

111<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION

# H. R. 1256

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## AN ACT

To protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes.

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

3 **DIVISION A—FAMILY SMOKING**  
 4 **PREVENTION AND TOBACCO**  
 5 **CONTROL ACT**

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

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

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

DIVISION A—FAMILY SMOKING PREVENTION AND TOBACCO  
 CONTROL ACT

- 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.

## DIVISION B—FEDERAL RETIREMENT REFORM ACT

Sec. 100. Short title; table of contents.

TITLE I—PROVISIONS RELATING TO FEDERAL EMPLOYEES  
RETIREMENT

## Subtitle A—Thrift Savings Plan Enhancement

- Sec. 101. Short title.  
 Sec. 102. Automatic enrollments.  
 Sec. 103. Qualified Roth contribution program.  
 Sec. 104. Authority to establish self-directed investment window.  
 Sec. 105. Reporting requirements.  
 Sec. 106. Acknowledgement of risk.

## Subtitle B—Other Retirement-Related Provisions

- Sec. 111. Credit for unused sick leave.  
 Sec. 112. Exemption of certain CSRS repayments from the requirement that they be made with interest.  
 Sec. 113. Computation of certain annuities based on part-time service.  
 Sec. 114. Treatment of members of the uniformed services under the Thrift Savings Plan.  
 Sec. 115. Authority to deposit refunds under FERS.  
 Sec. 116. Retirement credit for service of certain employees transferred from District of Columbia service to Federal service.

TITLE II—SPECIAL SURVIVOR INDEMNITY ALLOWANCE FOR  
SURVIVING SPOUSES OF ARMED FORCES MEMBERS

- Sec. 201. Increase in monthly amount of special survivor indemnity allowance for widows and widowers of deceased members of the Armed Forces affected by required Survivor Benefit Plan annuity offset for dependency and indemnity compensation.

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.

1           (3) Nicotine is an addictive drug.

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

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

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

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

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

22           (9) Under article I, section 8 of the Constitu-  
23 tion, the Congress is vested with the responsibility  
24 for regulating interstate commerce and commerce  
25 with Indian tribes.

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

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

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

20          (13) Tobacco use is the foremost preventable  
21          cause of premature death in America. It causes over  
22          400,000 deaths in the United States each year, and  
23          approximately 8,600,000 Americans have chronic ill-  
24          nesses related to smoking.

1           (14) Reducing the use of tobacco by minors by  
2           50 percent would prevent well over 10,000,000 of to-  
3           day's children from becoming regular, daily smokers,  
4           saving over 3,000,000 of them from premature  
5           death due to tobacco-induced disease. Such a reduc-  
6           tion in youth smoking would also result in approxi-  
7           mately \$75,000,000,000 in savings attributable to  
8           reduced health care costs.

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

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

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

24          (18) Tobacco product advertising is regularly  
25          seen by persons under the age of 18, and persons

1 under the age of 18 are regularly exposed to tobacco  
2 product promotional efforts.

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

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

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

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

22 (23) Children are more influenced by tobacco  
23 marketing than adults: more than 80 percent of  
24 youth smoke three heavily marketed brands, while

1       only 54 percent of adults, 26 and older, smoke these  
2       same brands.

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

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

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

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

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

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

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

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

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

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

1       vey information about their products to adult con-  
2       sumers.

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

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

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

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

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

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

1 smoking entirely and thereby lead to disease and  
2 death.

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

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

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

21 (42) Permitting manufacturers to make unsub-  
22 substantiated statements concerning modified risk to-  
23 bacco products, whether express or implied, even if  
24 accompanied by disclaimers would be detrimental to  
25 the public health.

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

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

23           (45) The Federal Trade Commission was cre-  
24 ated to protect consumers from unfair or deceptive  
25 acts or practices, and to regulate unfair methods of

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

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

24 (47) In August 2006 a United States district  
25 court judge found that the major United States cig-

1        arette companies continue to target and market to  
2        youth. *USA v. Philip Morris, USA, Inc., et al.* (Civil  
3        Action No. 99–2496 (GK), August 17, 2006).

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

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

21 **SEC. 3. PURPOSE.**

22        The purposes of this Act are—

23            (1) to provide authority to the Food and Drug  
24        Administration to regulate tobacco products under  
25        the Federal Food, Drug, and Cosmetic Act (21

1 U.S.C. 301 et seq.), by recognizing it as the primary  
2 Federal regulatory authority with respect to the  
3 manufacture, marketing, and distribution of tobacco  
4 products as provided for in this Act;

5 (2) to ensure that the Food and Drug Adminis-  
6 tration has the authority to address issues of par-  
7 ticular concern to public health officials, especially  
8 the use of tobacco by young people and dependence  
9 on tobacco;

10 (3) to authorize the Food and Drug Adminis-  
11 tration to set national standards controlling the  
12 manufacture of tobacco products and the identity,  
13 public disclosure, and amount of ingredients used in  
14 such products;

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

19 (5) to vest the Food and Drug Administration  
20 with the authority to regulate the levels of tar, nico-  
21 tine, and other harmful components of tobacco prod-  
22 ucts;

23 (6) in order to ensure that consumers are better  
24 informed, to require tobacco product manufacturers  
25 to disclose research which has not previously been

1 made available, as well as research generated in the  
2 future, relating to the health and dependency effects  
3 or safety of tobacco products;

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

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

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

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

15 **SEC. 4. SCOPE AND EFFECT.**

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

18 (1) establish a precedent with regard to any  
19 other industry, situation, circumstance, or legal ac-  
20 tion; or

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

24 (b) AGRICULTURAL ACTIVITIES.—The provisions of  
25 this Act (or an amendment made by this Act) which au-

1 thorize the Secretary to take certain actions with regard  
2 to tobacco and tobacco products shall not be construed to  
3 affect any authority of the Secretary of Agriculture under  
4 existing law regarding the growing, cultivation, or curing  
5 of raw tobacco.

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

12 **SEC. 5. SEVERABILITY.**

13 If any provision of this Act, the amendments made  
14 by this Act, or the application of any provision of this Act  
15 to any person or circumstance is held to be invalid, the  
16 remainder of this Act, the amendments made by this Act,  
17 and the application of the provisions of this Act to any  
18 other person or circumstance shall not be affected and  
19 shall continue to be enforced to the fullest extent possible.

1 **TITLE I—AUTHORITY OF THE**  
2 **FOOD AND DRUG ADMINIS-**  
3 **TRATION**

4 **SEC. 101. AMENDMENT OF FEDERAL FOOD, DRUG, AND**  
5 **COSMETIC ACT.**

6 (a) DEFINITION OF TOBACCO PRODUCTS.—Section  
7 201 of the Federal Food, Drug, and Cosmetic Act (21  
8 U.S.C. 321) is amended by adding at the end the fol-  
9 lowing:

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

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

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

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

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

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

5 (2) by redesignating sections 901 through 910  
6 as sections 1001 through 1010; and

7 (3) by inserting after chapter VIII the fol-  
8 lowing:

9 **“CHAPTER IX—TOBACCO PRODUCTS**

10 **“SEC. 900. DEFINITIONS.**

11 “In this chapter:

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

23 “(2) BRAND.—The term ‘brand’ means a vari-  
24 ety of tobacco product distinguished by the tobacco  
25 used, tar content, nicotine content, flavoring used,

1 size, filtration, packaging, logo, registered trade-  
2 mark, brand name, identifiable pattern of colors, or  
3 any combination of such attributes.

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

5 “(A) means a product that—

6 “(i) is a tobacco product; and

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

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

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

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

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

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

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

23           “(9) INDIAN COUNTRY.—The term ‘Indian  
24 country’ has the meaning given such term in section  
25 1151 of title 18, United States Code.

