be in
5 compliance with this chapter.

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

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

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

24 “(f) RESEARCH AND DEVELOPMENT.—The Secretary
25 may enter into contracts for research, testing, and dem-

1 onstrations respecting tobacco products and may obtain
2 tobacco products for research, testing, and demonstration
3 purposes.

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

5 “(a) IN GENERAL.—

6 “(1) SPECIAL RULES.—

7 “(A) SPECIAL RULE FOR CIGARETTES.—

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

1 “(B) ADDITIONAL SPECIAL RULE.—Begin-
2 ning 2 years after the date of enactment of the
3 Family Smoking Prevention and Tobacco Con-
4 trol Act, a tobacco product manufacturer shall
5 not use tobacco, including foreign grown to-
6 bacco, that contains a pesticide chemical res-
7 idue that is at a level greater than is specified
8 by any tolerance applicable under Federal law
9 to domestically grown tobacco.

10 “(2) REVISION OF TOBACCO PRODUCT STAND-
11 ARDS.—The Secretary may revise the tobacco prod-
12 uct standards in paragraph (1) in accordance with
13 subsection (c).

14 “(3) TOBACCO PRODUCT STANDARDS.—

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

20 “(B) DETERMINATIONS.—

21 “(i) CONSIDERATIONS.—In making a
22 finding described in subparagraph (A), the
23 Secretary shall consider scientific evidence
24 concerning—

1 “(I) the risks and benefits to the
2 population as a whole, including users
3 and nonusers of tobacco products, of
4 the proposed standard;

5 “(II) the increased or decreased
6 likelihood that existing users of to-
7 bacco products will stop using such
8 products; and

9 “(III) the increased or decreased
10 likelihood that those who do not use
11 tobacco products will start using such
12 products.

13 “(ii) ADDITIONAL CONSIDER-
14 ATIONS.—In the event that the Secretary
15 makes a determination, set forth in a pro-
16 posed tobacco product standard in a pro-
17 posed rule, that it is appropriate for the
18 protection of public health to require the
19 reduction or elimination of an additive,
20 constituent (including a smoke constitu-
21 ent), or other component of a tobacco
22 product because the Secretary has found
23 that the additive, constituent, or other
24 component is or may be harmful, any
25 party objecting to the proposed standard

1 on the ground that the proposed standard
2 will not reduce or eliminate the risk of ill-
3 ness or injury may provide for the Sec-
4 retary's consideration scientific evidence
5 that demonstrates that the proposed stand-
6 ard will not reduce or eliminate the risk of
7 illness or injury.

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

11 “(A) shall include provisions that are ap-
12 propriate for the protection of the public health,
13 including provisions, where appropriate—

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

15 “(ii) for the reduction or elimination
16 of other constituents, including smoke con-
17 stituents, or harmful components of the
18 product; or

19 “(iii) relating to any other require-
20 ment under subparagraph (B);

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

23 “(i) provisions respecting the con-
24 struction, components, ingredients, addi-
25 tives, constituents, including smoke con-

1 stituents, and properties of the tobacco
2 product;

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

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

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

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

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

1 “(D) shall require tobacco products con-
2 taining foreign-grown tobacco to meet the same
3 standards applicable to tobacco products con-
4 taining domestically grown tobacco.

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

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

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

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

23 “(C) invite appropriate participation,
24 through joint or other conferences, workshops,
25 or other means, by informed persons represent-

1 ative of scientific, professional, industry, agri-
2 cultural, or consumer organizations who in the
3 Secretary's judgment can make a significant
4 contribution.

5 “(b) CONSIDERATIONS BY SECRETARY.—

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

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

20 “(c) PROPOSED STANDARDS.—

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

1 “(2) REQUIREMENTS OF NOTICE.—A notice of
2 proposed rulemaking for the establishment or
3 amendment of a tobacco product standard for a to-
4 bacco product shall—

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

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

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

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

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

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

3 “(d) PROMULGATION.—

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

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

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

20 “(2) EFFECTIVE DATE.—A regulation estab-
21 lishing a tobacco product standard shall set forth
22 the date or dates upon which the standard shall take
23 effect, but no such regulation may take effect before
24 1 year after the date of its publication unless the
25 Secretary determines that an earlier effective date is

1 necessary for the protection of the public health.
2 Such date or dates shall be established so as to min-
3 imize, consistent with the public health, economic
4 loss to, and disruption or dislocation of, domestic
5 and international trade. In establishing such effec-
6 tive date or dates, the Secretary shall consider infor-
7 mation submitted in connection with a proposed
8 product standard by interested parties, including
9 manufacturers and tobacco growers, regarding the
10 technical achievability of compliance with the stand-
11 ard, and including information concerning the exist-
12 ence of patents that make it impossible to comply in
13 the timeframe envisioned in the proposed standard.
14 If the Secretary determines, based on the Sec-
15 retary's evaluation of submitted comments, that a
16 product standard can be met only by manufacturers
17 requiring substantial changes to the methods of
18 farming the domestically grown tobacco used by the
19 manufacturer, the effective date of that product
20 standard shall be not less than 2 years after the
21 date of publication of the final regulation estab-
22 lishing the standard.

23 “(3) LIMITATION ON POWER GRANTED TO THE
24 FOOD AND DRUG ADMINISTRATION.—Because of the

1 importance of a decision of the Secretary to issue a
2 regulation—

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

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

11 “(4) AMENDMENT; REVOCATION.—

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

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

1 “(5) REFERRAL TO ADVISORY COMMITTEE.—

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

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

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

14 or

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

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

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

22 “(C) PROVISION OF DATA.—If a proposed
23 regulation is referred under this paragraph to
24 the Tobacco Products Scientific Advisory Com-
25 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 African Americans, Hispanics, and
2 other racial and ethnic minorities. In its review, the
3 Tobacco Products Scientific Advisory Committee
4 shall address the considerations listed in subsections
5 (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 tigations 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) 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. Until
5 such date, other amounts available to the
6 Food and Drug Administration (excluding
7 fees collected under subsection (a)) are au-
8 thorized to be made available to pay the
9 costs described in subparagraph (A), pro-
10 vided that such amounts are reimbursed
11 through fees collected under subsection (a).

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

17 “(d) COLLECTION OF UNPAID FEES.—In any case
18 where the Secretary does not receive payment of a fee as-
19 sessed under subsection (a) within 30 days after it is due,
20 such fee shall be treated as a claim of the United States
21 Government subject to subchapter II of chapter 37 of title
22 31, United States Code.

23 “(e) APPLICABILITY TO FISCAL YEAR 2009.—If the
24 date of enactment of the Family Smoking Prevention and

1 Tobacco Control Act occurs during fiscal year 2009, the
2 following applies, subject to subsection (c):

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

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

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

22 **SEC. 102. FINAL RULE.**

23 (a) CIGARETTES AND SMOKELESS TOBACCO.—

24 (1) IN GENERAL.—On the first day of publica-
25 tion of the Federal Register that is 180 days or

1 more after the date of enactment of this Act, the
2 Secretary of Health and Human Services shall pub-
3 lish in the Federal Register a final rule regarding
4 cigarettes and smokeless tobacco, which—

5 (A) is deemed to be issued under chapter
6 9 of the Federal Food, Drug, and Cosmetic
7 Act, as added by section 101 of this Act; and

8 (B) shall be deemed to be in compliance
9 with all applicable provisions of chapter 5 of
10 title 5, United States Code, and all other provi-
11 sions of law relating to rulemaking procedures.

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

19 (A) provide for the designation of jurisdic-
20 tional authority that is in accordance with this
21 subsection in accordance with this Act and the
22 amendments made by this Act;

23 (B) strike Subpart C—Labels and section
24 897.32(c);

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

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

9 (E) become effective on the date that is 1
10 year after the date of enactment of this Act;
11 and

12 (F) amend paragraph (d) of section 897.16
13 to read as follows:

14 “(d)(1) Except as provided in subparagraph (2), no
15 manufacturer, distributor, or retailer may distribute or
16 cause to be distributed any free samples of cigarettes,
17 smokeless tobacco, or other tobacco products (as such
18 term is defined in section 201 of the Federal Food, Drug,
19 and Cosmetic Act).

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

24 “(B) This subparagraph does not affect the authority
25 of a State or local government to prohibit or otherwise

1 restrict the distribution of free samples of smokeless to-
2 bacco.

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

6 “(i) requires each person present to provide to
7 a law enforcement officer (whether on or off duty)
8 or to a security guard licensed by a governmental
9 entity government-issued identification showing a
10 photograph and at least the minimum age estab-
11 lished by applicable law for the purchase of smoke-
12 less tobacco;

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

14 “(iii) is not located adjacent to or immediately
15 across from (in any direction) a space that is used
16 primarily for youth-oriented marketing, promotional,
17 or other activities;

18 “(iv) is a temporary structure constructed, des-
19 igned, and operated as a distinct enclosed area for
20 the purpose of distributing free samples of smokeless
21 tobacco in accordance with this subparagraph; and

22 “(v) is enclosed by a barrier that—

23 “(I) is constructed of, or covered with, an
24 opaque material (except for entrances and
25 exits);

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

7 “(III) prevents persons outside the quali-
8 fied adult-only facility from seeing into the
9 qualified adult-only facility, unless they make
10 unreasonable efforts to do so; and

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

12 “(I) any tobacco product advertising;

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

16 “(III) any combination of words that
17 would imply to a reasonable observer that the
18 manufacturer, distributor, or retailer has a
19 sponsorship that would violate section
20 897.34(c).