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

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

7                   “(A) is a tobacco product; and

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

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

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

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

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

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

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

23          “(18) SMOKELESS TOBACCO.—The term  
24          ‘smokeless tobacco’ means any tobacco product that  
25          consists of cut, ground, powdered, or leaf tobacco

1 and that is intended to be placed in the oral or nasal  
2 cavity.

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

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

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

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

13 “(21) TOBACCO WAREHOUSE.—

14 “(A) Subject to subparagraphs (B) and  
15 (C), the term ‘tobacco warehouse’ includes any  
16 person—

17 “(i) who—

18 “(I) removes foreign material  
19 from tobacco leaf through nothing  
20 other than a mechanical process;

21 “(II) humidifies tobacco leaf with  
22 nothing other than potable water in  
23 the form of steam or mist; or

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

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

3 “(iii) who provides to any manufac-  
4 turer to whom the person sells tobacco all  
5 information related to the person’s actions  
6 described in clause (i) that is necessary for  
7 compliance with this Act.

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

10 “(i) reconstitutes tobacco leaf;

11 “(ii) is a manufacturer, distributor, or  
12 retailer of a tobacco product; or

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

16 “(C) The definition of the term ‘tobacco  
17 warehouse’ in subparagraph (A) shall not apply  
18 to the extent to which the Secretary determines,  
19 through rulemaking, that regulation under this  
20 chapter of the actions described in such sub-  
21 paragraph is appropriate for the protection of  
22 the public health.

23 “(22) UNITED STATES.—The term ‘United  
24 States’ means the 50 States of the United States of  
25 America and the District of Columbia, the Common-

1 wealth of Puerto Rico, Guam, the Virgin Islands,  
2 American Samoa, Wake Island, Midway Islands,  
3 Kingman Reef, Johnston Atoll, the Northern Mar-  
4 iana Islands, and any other trust territory or posses-  
5 sion of the United States.

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

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

12 “(b) APPLICABILITY.—This chapter shall apply to all  
13 cigarettes, cigarette tobacco, roll-your-own tobacco, and  
14 smokeless tobacco and to any other tobacco products that  
15 the Secretary by regulation deems to be subject to this  
16 chapter.

17 “(c) SCOPE.—

18 “(1) IN GENERAL.—Nothing in this chapter, or  
19 any policy issued or regulation promulgated there-  
20 under, or in sections 101(a), 102, or 103 of title I,  
21 title II, or title III of the Family Smoking Preven-  
22 tion and Tobacco Control Act, shall be construed to  
23 affect, expand, or limit the Secretary’s authority  
24 over (including the authority to determine whether  
25 products may be regulated), or the regulation of,

1 products under this Act that are not tobacco prod-  
2 ucts under chapter V or any other chapter.

3 “(2) LIMITATION OF AUTHORITY.—

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

14 “(B) EXCEPTION.—Notwithstanding sub-  
15 paragraph (A), if a producer of tobacco leaf is  
16 also a tobacco product manufacturer or con-  
17 trolled by a tobacco product manufacturer, the  
18 producer shall be subject to this chapter in the  
19 producer’s capacity as a manufacturer. The ex-  
20 ception in this subparagraph shall not apply to  
21 a producer of tobacco leaf who grows tobacco  
22 under a contract with a tobacco product manu-  
23 facturer and who is not otherwise engaged in  
24 the manufacturing process.

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

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

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

24          “(f) OFFICE TO ASSIST SMALL TOBACCO PRODUCT  
25          MANUFACTURERS.—The Secretary shall establish within

1 the Food and Drug Administration an identifiable office  
2 to provide technical and other nonfinancial assistance to  
3 small tobacco product manufacturers to assist them in  
4 complying with the requirements of this Act.

5 “(g) CONSULTATION PRIOR TO RULEMAKING.—Prior  
6 to promulgating rules under this chapter, the Secretary  
7 shall endeavor to consult with other Federal agencies as  
8 appropriate.

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

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

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

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

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

24 “(4) the manufacturer or importer of the to-  
25 bacco product fails to pay a user fee assessed to

1 such manufacturer or importer pursuant to section  
2 919 by the date specified in section 919 or by the  
3 30th day after final agency action on a resolution of  
4 any dispute as to the amount of such fee;

5 “(5) it is, or purports to be or is represented  
6 as, a tobacco product which is subject to a tobacco  
7 product standard established under section 907 un-  
8 less such tobacco product is in all respects in con-  
9 formity with such standard;

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

13 “(B) it is in violation of an order under section  
14 910(c)(1)(A);

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

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

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

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

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

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

5                 “(A) the name and place of business of the  
6 tobacco product manufacturer, packer, or dis-  
7 tributor;

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

11                 “(C) an accurate statement of the percent-  
12 age of the tobacco used in the product that is  
13 domestically grown tobacco and the percentage  
14 that is foreign grown tobacco; and

15                 “(D) the statement required under section  
16 920(a),

17 except that under subparagraph (B) reasonable vari-  
18 ations shall be permitted, and exemptions as to  
19 small packages shall be established, by regulations  
20 prescribed by the Secretary;

21           “(3) if any word, statement, or other informa-  
22 tion required by or under authority of this chapter  
23 to appear on the label or labeling is not prominently  
24 placed thereon with such conspicuousness (as com-  
25 pared with other words, statements, or designs in

1 the labeling) and in such terms as to render it likely  
2 to be read and understood by the ordinary individual  
3 under customary conditions of purchase and use;

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

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

15 “(6) if it was manufactured, prepared, propa-  
16 gated, compounded, or processed in an establishment  
17 not duly registered under section 905(b), 905(c),  
18 905(d), or 905(h), if it was not included in a list re-  
19 quired by section 905(i), if a notice or other infor-  
20 mation respecting it was not provided as required by  
21 such section or section 905(j), or if it does not bear  
22 such symbols from the uniform system for identifica-  
23 tion of tobacco products prescribed under section  
24 905(e) as the Secretary by regulation requires;

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

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

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

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

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

17           “(B) a brief statement of—

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

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

1 of the components of such tobacco product  
2 or the formula showing quantitatively each  
3 ingredient of such tobacco product to the  
4 extent required in regulations which shall  
5 be issued by the Secretary after an oppor-  
6 tunity for a hearing;

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

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

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

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

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

17 The Secretary may, by regulation, require prior approval  
18 of statements made on the label of a tobacco product. No  
19 regulation issued under this subsection may require prior  
20 approval by the Secretary of the content of any advertise-  
21 ment, except for modified risk tobacco products as pro-  
22 vided in section 911. No advertisement of a tobacco prod-  
23 uct published after the date of enactment of the Family  
24 Smoking Prevention and Tobacco Control Act shall, with  
25 respect to the language of label statements as prescribed

1 under section 4 of the Federal Cigarette Labeling and Ad-  
2 vertising Act and section 3 of the Comprehensive Smoke-  
3 less Tobacco Health Education Act of 1986 or the regula-  
4 tions issued under such sections, be subject to the provi-  
5 sions of sections 12 through 15 of the Federal Trade Com-  
6 mission Act.

7 **“SEC. 904. SUBMISSION OF HEALTH INFORMATION TO THE**  
8 **SECRETARY.**

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

12 “(1) Not later than 6 months after the date of  
13 enactment of the Family Smoking Prevention and  
14 Tobacco Control Act, a listing of all ingredients, in-  
15 cluding tobacco, substances, compounds, and addi-  
16 tives that are, as of such date, added by the manu-  
17 facturer to the tobacco, paper, filter, or other part  
18 of each tobacco product by brand and by quantity in  
19 each brand and subbrand.

20 “(2) A description of the content, delivery, and  
21 form of nicotine in each tobacco product measured  
22 in milligrams of nicotine in accordance with regula-  
23 tions promulgated by the Secretary in accordance  
24 with section 4(e) of the Federal Cigarette Labeling  
25 and Advertising Act.