21 “(D) Distribution of samples of smokeless tobacco
22 under this subparagraph permitted to be taken out of the
23 qualified adult-only facility shall be limited to 1 package
24 per adult consumer containing no more than 0.53 ounces
25 (15 grams) of smokeless tobacco. If such package of

1 smokeless tobacco contains individual portions of smoke-
2 less tobacco, the individual portions of smokeless tobacco
3 shall not exceed 8 individual portions and the collective
4 weight of such individual portions shall not exceed 0.53
5 ounces (15 grams). Any manufacturer, distributor, or re-
6 tailer who distributes or causes to be distributed free sam-
7 ples also shall take reasonable steps to ensure that the
8 above amounts are limited to one such package per adult
9 consumer per day.

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

13 “(A) to a sports team or entertainment group;
14 or

15 “(B) at any football, basketball, baseball, soc-
16 cer, or hockey event or any other sporting or enter-
17 tainment event determined by the Secretary to be
18 covered by this subparagraph.

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

24 “(5) Nothing in this paragraph shall be construed to
25 authorize any person to distribute or cause to be distrib-

1 uted any sample of a tobacco product to any individual
2 who has not attained the minimum age established by ap-
3 plicable law for the purchase of such product.”.

4 (3) AMENDMENTS TO RULE.—Prior to making
5 amendments to the rule published under paragraph
6 (1), the Secretary shall promulgate a proposed rule
7 in accordance with chapter 5 of title 5, United
8 States Code.

9 (4) RULE OF CONSTRUCTION.—Except as pro-
10 vided in paragraph (3), nothing in this section shall
11 be construed to limit the authority of the Secretary
12 to amend, in accordance with chapter 5 of title 5,
13 United States Code, the regulation promulgated pur-
14 suant to this section, including the provisions of
15 such regulation relating to distribution of free sam-
16 ples.

17 (5) ENFORCEMENT OF RETAIL SALE PROVI-
18 SIONS.—The Secretary of Health and Human Serv-
19 ices shall ensure that the provisions of this Act, the
20 amendments made by this Act, and the imple-
21 menting regulations (including such provisions,
22 amendments, and regulations relating to the retail
23 sale of tobacco products) are enforced with respect
24 to the United States and Indian tribes.

1 (6) QUALIFIED ADULT-ONLY FACILITY.—A
2 qualified adult-only facility (as such term is defined
3 in section 897.16(d) of the final rule published
4 under paragraph (1)) that is also a retailer and that
5 commits a violation as a retailer shall not be subject
6 to the limitations in section 103(q) and shall be sub-
7 ject to penalties applicable to a qualified adult-only
8 facility.

9 (7) CONGRESSIONAL REVIEW PROVISIONS.—
10 Section 801 of title 5, United States Code, shall not
11 apply to the final rule published under paragraph
12 (1).

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

21 (1) The preamble to the proposed rule in the
22 document titled “Regulations Restricting the Sale
23 and Distribution of Cigarettes and Smokeless To-
24 bacco Products to Protect Children and Adoles-

1 cents” (60 Fed. Reg. 41314–41372 (August 11,
2 1995)).

3 (2) The document titled “Nicotine in Cigarettes
4 and Smokeless Tobacco Products is a Drug and
5 These Products Are Nicotine Delivery Devices
6 Under the Federal Food, Drug, and Cosmetic Act”
7 (60 Fed. Reg. 41453–41787 (August 11, 1995)).

8 (3) The preamble to the final rule in the docu-
9 ment titled “Regulations Restricting the Sale and
10 Distribution of Cigarettes and Smokeless Tobacco to
11 Protect Children and Adolescents” (61 Fed. Reg.
12 44396–44615 (August 28, 1996)).

13 (4) The document titled “Nicotine in Cigarettes
14 and Smokeless Tobacco is a Drug and These Prod-
15 ucts are Nicotine Delivery Devices Under the Fed-
16 eral Food, Drug, and Cosmetic Act; Jurisdictional
17 Determination” (61 Fed. Reg. 44619–45318 (Au-
18 gust 28, 1996)).

19 **SEC. 103. CONFORMING AND OTHER AMENDMENTS TO GEN-**
20 **ERAL PROVISIONS.**

21 (a) AMENDMENT OF FEDERAL FOOD, DRUG, AND
22 COSMETIC ACT.—Except as otherwise expressly provided,
23 whenever in this section an amendment is expressed in
24 terms of an amendment to, or repeal of, a section or other
25 provision, the reference is to a section or other provision

1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
2 301 et seq.).

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

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

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

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

11 (4) in subsection (e)—

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

13 and

14 (B) by striking “or 761 or the refusal to
15 permit access to” and inserting “761, 909, or
16 920 or the refusal to permit access to”;

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

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

21 (7) in subsection (j)—

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

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

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

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

5 “(p) The failure to register in accordance with section
6 510 or 905, the failure to provide any information re-
7 quired by section 510(j), 510(k), 905(i), or 905(j), or the
8 failure to provide a notice required by section 510(j)(2)
9 or 905(i)(3).”;

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

12 “(q)(1) The failure or refusal—

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

15 “(B) to furnish any notification or other mate-
16 rial or information required by or under section 519,
17 520(g), 904, 909, or 920; or

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

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

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

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

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

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

6 “(qq)(1) Forging, counterfeiting, simulating, or false-
7 ly representing, or without proper authority using any
8 mark, stamp (including tax stamp), tag, label, or other
9 identification device upon any tobacco product or con-
10 tainer or labeling thereof so as to render such tobacco
11 product a counterfeit tobacco product.

12 “(2) Making, selling, disposing of, or keeping in pos-
13 session, control, or custody, or concealing any punch, die,
14 plate, stone, or other item that is designed to print, im-
15 print, or reproduce the trademark, trade name, or other
16 identifying mark, imprint, or device of another or any like-
17 ness of any of the foregoing upon any tobacco product or
18 container or labeling thereof so as to render such tobacco
19 product a counterfeit tobacco product.

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

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

1 “(ss) The failure of a manufacturer or distributor to
2 notify the Attorney General and the Secretary of the
3 Treasury of their knowledge of tobacco products used in
4 illicit trade.

5 “(tt) With respect to a tobacco product, any state-
6 ment directed to consumers through the media or through
7 the label, labeling, or advertising that would reasonably
8 be expected to result in consumers believing that the prod-
9 uct is regulated, inspected or approved by the Food and
10 Drug Administration, or that the product complies with
11 the requirements of the Food and Drug Administration,
12 including a statement or implication in the label, labeling,
13 or advertising of such product, and that could result in
14 consumers believing that the product is endorsed for use
15 by the Food and Drug Administration or in consumers
16 being misled about the harmfulness of the product because
17 of such regulation, inspection, or compliance.”.

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

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

23 (2) in paragraph (5)—

24 (A) in subparagraph (A)—

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

5 (ii) by striking “penalty” the second
6 time it appears and inserting “penalty, or
7 upon whom a no-tobacco-sale order is to be
8 imposed,”;

9 (B) in subparagraph (B)—

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

13 (ii) by adding at the end the fol-
14 lowing: “A no-tobacco-sale order perma-
15 nently prohibiting an individual retail out-
16 let from selling tobacco products shall in-
17 clude provisions that allow the outlet, after
18 a specified period of time, to request that
19 the Secretary compromise, modify, or ter-
20 minate the order.”; and

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

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

25 (3) in paragraph (6)—

1 (A) by inserting “or the imposition of a
2 no-tobacco-sale order” after the term “penalty”
3 each place such term appears; and

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

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

8 “(8) If the Secretary finds that a person has
9 committed repeated violations of restrictions promul-
10 gated under section 906(d) at a particular retail out-
11 let then the Secretary may impose a no-tobacco-sale
12 order on that person prohibiting the sale of tobacco
13 products in that outlet. A no-tobacco-sale order may
14 be imposed with a civil penalty under paragraph (1).
15 Prior to the entry of a no-sale order under this para-
16 graph, a person shall be entitled to a hearing pursu-
17 ant to the procedures established through regula-
18 tions of the Food and Drug Administration for as-
19 sessing civil money penalties, including at a retailer’s
20 request a hearing by telephone, or at the nearest re-
21 gional or field office of the Food and Drug Adminis-
22 tration, or at a Federal, State, or county facility
23 within 100 miles from the location of the retail out-
24 let, if such a facility is available.”.

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

3 (1) in subsection (a)(2)—

4 (A) by striking “and” before “(D)”; and

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

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

10 (3) in subsection (g)(1), by inserting “or to-
11 bacco product” after the term “device” each place
12 such term appears; and

13 (4) in subsection (g)(2)(A), by inserting “or to-
14 bacco product” after “device”.