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

14          “(4) Beginning 6 months after the date of en-  
15          actment of the Family Smoking Prevention and To-  
16          bacco Control Act, all documents developed after  
17          such date of enactment that relate to health, toxi-  
18          cological, behavioral, or physiologic effects of current  
19          or future tobacco products, their constituents (in-  
20          cluding smoke constituents), ingredients, compo-  
21          nents, and additives.

22          “(b) DATA SUBMISSION.—At the request of the Sec-  
23          retary, each tobacco product manufacturer or importer of  
24          tobacco products, or agents thereof, shall submit the fol-  
25          lowing:

1           “(1) Any or all documents (including under-  
2           lying scientific information) relating to research ac-  
3           tivities, and research findings, conducted, supported,  
4           or possessed by the manufacturer (or agents thereof)  
5           on the health, toxicological, behavioral, or physio-  
6           logic effects of tobacco products and their constitu-  
7           ents (including smoke constituents), ingredients,  
8           components, and additives.

9           “(2) Any or all documents (including under-  
10          lying scientific information) relating to research ac-  
11          tivities, and research findings, conducted, supported,  
12          or possessed by the manufacturer (or agents thereof)  
13          that relate to the issue of whether a reduction in  
14          risk to health from tobacco products can occur upon  
15          the employment of technology available or known to  
16          the manufacturer.

17          “(3) Any or all documents (including under-  
18          lying scientific or financial information) relating to  
19          marketing research involving the use of tobacco  
20          products or marketing practices and the effective-  
21          ness of such practices used by tobacco manufactur-  
22          ers and distributors.

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

1 “(c) TIME FOR SUBMISSION.—

2 “(1) IN GENERAL.—At least 90 days prior to  
3 the delivery for introduction into interstate com-  
4 merce of a tobacco product not on the market on the  
5 date of enactment of the Family Smoking Preven-  
6 tion and Tobacco Control Act, the manufacturer of  
7 such product shall provide the information required  
8 under subsection (a).

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

16 “(3) DISCLOSURE OF OTHER ACTIONS.—If at  
17 any time a tobacco product manufacturer eliminates  
18 or decreases an existing additive, or adds or in-  
19 creases an additive that has by regulation been des-  
20 ignated by the Secretary as an additive that is not  
21 a human or animal carcinogen, or otherwise harmful  
22 to health under intended conditions of use, the man-  
23 ufacturer shall within 60 days of such action so ad-  
24 vise the Secretary in writing.

25 “(d) DATA LIST.—

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

9           “(2) CONSUMER RESEARCH.—The Secretary  
10 shall conduct periodic consumer research to ensure  
11 that the list published under paragraph (1) is not  
12 misleading to lay persons. Not later than 5 years  
13 after the date of enactment of the Family Smoking  
14 Prevention and Tobacco Control Act, the Secretary  
15 shall submit to the appropriate committees of Con-  
16 gress a report on the results of such research, to-  
17 gether with recommendations on whether such publi-  
18 cation should be continued or modified.

19           “(e) DATA COLLECTION.—Not later than 24 months  
20 after the date of enactment of the Family Smoking Pre-  
21 vention and Tobacco Control Act, the Secretary shall es-  
22 tablish, and periodically revise as appropriate, a list of  
23 harmful and potentially harmful constituents, including  
24 smoke constituents, to health in each tobacco product by  
25 brand and by quantity in each brand and subbrand. The

1 Secretary shall publish a public notice requesting the sub-  
2 mission by interested persons of scientific and other infor-  
3 mation concerning the harmful and potentially harmful  
4 constituents in tobacco products and tobacco smoke.

5 **“SEC. 905. ANNUAL REGISTRATION.**

6 “(a) DEFINITIONS.—In this section:

7 “(1) MANUFACTURE, PREPARATION,  
8 COMPOUNDING, OR PROCESSING.—The term ‘manu-  
9 facture, preparation, compounding, or processing’  
10 shall include repackaging or otherwise changing the  
11 container, wrapper, or labeling of any tobacco prod-  
12 uct package in furtherance of the distribution of the  
13 tobacco product from the original place of manufac-  
14 ture to the person who makes final delivery or sale  
15 to the ultimate consumer or user.

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

21 “(b) REGISTRATION BY OWNERS AND OPERATORS.—  
22 On or before December 31 of each year, every person who  
23 owns or operates any establishment in any State engaged  
24 in the manufacture, preparation, compounding, or proc-  
25 essing of a tobacco product or tobacco products shall reg-

1 ister with the Secretary the name, places of business, and  
2 all such establishments of that person. If enactment of the  
3 Family Smoking Prevention and Tobacco Control Act oc-  
4 curs in the second half of the calendar year, the Secretary  
5 shall designate a date no later than 6 months into the  
6 subsequent calendar year by which registration pursuant  
7 to this subsection shall occur.

8       “(c) REGISTRATION BY NEW OWNERS AND OPERA-  
9 TORS.—Every person upon first engaging in the manufac-  
10 ture, preparation, compounding, or processing of a tobacco  
11 product or tobacco products in any establishment owned  
12 or operated in any State by that person shall immediately  
13 register with the Secretary that person’s name, place of  
14 business, and such establishment.

15       “(d) REGISTRATION OF ADDED ESTABLISHMENTS.—  
16 Every person required to register under subsection (b) or  
17 (c) shall immediately register with the Secretary any addi-  
18 tional establishment which that person owns or operates  
19 in any State and in which that person begins the manufac-  
20 ture, preparation, compounding, or processing of a tobacco  
21 product or tobacco products.

22       “(e) UNIFORM PRODUCT IDENTIFICATION SYS-  
23 TEM.—The Secretary may by regulation prescribe a uni-  
24 form system for the identification of tobacco products and  
25 may require that persons who are required to list such

1 tobacco products under subsection (i) shall list such to-  
2 bacco products in accordance with such system.

3 “(f) PUBLIC ACCESS TO REGISTRATION INFORMA-  
4 TION.—The Secretary shall make available for inspection,  
5 to any person so requesting, any registration filed under  
6 this section.

7 “(g) BIENNIAL INSPECTION OF REGISTERED ESTAB-  
8 LISHMENTS.—Every establishment registered with the  
9 Secretary under this section shall be subject to inspection  
10 under section 704 or subsection (h), and every such estab-  
11 lishment engaged in the manufacture, compounding, or  
12 processing of a tobacco product or tobacco products shall  
13 be so inspected by 1 or more officers or employees duly  
14 designated by the Secretary at least once in the 2-year  
15 period beginning with the date of registration of such es-  
16 tablishment under this section and at least once in every  
17 successive 2-year period thereafter.

18 “(h) REGISTRATION BY FOREIGN ESTABLISH-  
19 MENTS.—Any establishment within any foreign country  
20 engaged in the manufacture, preparation, compounding,  
21 or processing of a tobacco product or tobacco products,  
22 shall register under this section under regulations promul-  
23 gated by the Secretary. Such regulations shall require  
24 such establishment to provide the information required by  
25 subsection (i) and shall include provisions for registration

1 of any such establishment upon condition that adequate  
2 and effective means are available, by arrangement with the  
3 government of such foreign country or otherwise, to enable  
4 the Secretary to determine from time to time whether to-  
5 bacco products manufactured, prepared, compounded, or  
6 processed in such establishment, if imported or offered for  
7 import into the United States, shall be refused admission  
8 on any of the grounds set forth in section 801(a).