15 (e) SECTION 505.—Section 505(n)(2) (21 U.S.C.
16 355(n)(2)) is amended by striking “section 904” and in-
17 serting “section 1004”.

18 (f) SECTION 523.—Section 523(b)(2)(D) (21 U.S.C.
19 360m(b)(2)(D)) is amended by striking “section 903(g)”
20 and inserting “section 1003(g)”.

21 (g) SECTION 702.—Section 702(a)(1) (U.S.C.
22 372(a)(1)) is amended—

23 (1) by striking “(a)(1)” and inserting
24 “(a)(1)(A)”; and

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

1 “(B)(i) For a tobacco product, to the extent feasible,
2 the Secretary shall contract with the States in accordance
3 with this paragraph to carry out inspections of retailers
4 within that State in connection with the enforcement of
5 this Act.

6 “(ii) The Secretary shall not enter into any contract
7 under clause (i) with the government of any of the several
8 States to exercise enforcement authority under this Act
9 on Indian country without the express written consent of
10 the Indian tribe involved.”.

11 (h) SECTION 703.—Section 703 (21 U.S.C. 373) is
12 amended—

13 (1) by inserting “tobacco product,” after the
14 term “device,” each place such term appears; and

15 (2) by inserting “tobacco products,” after the
16 term “devices,” each place such term appears.

17 (i) SECTION 704.—Section 704 (21 U.S.C. 374) is
18 amended—

19 (1) in subsection (a)(1)(A), by inserting “to-
20 bacco products,” after the term “devices,” each
21 place such term appears;

22 (2) in subsection (a)(1)(B), by inserting “or to-
23 bacco products” after the term “restricted devices”
24 each place such term appears;

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

3 (4) in subsection (g)(13), by striking “section
4 903(g)” and inserting “section 1003(g)”.

5 (j) SECTION 705.—Section 705(b) (21 U.S.C.
6 375(b)) is amended by inserting “tobacco products,” after
7 “devices,”.

8 (k) SECTION 709.—Section 709 (21 U.S.C. 379a) is
9 amended by inserting “tobacco product,” after “device,”.

10 (l) SECTION 801.—Section 801 (21 U.S.C. 381) is
11 amended—

12 (1) in subsection (a)—

13 (A) by inserting “tobacco products,” after
14 the term “devices,” ;

15 (B) by inserting “or section 905(h)” after
16 “section 510”; and

17 (C) by striking the term “drugs or de-
18 vices” each time such term appears and insert-
19 ing “drugs, devices, or tobacco products”;

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

22 (3) by adding at the end the following:

23 “(p)(1) Not later than 36 months after the date of
24 enactment of the Family Smoking Prevention and To-
25 bacco Control Act, and annually thereafter, the Secretary

1 shall submit to the Committee on Health, Education,
2 Labor, and Pensions of the Senate and the Committee on
3 Energy and Commerce of the House of Representatives,
4 a report regarding—

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

9 “(B) the public health implications of such ex-
10 ports, including any evidence of a negative public
11 health impact; and

12 “(C) recommendations or assessments of policy
13 alternatives available to Congress and the executive
14 branch to reduce any negative public health impact
15 caused by such exports.

16 “(2) The Secretary is authorized to establish appro-
17 priate information disclosure requirements to carry out
18 this subsection.”.

19 (m) SECTION 1003.—Section 1003(d)(2)(C) (as re-
20 designated by section 101(b)) is amended—

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

22 (2) inserting “, and tobacco products” after
23 “devices”.

1 (n) SECTION 1009.—Section 1009(b) (as redesignig-
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 at least the top

1 30 percent of the front and rear panels of the pack-
2 age. The word ‘WARNING’ shall appear in capital
3 letters and all text shall be in conspicuous and leg-
4 ible 17-point type, unless the text of the label state-
5 ment would occupy more than 70 percent of such
6 area, in which case the text may be in a smaller con-
7 spicuous and legible type size, provided that at least
8 60 percent of such area is occupied by required text.
9 The text shall be black on a white background, or
10 white on a black background, in a manner that con-
11 trasts, by typography, layout, or color, with all other
12 printed material on the package, in an alternating
13 fashion under the plan submitted under subsection
14 (c).