9 “(i) REGISTRATION INFORMATION.—

10 “(1) PRODUCT LIST.—Every person who reg-  
11 isters with the Secretary under subsection (b), (c),  
12 (d), or (h) shall, at the time of registration under  
13 any such subsection, file with the Secretary a list of  
14 all tobacco products which are being manufactured,  
15 prepared, compounded, or processed by that person  
16 for commercial distribution and which have not been  
17 included in any list of tobacco products filed by that  
18 person with the Secretary under this paragraph or  
19 paragraph (2) before such time of registration. Such  
20 list shall be prepared in such form and manner as  
21 the Secretary may prescribe and shall be accom-  
22 panied by—

23 “(A) in the case of a tobacco product con-  
24 tained in the applicable list with respect to  
25 which a tobacco product standard has been es-

1           tablished under section 907 or which is subject  
2           to section 910, a reference to the authority for  
3           the marketing of such tobacco product and a  
4           copy of all labeling for such tobacco product;

5           “(B) in the case of any other tobacco prod-  
6           uct contained in an applicable list, a copy of all  
7           consumer information and other labeling for  
8           such tobacco product, a representative sampling  
9           of advertisements for such tobacco product,  
10          and, upon request made by the Secretary for  
11          good cause, a copy of all advertisements for a  
12          particular tobacco product; and

13          “(C) if the registrant filing a list has de-  
14          termined that a tobacco product contained in  
15          such list is not subject to a tobacco product  
16          standard established under section 907, a brief  
17          statement of the basis upon which the reg-  
18          istrant made such determination if the Sec-  
19          retary requests such a statement with respect  
20          to that particular tobacco product.

21          “(2) CONSULTATION WITH RESPECT TO  
22          FORMS.—The Secretary shall consult with the Sec-  
23          retary of the Treasury in developing the forms to be  
24          used for registration under this section to minimize  
25          the burden on those persons required to register

1 with both the Secretary and the Tax and Trade Bu-  
2 reau of the Department of the Treasury.

3 “(3) BIENNIAL REPORT OF ANY CHANGE IN  
4 PRODUCT LIST.—Each person who registers with the  
5 Secretary under this section shall report to the Sec-  
6 retary once during the month of June of each year  
7 and once during the month of December of each  
8 year the following:

9 “(A) A list of each tobacco product intro-  
10 duced by the registrant for commercial distribu-  
11 tion which has not been included in any list  
12 previously filed by that person with the Sec-  
13 retary under this subparagraph or paragraph  
14 (1). A list under this subparagraph shall list a  
15 tobacco product by its established name and  
16 shall be accompanied by the other information  
17 required by paragraph (1).

18 “(B) If since the date the registrant last  
19 made a report under this paragraph that person  
20 has discontinued the manufacture, preparation,  
21 compounding, or processing for commercial dis-  
22 tribution of a tobacco product included in a list  
23 filed under subparagraph (A) or paragraph (1),  
24 notice of such discontinuance, the date of such

1           discontinuance, and the identity of its estab-  
2           lished name.

3           “(C) If since the date the registrant re-  
4           ported under subparagraph (B) a notice of dis-  
5           continuance that person has resumed the manu-  
6           facture, preparation, compounding, or proc-  
7           essing for commercial distribution of the to-  
8           bacco product with respect to which such notice  
9           of discontinuance was reported, notice of such  
10          resumption, the date of such resumption, the  
11          identity of such tobacco product by established  
12          name, and other information required by para-  
13          graph (1), unless the registrant has previously  
14          reported such resumption to the Secretary  
15          under this subparagraph.

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

19          “(j) REPORT PRECEDING INTRODUCTION OF CER-  
20          TAIN SUBSTANTIALLY EQUIVALENT PRODUCTS INTO  
21          INTERSTATE COMMERCE.—

22          “(1) IN GENERAL.—Each person who is re-  
23          quired to register under this section and who pro-  
24          poses to begin the introduction or delivery for intro-  
25          duction into interstate commerce for commercial dis-

1       tribution of a tobacco product intended for human  
2       use that was not commercially marketed (other than  
3       for test marketing) in the United States as of Feb-  
4       ruary 15, 2007, shall, at least 90 days prior to mak-  
5       ing such introduction or delivery, report to the Sec-  
6       retary (in such form and manner as the Secretary  
7       shall prescribe)—

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

10               “(i) the tobacco product is substan-  
11               tially equivalent, within the meaning of  
12               section 910, to a tobacco product commer-  
13               cially marketed (other than for test mar-  
14               keting) in the United States as of Feb-  
15               ruary 15, 2007, or to a tobacco product  
16               that the Secretary has previously deter-  
17               mined, pursuant to subsection (a)(3) of  
18               section 910, is substantially equivalent and  
19               that is in compliance with the require-  
20               ments of this Act; or

21               “(ii) the tobacco product is modified  
22               within the meaning of paragraph (3), the  
23               modifications are to a product that is com-  
24               mercially marketed and in compliance with  
25               the requirements of this Act, and all of the

1 modifications are covered by exemptions  
2 granted by the Secretary pursuant to para-  
3 graph (3); and

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

7 “(2) APPLICATION TO CERTAIN POST-FEB-  
8 RUARY 15, 2007, PRODUCTS.—A report under this  
9 subsection for a tobacco product that was first intro-  
10 duced or delivered for introduction into interstate  
11 commerce for commercial distribution in the United  
12 States after February 15, 2007, and prior to the  
13 date that is 21 months after the date of enactment  
14 of the Family Smoking Prevention and Tobacco  
15 Control Act shall be submitted to the Secretary not  
16 later than 21 months after such date of enactment.

17 “(3) EXEMPTIONS.—

18 “(A) IN GENERAL.—The Secretary may  
19 exempt from the requirements of this sub-  
20 section relating to the demonstration that a to-  
21 bacco product is substantially equivalent within  
22 the meaning of section 910, tobacco products  
23 that are modified by adding or deleting a to-  
24 bacco additive, or increasing or decreasing the

1 quantity of an existing tobacco additive, if the  
2 Secretary determines that—

3 “(i) such modification would be a  
4 minor modification of a tobacco product  
5 that can be sold under this Act;

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

11 “(iii) an exemption is otherwise appro-  
12 priate.

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

18 **“SEC. 906. GENERAL PROVISIONS RESPECTING CONTROL**  
19 **OF TOBACCO PRODUCTS.**

20 “(a) IN GENERAL.—Any requirement established by  
21 or under section 902, 903, 905, or 909 applicable to a  
22 tobacco product shall apply to such tobacco product until  
23 the applicability of the requirement to the tobacco product  
24 has been changed by action taken under section 907, sec-  
25 tion 910, section 911, or subsection (d) of this section,

1 and any requirement established by or under section 902,  
2 903, 905, or 909 which is inconsistent with a requirement  
3 imposed on such tobacco product under section 907, sec-  
4 tion 910, section 911, or subsection (d) of this section  
5 shall not apply to such tobacco product.

6       “(b) INFORMATION ON PUBLIC ACCESS AND COM-  
7 MENT.—Each notice of proposed rulemaking or other noti-  
8 fication under section 907, 908, 909, 910, or 911 or under  
9 this section, any other notice which is published in the  
10 Federal Register with respect to any other action taken  
11 under any such section and which states the reasons for  
12 such action, and each publication of findings required to  
13 be made in connection with rulemaking under any such  
14 section shall set forth—

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

18               “(2) the period within which interested persons  
19 may present their comments on the notice or find-  
20 ings (including the need therefore) orally or in writ-  
21 ing, which period shall be at least 60 days but may  
22 not exceed 90 days unless the time is extended by  
23 the Secretary by a notice published in the Federal  
24 Register stating good cause therefore.

1       “(c) LIMITED CONFIDENTIALITY OF INFORMA-  
2 TION.—Any information reported to or otherwise obtained  
3 by the Secretary or the Secretary’s representative under  
4 section 903, 904, 907, 908, 909, 910, 911, or 704, or  
5 under subsection (e) or (f) of this section, which is exempt  
6 from disclosure under subsection (a) of section 552 of title  
7 5, United States Code, by reason of subsection (b)(4) of  
8 that section shall be considered confidential and shall not  
9 be disclosed, except that the information may be disclosed  
10 to other officers or employees concerned with carrying out  
11 this chapter, or when relevant in any proceeding under  
12 this chapter.

13       “(d) RESTRICTIONS.—

14               “(1) IN GENERAL.—The Secretary may by reg-  
15 ulation require restrictions on the sale and distribu-  
16 tion of a tobacco product, including restrictions on  
17 the access to, and the advertising and promotion of,  
18 the tobacco product, if the Secretary determines that  
19 such regulation would be appropriate for the protec-  
20 tion of the public health. The Secretary may by reg-  
21 ulation impose restrictions on the advertising and  
22 promotion of a tobacco product consistent with and  
23 to full extent permitted by the first amendment to  
24 the Constitution. The finding as to whether such  
25 regulation would be appropriate for the protection of

1 the public health shall be determined with respect to  
2 the risks and benefits to the population as a whole,  
3 including users and nonusers of the tobacco product,  
4 and taking into account—

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

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

11 No such regulation may require that the sale or dis-  
12 tribution of a tobacco product be limited to the writ-  
13 ten or oral authorization of a practitioner licensed  
14 by law to prescribe medical products.

15 “(2) LABEL STATEMENTS.—The label of a to-  
16 bacco product shall bear such appropriate state-  
17 ments of the restrictions required by a regulation  
18 under subsection (a) as the Secretary may in such  
19 regulation prescribe.

20 “(3) LIMITATIONS.—

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

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

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

4                   “(B) MATCHBOOKS.—For purposes of any  
5                   regulations issued by the Secretary, matchbooks  
6                   of conventional size containing not more than  
7                   20 paper matches, and which are customarily  
8                   given away for free with the purchase of to-  
9                   bacco products, shall be considered as adult-  
10                  written publications which shall be permitted to  
11                  contain advertising. Notwithstanding the pre-  
12                  ceding sentence, if the Secretary finds that such  
13                  treatment of matchbooks is not appropriate for  
14                  the protection of the public health, the Sec-  
15                  retary may determine by regulation that match-  
16                  books shall not be considered adult-written pub-  
17                  lications.

18                  “(4) REMOTE SALES.—

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

20                                 “(i) within 18 months after the date  
21                                 of enactment of the Family Smoking Pre-  
22                                 vention and Tobacco Control Act, promul-  
23                                 gate regulations regarding the sale and  
24                                 distribution of tobacco products that occur  
25                                 through means other than a direct, face-to-

1 face exchange between a retailer and a  
2 consumer in order to prevent the sale and  
3 distribution of tobacco products to individ-  
4 uals who have not attained the minimum  
5 age established by applicable law for the  
6 purchase of such products, including re-  
7 quirements for age verification; and

8 “(ii) within 2 years after such date of  
9 enactment, issue regulations to address the  
10 promotion and marketing of tobacco prod-  
11 ucts that are sold or distributed through  
12 means other than a direct, face-to-face ex-  
13 change between a retailer and a consumer  
14 in order to protect individuals who have  
15 not attained the minimum age established  
16 by applicable law for the purchase of such  
17 products.

18 “(B) RELATION TO OTHER AUTHORITY.—

19 Nothing in this paragraph limits the authority  
20 of the Secretary to take additional actions  
21 under the other paragraphs of this subsection.

22 “(e) GOOD MANUFACTURING PRACTICE REQUIRE-  
23 MENTS.—

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

1           “(A) IN GENERAL.—In applying manufac-  
2           turing restrictions to tobacco, the Secretary  
3           shall, in accordance with subparagraph (B),  
4           prescribe regulations (which may differ based  
5           on the type of tobacco product involved) requir-  
6           ing that the methods used in, and the facilities  
7           and controls used for, the manufacture,  
8           preproduction design validation (including a  
9           process to assess the performance of a tobacco  
10          product), packing, and storage of a tobacco  
11          product conform to current good manufacturing  
12          practice, or hazard analysis and critical control  
13          point methodology, as prescribed in such regu-  
14          lations to assure that the public health is pro-  
15          tected and that the tobacco product is in com-  
16          pliance with this chapter. Such regulations may  
17          provide for the testing of raw tobacco for pes-  
18          ticide chemical residues regardless of whether a  
19          tolerance for such chemical residues has been  
20          established.

21           “(B) REQUIREMENTS.—The Secretary  
22          shall—

23                   “(i) before promulgating any regula-  
24                   tion under subparagraph (A), afford the  
25                   Tobacco Products Scientific Advisory Com-

1           mittee an opportunity to submit rec-  
2           ommendations with respect to the regula-  
3           tion proposed to be promulgated;

4           “(ii) before promulgating any regula-  
5           tion under subparagraph (A), afford oppor-  
6           tunity for an oral hearing;

7           “(iii) provide the Tobacco Products  
8           Scientific Advisory Committee a reasonable  
9           time to make its recommendation with re-  
10          spect to proposed regulations under sub-  
11          paragraph (A);

12          “(iv) in establishing the effective date  
13          of a regulation promulgated under this  
14          subsection, take into account the dif-  
15          ferences in the manner in which the dif-  
16          ferent types of tobacco products have his-  
17          torically been produced, the financial re-  
18          sources of the different tobacco product  
19          manufacturers, and the state of their exist-  
20          ing manufacturing facilities, and shall pro-  
21          vide for a reasonable period of time for  
22          such manufacturers to conform to good  
23          manufacturing practices; and

24          “(v) not require any small tobacco  
25          product manufacturer to comply with a

1 regulation under subparagraph (A) for at  
2 least 4 years following the effective date  
3 established by the Secretary for such regu-  
4 lation.

5 “(2) EXEMPTIONS; VARIANCES.—

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

13 “(i) in the case of a petition for an ex-  
14 emption from a requirement, set forth the  
15 basis for the petitioner’s determination  
16 that compliance with the requirement is  
17 not required to assure that the tobacco  
18 product will be in compliance with this  
19 chapter;

20 “(ii) in the case of a petition for a  
21 variance from a requirement, set forth the  
22 methods proposed to be used in, and the  
23 facilities and controls proposed to be used  
24 for, the manufacture, packing, and storage  
25 of the tobacco product in lieu of the meth-

1           ods, facilities, and controls prescribed by  
2           the requirement; and

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

5                   “(B) REFERRAL TO THE TOBACCO PROD-  
6           UCTS SCIENTIFIC ADVISORY COMMITTEE.—The  
7           Secretary may refer to the Tobacco Products  
8           Scientific Advisory Committee any petition sub-  
9           mitted under subparagraph (A). The Tobacco  
10          Products Scientific Advisory Committee shall  
11          report its recommendations to the Secretary  
12          with respect to a petition referred to it within  
13          60 days after the date of the petition’s referral.  
14          Within 60 days after—

15                   “(i) the date the petition was sub-  
16                  mitted to the Secretary under subpara-  
17                  graph (A); or

18                   “(ii) the day after the petition was re-  
19                  ferred to the Tobacco Products Scientific  
20                  Advisory Committee,

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

23                   “(C) APPROVAL.—The Secretary may ap-  
24          prove—

1           “(i) a petition for an exemption for a  
2 tobacco product from a requirement if the  
3 Secretary determines that compliance with  
4 such requirement is not required to assure  
5 that the tobacco product will be in compli-  
6 ance with this chapter; and

7           “(ii) a petition for a variance for a to-  
8 bacco product from a requirement if the  
9 Secretary determines that the methods to  
10 be used in, and the facilities and controls  
11 to be used for, the manufacture, packing,  
12 and storage of the tobacco product in lieu  
13 of the methods, facilities, and controls pre-  
14 scribed by the requirement are sufficient to  
15 assure that the tobacco product will be in  
16 compliance with this chapter.