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

21 “(4) APPLICABILITY TO RETAILERS.—A retailer
22 of cigarettes shall not be in violation of this sub-
23 section for packaging that—

24 “(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 may, by a rulemaking conducted under section
25 553 of title 5, United States Code, adjust the format, type

1 size, and text of any of the label requirements, require
2 color graphics to accompany the text, increase the re-
3 quired label area from 30 percent up to 50 percent of the
4 front and rear panels of the package, or establish the for-
5 mat, type size, and text of any other disclosures required
6 under the Federal Food, Drug, and Cosmetic Act, if the
7 Secretary finds that such a change would promote greater
8 public understanding of the risks associated with the use
9 of tobacco products.”.

10 **SEC. 203. STATE REGULATION OF CIGARETTE ADVER-**
11 **TISING AND PROMOTION.**

12 Section 5 of the Federal Cigarette Labeling and Ad-
13 vertising Act (15 U.S.C. 1334) is amended by adding at
14 the end the following:

15 “(c) EXCEPTION.—Notwithstanding subsection (b), a
16 State or locality may enact statutes and promulgate regu-
17 lations, based on smoking and health, that take effect
18 after the effective date of the Family Smoking Prevention
19 and Tobacco Control Act, imposing specific bans or re-
20 strictions on the time, place, and manner, but not content,
21 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 **SEC. 302. STUDY AND REPORT.**

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

11 (1) collect data on cross-border trade in tobacco
12 products, including illicit trade and trade of counter-
13 feit tobacco products and make recommendations on
14 the monitoring of such trade;

15 (2) collect data on cross-border advertising (any
16 advertising intended to be broadcast, transmitted, or
17 distributed from the United States to another coun-
18 try) of tobacco products and make recommendations
19 on how to prevent or eliminate, and what tech-
20 nologies could help facilitate the elimination of,
21 cross-border advertising; and

22 (3) collect data on the health effects (particu-
23 larly with respect to individuals under 18 years of
24 age) resulting from cross-border trade in tobacco

1 products, including the health effects resulting
2 from—

3 (A) the illicit trade of tobacco products
4 and the trade of counterfeit tobacco products;
5 and

6 (B) the differing tax rates applicable to to-
7 bacco products.

8 (b) REPORT.—Not later than 18 months after the
9 date of enactment of this Act, the Comptroller General
10 of the United States shall submit to the Committee on
11 Health, Education, Labor, and Pensions of the Senate and
12 the Committee on Energy and Commerce of the House
13 of Representatives a report on the study described in sub-
14 section (a).

15 (c) DEFINITION.—In this section:

16 (1) The term “cross-border trade” means trade
17 across a border of the United States, a State or Ter-
18 ritory, or Indian country.

19 (2) The term “Indian country” has the mean-
20 ing given to such term in section 1151 of title 18,
21 United States Code.

22 (3) The terms “State” and “Territory” have
23 the meanings given to those terms in section 201 of
24 the Federal Food, Drug, and Cosmetic Act (21
25 U.S.C. 321).

1 **TITLE IV—THRIFT SAVINGS**
2 **PLAN ENHANCEMENT**

3 **SEC. 401. SHORT TITLE.**

4 This title may be cited as the “Thrift Savings Plan
5 Enhancement Act of 2009”.

6 **SEC. 402. AUTOMATIC ENROLLMENTS.**

7 (a) IN GENERAL.—Section 8432(b) of title 5, United
8 States Code, is amended by striking paragraphs (2)
9 through (4) and inserting the following:

10 “(2)(A) The Board shall by regulation provide for an
11 eligible individual to be automatically enrolled to make
12 contributions under subsection (a) at the default percent-
13 age of basic pay.

14 “(B) For purposes of this paragraph, the default per-
15 centage shall be equal to 3 percent or such other percent-
16 age, not less than 2 percent nor more than 5 percent, as
17 the Board may by regulation prescribe.

18 “(C) The regulations shall include provisions under
19 which any individual who would otherwise be automatically
20 enrolled in accordance with subparagraph (A) may—

21 “(i) modify the percentage or amount to be con-
22 tributed pursuant to automatic enrollment, effective
23 from the start of such enrollment; or

24 “(ii) decline automatic enrollment altogether.

1 “(D) For purposes of this paragraph, the term ‘eligi-
2 ble individual’ means any individual who, after any regula-
3 tions under subparagraph (A) first take effect, is ap-
4 pointed, transferred, or reappointed to a position in which
5 that individual is eligible to contribute to the Thrift Sav-
6 ings Fund.

7 “(E) Sections 8351(a)(1), 8440a(a)(1), 8440b(a)(1),
8 8440c(a)(1), 8440d(a)(1), and 8440e(a)(1) shall be ap-
9 plied in a manner consistent with the purposes of this
10 paragraph.”.