17           “(D) CONDITIONS.—An order of the Sec-  
18 retary approving a petition for a variance shall  
19 prescribe such conditions respecting the meth-  
20 ods used in, and the facilities and controls used  
21 for, the manufacture, packing, and storage of  
22 the tobacco product to be granted the variance  
23 under the petition as may be necessary to as-  
24 sure that the tobacco product will be in compli-  
25 ance with this chapter.

1           “(E) HEARING.—After the issuance of an  
2           order under subparagraph (B) respecting a pe-  
3           tition, the petitioner shall have an opportunity  
4           for an informal hearing on such order.

5           “(3) COMPLIANCE.—Compliance with require-  
6           ments under this subsection shall not be required be-  
7           fore the end of the 3-year period following the date  
8           of enactment of the Family Smoking Prevention and  
9           Tobacco Control Act.

10          “(f) RESEARCH AND DEVELOPMENT.—The Secretary  
11          may enter into contracts for research, testing, and dem-  
12          onstrations respecting tobacco products and may obtain  
13          tobacco products for research, testing, and demonstration  
14          purposes.

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

16          “(a) IN GENERAL.—

17                  “(1) SPECIAL RULES.—

18                          “(A) SPECIAL RULE FOR CIGARETTES.—

19                          Beginning 3 months after the date of enact-  
20                          ment of the Family Smoking Prevention and  
21                          Tobacco Control Act, a cigarette or any of its  
22                          component parts (including the tobacco, filter,  
23                          or paper) shall not contain, as a constituent (in-  
24                          cluding a smoke constituent) or additive, an ar-  
25                          tificial or natural flavor (other than tobacco or

1 menthol) or an herb or spice, including straw-  
2 berry, grape, orange, clove, cinnamon, pine-  
3 apple, vanilla, coconut, licorice, cocoa, chocolate,  
4 cherry, or coffee, that is a characterizing flavor  
5 of the tobacco product or tobacco smoke. Noth-  
6 ing in this subparagraph shall be construed to  
7 limit the Secretary's authority to take action  
8 under this section or other sections of this Act  
9 applicable to menthol or any artificial or nat-  
10 ural flavor, herb, or spice not specified in this  
11 subparagraph.

12 “(B) ADDITIONAL SPECIAL RULE.—Begin-  
13 ning 2 years after the date of enactment of the  
14 Family Smoking Prevention and Tobacco Con-  
15 trol Act, a tobacco product manufacturer shall  
16 not use tobacco, including foreign grown to-  
17 bacco, that contains a pesticide chemical res-  
18 idue that is at a level greater than is specified  
19 by any tolerance applicable under Federal law  
20 to domestically grown tobacco.

21 “(2) REVISION OF TOBACCO PRODUCT STAND-  
22 ARDS.—The Secretary may revise the tobacco prod-  
23 uct standards in paragraph (1) in accordance with  
24 subsection (c).

25 “(3) TOBACCO PRODUCT STANDARDS.—

1           “(A) IN GENERAL.—The Secretary may  
2           adopt tobacco product standards in addition to  
3           those in paragraph (1) if the Secretary finds  
4           that a tobacco product standard is appropriate  
5           for the protection of the public health.

6           “(B) DETERMINATIONS.—

7           “(i) CONSIDERATIONS.—In making a  
8           finding described in subparagraph (A), the  
9           Secretary shall consider scientific evidence  
10          concerning—

11           “(I) the risks and benefits to the  
12           population as a whole, including users  
13           and nonusers of tobacco products, of  
14           the proposed standard;

15           “(II) the increased or decreased  
16           likelihood that existing users of to-  
17           bacco products will stop using such  
18           products; and

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

23           “(ii)        ADDITIONAL        CONSIDER-  
24           ATIONS.—In the event that the Secretary  
25           makes a determination, set forth in a pro-

1           posed tobacco product standard in a pro-  
2           posed rule, that it is appropriate for the  
3           protection of public health to require the  
4           reduction or elimination of an additive,  
5           constituent (including a smoke constitu-  
6           ent), or other component of a tobacco  
7           product because the Secretary has found  
8           that the additive, constituent, or other  
9           component is or may be harmful, any  
10          party objecting to the proposed standard  
11          on the ground that the proposed standard  
12          will not reduce or eliminate the risk of ill-  
13          ness or injury may provide for the Sec-  
14          retary's consideration scientific evidence  
15          that demonstrates that the proposed stand-  
16          ard will not reduce or eliminate the risk of  
17          illness or injury.

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

21                         “(A) shall include provisions that are ap-  
22                         propriate for the protection of the public health,  
23                         including provisions, where appropriate—

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

1           “(ii) for the reduction or elimination  
2 of other constituents, including smoke con-  
3 stituents, or harmful components of the  
4 product; or

5           “(iii) relating to any other require-  
6 ment under subparagraph (B);

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

9           “(i) provisions respecting the con-  
10 struction, components, ingredients, addi-  
11 tives, constituents, including smoke con-  
12 stituents, and properties of the tobacco  
13 product;

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

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

20           “(iv) provisions requiring that the re-  
21 sults of each or of certain of the tests of  
22 the tobacco product required to be made  
23 under clause (ii) show that the tobacco  
24 product is in conformity with the portions

1 of the standard for which the test or tests  
2 were required; and

3 “(v) a provision requiring that the  
4 sale and distribution of the tobacco prod-  
5 uct be restricted but only to the extent  
6 that the sale and distribution of a tobacco  
7 product may be restricted under a regula-  
8 tion under section 906(d);

9 “(C) shall, where appropriate, require the  
10 use and prescribe the form and content of label-  
11 ing for the proper use of the tobacco product;  
12 and

13 “(D) shall require tobacco products con-  
14 taining foreign-grown tobacco to meet the same  
15 standards applicable to tobacco products con-  
16 taining domestically grown tobacco.

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

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

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

7                   “(B) consult with other Federal agencies  
8                   concerned with standard setting and other na-  
9                   tionally or internationally recognized standard-  
10                  setting entities; and

11                  “(C) invite appropriate participation,  
12                  through joint or other conferences, workshops,  
13                  or other means, by informed persons represent-  
14                  ative of scientific, professional, industry, agri-  
15                  cultural, or consumer organizations who in the  
16                  Secretary’s judgment can make a significant  
17                  contribution.

18           “(b) CONSIDERATIONS BY SECRETARY.—

19                   “(1) TECHNICAL ACHIEVABILITY.—The Sec-  
20                   retary shall consider information submitted in con-  
21                   nection with a proposed standard regarding the tech-  
22                   nical achievability of compliance with such standard.

23                   “(2) OTHER CONSIDERATIONS.—The Secretary  
24                   shall consider all other information submitted in  
25                   connection with a proposed standard, including in-

1 formation concerning the countervailing effects of  
2 the tobacco product standard on the health of ado-  
3 lescent tobacco users, adult tobacco users, or non-  
4 tobacco users, such as the creation of a significant  
5 demand for contraband or other tobacco products  
6 that do not meet the requirements of this chapter  
7 and the significance of such demand.

8 “(c) PROPOSED STANDARDS.—

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

13 “(2) REQUIREMENTS OF NOTICE.—A notice of  
14 proposed rulemaking for the establishment or  
15 amendment of a tobacco product standard for a to-  
16 bacco product shall—

17 “(A) set forth a finding with supporting  
18 justification that the tobacco product standard  
19 is appropriate for the protection of the public  
20 health;

21 “(B) invite interested persons to submit a  
22 draft or proposed tobacco product standard for  
23 consideration by the Secretary;

24 “(C) invite interested persons to submit  
25 comments on structuring the standard so that

1           it does not advantage foreign-grown tobacco  
2           over domestically grown tobacco; and

3           “(D) invite the Secretary of Agriculture to  
4           provide any information or analysis which the  
5           Secretary of Agriculture believes is relevant to  
6           the proposed tobacco product standard.

7           “(3) FINDING.—A notice of proposed rule-  
8           making for the revocation of a tobacco product  
9           standard shall set forth a finding with supporting  
10          justification that the tobacco product standard is no  
11          longer appropriate for the protection of the public  
12          health.

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

15          “(d) PROMULGATION.—

16          “(1) IN GENERAL.—After the expiration of the  
17          period for comment on a notice of proposed rule-  
18          making published under subsection (c) respecting a  
19          tobacco product standard and after consideration of  
20          comments submitted under subsections (b) and (c)  
21          and any report from the Tobacco Products Scientific  
22          Advisory Committee, the Secretary shall—

23                  “(A) if the Secretary determines that the  
24                  standard would be appropriate for the protec-  
25                  tion of the public health, promulgate a regula-

1           tion establishing a tobacco product standard  
2           and publish in the Federal Register findings on  
3           the matters referred to in subsection (c); or

4           “(B) publish a notice terminating the pro-  
5           ceeding for the development of the standard to-  
6           gether with the reasons for such termination.

7           “(2) EFFECTIVE DATE.—A regulation estab-  
8           lishing a tobacco product standard shall set forth  
9           the date or dates upon which the standard shall take  
10          effect, but no such regulation may take effect before  
11          1 year after the date of its publication unless the  
12          Secretary determines that an earlier effective date is  
13          necessary for the protection of the public health.  
14          Such date or dates shall be established so as to min-  
15          imize, consistent with the public health, economic  
16          loss to, and disruption or dislocation of, domestic  
17          and international trade. In establishing such effec-  
18          tive date or dates, the Secretary shall consider infor-  
19          mation submitted in connection with a proposed  
20          product standard by interested parties, including  
21          manufacturers and tobacco growers, regarding the  
22          technical achievability of compliance with the stand-  
23          ard, and including information concerning the exist-  
24          ence of patents that make it impossible to comply in  
25          the timeframe envisioned in the proposed standard.

1 If the Secretary determines, based on the Sec-  
2 retary's evaluation of submitted comments, that a  
3 product standard can be met only by manufacturers  
4 requiring substantial changes to the methods of  
5 farming the domestically grown tobacco used by the  
6 manufacturer, the effective date of that product  
7 standard shall be not less than 2 years after the  
8 date of publication of the final regulation estab-  
9 lishing the standard.

10 “(3) LIMITATION ON POWER GRANTED TO THE  
11 FOOD AND DRUG ADMINISTRATION.—Because of the  
12 importance of a decision of the Secretary to issue a  
13 regulation—

14 “(A) banning all cigarettes, all smokeless  
15 tobacco products, all little cigars, all cigars  
16 other than little cigars, all pipe tobacco, or all  
17 roll-your-own tobacco products; or

18 “(B) requiring the reduction of nicotine  
19 yields of a tobacco product to zero,  
20 the Secretary is prohibited from taking such actions  
21 under this Act.

22 “(4) AMENDMENT; REVOCATION.—

23 “(A) AUTHORITY.—The Secretary, upon  
24 the Secretary's own initiative or upon petition  
25 of an interested person, may by a regulation,

1 promulgated in accordance with the require-  
2 ments of subsection (c) and paragraph (2),  
3 amend or revoke a tobacco product standard.

4 “(B) EFFECTIVE DATE.—The Secretary  
5 may declare a proposed amendment of a to-  
6 bacco product standard to be effective on and  
7 after its publication in the Federal Register and  
8 until the effective date of any final action taken  
9 on such amendment if the Secretary determines  
10 that making it so effective is in the public inter-  
11 est.

12 “(5) REFERRAL TO ADVISORY COMMITTEE.—

13 “(A) IN GENERAL.—The Secretary may  
14 refer a proposed regulation for the establish-  
15 ment, amendment, or revocation of a tobacco  
16 product standard to the Tobacco Products Sci-  
17 entific Advisory Committee for a report and  
18 recommendation with respect to any matter in-  
19 volved in the proposed regulation which requires  
20 the exercise of scientific judgment.

21 “(B) INITIATION OF REFERRAL.—The Sec-  
22 retary may make a referral under this para-  
23 graph—

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

25 or

1                   “(ii) upon the request of an interested  
2                   person that—

3                               “(I) demonstrates good cause for  
4                               the referral; and

5                               “(II) is made before the expira-  
6                               tion of the period for submission of  
7                               comments on the proposed regulation.

8                   “(C) PROVISION OF DATA.—If a proposed  
9                   regulation is referred under this paragraph to  
10                   the Tobacco Products Scientific Advisory Com-  
11                   mittee, the Secretary shall provide the Advisory  
12                   Committee with the data and information on  
13                   which such proposed regulation is based.

14                   “(D) REPORT AND RECOMMENDATION.—  
15                   The Tobacco Products Scientific Advisory Com-  
16                   mittee shall, within 60 days after the referral of  
17                   a proposed regulation under this paragraph and  
18                   after independent study of the data and infor-  
19                   mation furnished to it by the Secretary and  
20                   other data and information before it, submit to  
21                   the Secretary a report and recommendation re-  
22                   specting such regulation, together with all un-  
23                   derlying data and information and a statement  
24                   of the reason or basis for the recommendation.

1           “(E) PUBLIC AVAILABILITY.—The Sec-  
2           retary shall make a copy of each report and rec-  
3           ommendation under subparagraph (D) publicly  
4           available.

5           “(e) MENTHOL CIGARETTES.—

6           “(1) REFERRAL; CONSIDERATIONS.—Imme-  
7           diately upon the establishment of the Tobacco Prod-  
8           ucts Scientific Advisory Committee under section  
9           917(a), the Secretary shall refer to the Committee  
10          for report and recommendation, under section  
11          917(c)(4), the issue of the impact of the use of men-  
12          thol in cigarettes on the public health, including  
13          such use among children, African Americans, His-  
14          panics, and other racial and ethnic minorities. In its  
15          review, the Tobacco Products Scientific Advisory  
16          Committee shall address the considerations listed in  
17          subsections (a)(3)(B)(i) and (b).

18          “(2) REPORT AND RECOMMENDATION.—Not  
19          later than 1 year after its establishment, the To-  
20          bacco Product Scientific Advisory Committee shall  
21          submit to the Secretary the report and recommenda-  
22          tions required pursuant to paragraph (1).

23          “(3) RULE OF CONSTRUCTION.—Nothing in  
24          this subsection shall be construed to limit the Sec-

1       retary’s authority to take action under this section  
2       or other sections of this Act applicable to menthol.

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

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

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

10              “(2) notification under this subsection is nec-  
11       essary to eliminate the unreasonable risk of such  
12       harm and no more practicable means is available  
13       under the provisions of this chapter (other than this  
14       section) to eliminate such risk,

15       the Secretary may issue such order as may be necessary  
16       to assure that adequate notification is provided in an ap-  
17       propriate form, by the persons and means best suited  
18       under the circumstances involved, to all persons who  
19       should properly receive such notification in order to elimi-  
20       nate such risk. The Secretary may order notification by  
21       any appropriate means, including public service announce-  
22       ments. Before issuing an order under this subsection, the  
23       Secretary shall consult with the persons who are to give  
24       notice under the order.

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

8       “(c) RECALL AUTHORITY.—

9           “(1) IN GENERAL.—If the Secretary finds that  
10 there is a reasonable probability that a tobacco prod-  
11 uct contains a manufacturing or other defect not or-  
12 dinarily contained in tobacco products on the market  
13 that would cause serious, adverse health con-  
14 sequences or death, the Secretary shall issue an  
15 order requiring the appropriate person (including  
16 the manufacturers, importers, distributors, or retail-  
17 ers of the tobacco product) to immediately cease dis-  
18 tribution of such tobacco product. The order shall  
19 provide the person subject to the order with an op-  
20 portunity for an informal hearing, to be held not  
21 later than 10 days after the date of the issuance of  
22 the order, on the actions required by the order and  
23 on whether the order should be amended to require  
24 a recall of such tobacco product. If, after providing  
25 an opportunity for such a hearing, the Secretary de-

1       termines that inadequate grounds exist to support  
2       the actions required by the order, the Secretary shall  
3       vacate the order.