11 (b) TECHNICAL AMENDMENT.—Section 8432(b)(1)
12 of title 5, United States Code, is amended by striking the
13 parenthetical matter in subparagraph (B).

14 **SEC. 403. QUALIFIED ROTH CONTRIBUTION PROGRAM.**

15 (a) IN GENERAL.—Subchapter III of chapter 84 of
16 title 5, United States Code, is amended by inserting after
17 section 8432c the following:

18 **“§ 8432d. Qualified Roth contribution program**

19 “(a) DEFINITIONS.—For purposes of this section—

20 “(1) the term ‘qualified Roth contribution pro-
21 gram’ means a program described in paragraph (1)
22 of section 402A(b) of the Internal Revenue Code of
23 1986 which meets the requirements of paragraph (2)
24 of such section; and

1 “(2) the terms ‘designated Roth contribution’
2 and ‘elective deferral’ have the meanings given such
3 terms in section 402A of the Internal Revenue Code
4 of 1986.

5 “(b) AUTHORITY TO ESTABLISH.—The Board shall
6 by regulation provide for the inclusion in the Thrift Sav-
7 ings Plan of a qualified Roth contribution program, under
8 such terms and conditions as the Board may prescribe.

9 “(c) REQUIRED PROVISIONS.—The regulations under
10 subsection (b) shall include—

11 “(1) provisions under which an election to make
12 designated Roth contributions may be made—

13 “(A) by any individual who is eligible to
14 make contributions under section 8351,
15 8432(a), 8440a, 8440b, 8440c, 8440d, or
16 8440e; and

17 “(B) by any individual, not described in
18 subparagraph (A), who is otherwise eligible to
19 make elective deferrals under the Thrift Sav-
20 ings Plan;

21 “(2) any provisions which may, as a result of
22 enactment of this section, be necessary in order to
23 clarify the meaning of any reference to an ‘account’
24 made in section 8432(f), 8433, 8434(d), 8435,
25 8437, or any other provision of law; and

1 “(B) The self-directed investment window shall be
2 limited to—

3 “(i) low-cost, passively-managed index funds
4 that offer diversification benefits; and

5 “(ii) other investment options, if the Board de-
6 termines the options to be appropriate retirement in-
7 vestment vehicles for participants.

8 “(C) The Board shall ensure that any administrative
9 expenses related to use of the self-directed investment win-
10 dow are borne solely by the participants who use such win-
11 dow.

12 “(D) The Board may establish such other terms and
13 conditions for the self-directed investment window as the
14 Board considers appropriate to protect the interests of
15 participants, including requirements relating to risk dis-
16 closure.

17 “(E) The Board shall consult with the Employee
18 Thrift Advisory Council (established under section 8473)
19 before establishing any self-directed investment window.”.

20 **SEC. 405. REPORTING REQUIREMENTS.**

21 (a) ANNUAL REPORT.—The Board shall, not later
22 than June 30 of each year, submit to Congress an annual
23 report on the operations of the Thrift Savings Plan. Such
24 report shall include, for the prior calendar year, informa-
25 tion on the number of participants as of the last day of

1 such prior calendar year, the median balance in partici-
2 pants' accounts as of such last day, demographic informa-
3 tion on participants, the percentage allocation of amounts
4 among investment funds or options, the status of the de-
5 velopment and implementation of the self-directed invest-
6 ment window, the diversity demographics of any company,
7 investment adviser, or other entity retained to invest and
8 manage the assets of the Thrift Savings Fund, and such
9 other information as the Board considers appropriate. A
10 copy of each annual report under this subsection shall be
11 made available to the public through an Internet website.

12 (b) REPORTING OF FEES AND OTHER INFORMA-
13 TION.—

14 (1) IN GENERAL.—The Board shall include in
15 the periodic statements provided to participants
16 under section 8439(c) the amount of the investment
17 management fees, administrative expenses, and any
18 other fees or expenses paid with respect to each in-
19 vestment fund and option under the Thrift Savings
20 Plan. Any such statement shall also provide a state-
21 ment notifying participants as to how they may ac-
22 cess the annual report described in subsection (a), as
23 well as any other information concerning the Thrift
24 Savings Plan that might be useful.

1 (2) USE OF ESTIMATES.—For purposes of pro-
2 viding the information required under this sub-
3 section, the Executive Director may provide a rea-
4 sonable and representative estimate of any fees or
5 expenses described in paragraph (1) and shall indi-
6 cate any such estimate as being such an estimate.
7 Any such estimate shall be based on the previous
8 year’s experience.

9 (c) DEFINITIONS.—For purposes of this section—

10 (1) the term “Board” has the meaning given
11 such term by 8401(5) of title 5, United States Code;

12 (2) the term “participant” has the meaning
13 given such term by section 8471(3) of title 5, United
14 States Code; and

15 (3) the term “account” means an account es-
16 tablished under section 8439 of title 5, United
17 States Code.

18 **SEC. 406. ACKNOWLEDGEMENT OF RISK.**

19 (a) IN GENERAL.—Section 8439(d) of title 5, United
20 States Code, is amended—

21 (1) by striking the matter after “who elects to
22 invest in” and before “shall sign an acknowledge-
23 ment” and inserting “any investment fund or option
24 under this chapter, other than the Government Se-
25 curities Investment Fund,”; and

1 (2) by striking “either such Fund” and insert-
2 ing “any such fund or option”.

3 (b) COORDINATION WITH PROVISIONS RELATING TO
4 INVESTMENTS IN THE ABSENCE OF AN ELECTION.—Sub-
5 section (d) of section 8439 of title 5, United States Code
6 (as amended by subsection (a)) is further amended—

7 (1) by redesignating subsection (d) as sub-
8 section (d)(1); and

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

10 “(2)(A) In the case of an investment made under sec-
11 tion 8438(c)(2) in any fund or option to which paragraph
12 (1) would otherwise apply, the participant involved shall,
13 for purposes of this subsection, be deemed—

14 “(i) to have elected to invest in such fund or
15 option; and

16 “(ii) to have executed the acknowledgement re-
17 quired under paragraph (1).

18 “(B)(i) The Executive Director shall prescribe regu-
19 lations under which written notice shall be provided to a
20 participant whenever an investment is made under section
21 8438(c)(2)(B) on behalf of such participant in the absence
22 of an affirmative election described in section 8438(c)(1).

23 “(ii) The regulations shall ensure that any such no-
24 tice shall be provided to the participant within 7 calendar
25 days after the effective date of the default election.

1 “(C) For purposes of this paragraph, the term ‘par-
2 ticipant’ has the meaning given such term by section
3 8471(3).”.

4 (c) COORDINATION WITH PROVISIONS RELATING TO
5 FIDUCIARY RESPONSIBILITIES, LIABILITIES, AND PEN-
6 ALTIES.—Section 8477(e)(1)(C) of title 5, United States
7 Code, is amended—

8 (1) by redesignating subparagraph (C) as sub-
9 paragraph (C)(i); and

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

11 “(ii) A fiduciary shall not be liable under subpara-
12 graph (A), and no civil action may be brought against a
13 fiduciary—

14 “(I) for providing for the automatic enrollment
15 of a participant in accordance with section
16 8432(b)(2)(A);

17 “(II) for enrolling a participant in a default in-
18 vestment fund in accordance with section
19 8438(e)(2)(B); or

20 “(III) for allowing a participant to invest
21 through the self-directed investment window or for
22 establishing restrictions applicable to participants’
23 ability to invest through the self-directed investment
24 window.”.

1 **SEC. 407. CREDIT FOR UNUSED SICK LEAVE.**

2 (a) IN GENERAL.—Section 8415 of title 5, United
3 States Code, is amended—

4 (1) by redesignating the second subsection (k)
5 and subsection (l) as subsections (l) and (m), respec-
6 tively; and

7 (2) in subsection (l) (as so redesignated by
8 paragraph (1))—

9 (A) by striking “(l) In computing” and in-
10 serting “(l)(1) In computing”; and

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

12 “(2) Except as provided in paragraph (1), in com-
13 puting an annuity under this subchapter, the total service
14 of an employee who retires on an immediate annuity or
15 who dies leaving a survivor or survivors entitled to annuity
16 includes the days of unused sick leave to his credit under
17 a formal leave system, except that these days will not be
18 counted in determining average pay or annuity eligibility
19 under this subchapter. For purposes of this subsection, in
20 the case of any such employee who is excepted from sub-
21 chapter I of chapter 63 under section 6301(2)(x)-(xiii),
22 the days of unused sick leave to his credit include any un-
23 used sick leave standing to his credit when he was ex-
24 cepted from such subchapter.”.

25 (b) EXCEPTION FROM DEPOSIT REQUIREMENT.—
26 Section 8422(d)(2) of title 5, United States Code, is

1 amended by striking “section 8415(k)” and inserting
2 “paragraph (1) or (2) of section 8415(l)”.

3 (c) EFFECTIVE DATE.—The amendments made by
4 this section shall apply with respect to annuities computed
5 based on separations occurring on or after the date of en-
6 actment of this Act.

○