4               “(2) AMENDMENT OF ORDER TO REQUIRE RE-  
5       CALL.—

6               “(A) IN GENERAL.—If, after providing an  
7       opportunity for an informal hearing under  
8       paragraph (1), the Secretary determines that  
9       the order should be amended to include a recall  
10      of the tobacco product with respect to which the  
11      order was issued, the Secretary shall, except as  
12      provided in subparagraph (B), amend the order  
13      to require a recall. The Secretary shall specify  
14      a timetable in which the tobacco product recall  
15      will occur and shall require periodic reports to  
16      the Secretary describing the progress of the re-  
17      call.

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

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

22                      “(ii) shall provide for notice to per-  
23                      sons subject to the risks associated with  
24                      the use of such tobacco product.

1           In providing the notice required by clause (ii),  
2           the Secretary may use the assistance of retail-  
3           ers and other persons who distributed such to-  
4           bacco product. If a significant number of such  
5           persons cannot be identified, the Secretary shall  
6           notify such persons under section 705(b).

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

10 **“SEC. 909. RECORDS AND REPORTS ON TOBACCO PROD-**  
11 **UCTS.**

12           “(a) IN GENERAL.—Every person who is a tobacco  
13           product manufacturer or importer of a tobacco product  
14           shall establish and maintain such records, make such re-  
15           ports, and provide such information, as the Secretary may  
16           by regulation reasonably require to assure that such to-  
17           bacco product is not adulterated or misbranded and to  
18           otherwise protect public health. Regulations prescribed  
19           under the preceding sentence—

20           “(1) may require a tobacco product manufac-  
21           turer or importer to report to the Secretary when-  
22           ever the manufacturer or importer receives or other-  
23           wise becomes aware of information that reasonably  
24           suggests that one of its marketed tobacco products  
25           may have caused or contributed to a serious unex-

1       pected adverse experience associated with the use of  
2       the product or any significant increase in the fre-  
3       quency of a serious, expected adverse product experi-  
4       ence;

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

8               “(3) shall not impose requirements unduly bur-  
9       densome to a tobacco product manufacturer or im-  
10      porter, taking into account the cost of complying  
11      with such requirements and the need for the protec-  
12      tion of the public health and the implementation of  
13      this chapter;

14              “(4) when prescribing the procedure for making  
15      requests for reports or information, shall require  
16      that each request made under such regulations for  
17      submission of a report or information to the Sec-  
18      retary state the reason or purpose for such request  
19      and identify to the fullest extent practicable such re-  
20      port or information;

21              “(5) when requiring submission of a report or  
22      information to the Secretary, shall state the reason  
23      or purpose for the submission of such report or in-  
24      formation and identify to the fullest extent prac-  
25      ticable such report or information; and

1           “(6) may not require that the identity of any  
2           patient or user be disclosed in records, reports, or  
3           information required under this subsection unless re-  
4           quired for the medical welfare of an individual, to  
5           determine risks to public health of a tobacco prod-  
6           uct, or to verify a record, report, or information sub-  
7           mitted under this chapter.

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

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

16                 “(1) IN GENERAL.—Except as provided in para-  
17                 graph (2), the Secretary shall by regulation require  
18                 a tobacco product manufacturer or importer of a to-  
19                 bacco product to report promptly to the Secretary  
20                 any corrective action taken or removal from the  
21                 market of a tobacco product undertaken by such  
22                 manufacturer or importer if the removal or correc-  
23                 tion was undertaken—

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

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

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

9           “(2) EXCEPTION.—No report of the corrective  
10          action or removal of a tobacco product may be re-  
11          quired under paragraph (1) if a report of the correc-  
12          tive action or removal is required and has been sub-  
13          mitted under subsection (a).

14 **“SEC. 910. APPLICATION FOR REVIEW OF CERTAIN TO-**  
15 **BACCO PRODUCTS.**

16          “(a) IN GENERAL.—

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

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

24                         “(B) any modification (including a change  
25                         in design, any component, any part, or any con-

1           stituent, including a smoke constituent, or in  
2           the content, delivery or form of nicotine, or any  
3           other additive or ingredient) of a tobacco prod-  
4           uct where the modified product was commer-  
5           cially marketed in the United States after Feb-  
6           ruary 15, 2007.

7           “(2) PREMARKET REVIEW REQUIRED.—

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

11                           “(i) the manufacturer has submitted a  
12                           report under section 905(j); and the Sec-  
13                           retary has issued an order that the tobacco  
14                           product—

15                                   “(I) is substantially equivalent to  
16                                   a tobacco product commercially mar-  
17                                   keted (other than for test marketing)  
18                                   in the United States as of February  
19                                   15, 2007; and

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

22                                   “(ii) the tobacco product is exempt  
23                                   from the requirements of section 905(j)  
24                                   pursuant to a regulation issued under sec-  
25                                   tion 905(j)(3).

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

4                   “(i) that was first introduced or deliv-  
5                   ered for introduction into interstate com-  
6                   merce for commercial distribution in the  
7                   United States after February 15, 2007,  
8                   and prior to the date that is 21 months  
9                   after the date of enactment of the Family  
10                  Smoking Prevention and Tobacco Control  
11                  Act; and

12                   “(ii) for which a report was submitted  
13                   under section 905(j) within such 21-month  
14                   period,

15           except that subparagraph (A) shall apply to the  
16           tobacco product if the Secretary issues an order  
17           that the tobacco product is not substantially  
18           equivalent.

19           “(3) SUBSTANTIALLY EQUIVALENT DEFINED.—

20                   “(A) IN GENERAL.—In this section and  
21                   section 905(j), the term ‘substantially equiva-  
22                   lent’ or ‘substantial equivalence’ means, with  
23                   respect to the tobacco product being compared  
24                   to the predicate tobacco product, that the Sec-

1           retary by order has found that the tobacco  
2           product—

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

5                   “(ii) has different characteristics and  
6                   the information submitted contains infor-  
7                   mation, including clinical data if deemed  
8                   necessary by the Secretary, that dem-  
9                   onstrates that it is not appropriate to reg-  
10                  ulate the product under this section be-  
11                  cause the product does not raise different  
12                  questions of public health.

13                  “(B) CHARACTERISTICS.—In subpara-  
14                  graph (A), the term ‘characteristics’ means the  
15                  materials, ingredients, design, composition,  
16                  heating source, or other features of a tobacco  
17                  product.

18                  “(C) LIMITATION.—A tobacco product may  
19                  not be found to be substantially equivalent to a  
20                  predicate tobacco product that has been re-  
21                  moved from the market at the initiative of the  
22                  Secretary or that has been determined by a ju-  
23                  dicial order to be misbranded or adulterated.

24                  “(4) HEALTH INFORMATION.—

1           “(A) SUMMARY.—As part of a submission  
2 under section 905(j) respecting a tobacco prod-  
3 uct, the person required to file a premarket no-  
4 tification under such section shall provide an  
5 adequate summary of any health information  
6 related to the tobacco product or state that  
7 such information will be made available upon  
8 request by any person.

9           “(B) REQUIRED INFORMATION.—Any sum-  
10 mary under subparagraph (A) respecting a to-  
11 bacco product shall contain detailed information  
12 regarding data concerning adverse health ef-  
13 fects and shall be made available to the public  
14 by the Secretary within 30 days of the issuance  
15 of a determination that such tobacco product is  
16 substantially equivalent to another tobacco  
17 product.

18       “(b) APPLICATION.—

19           “(1) CONTENTS.—An application under this  
20 section shall contain—

21           “(A) full reports of all information, pub-  
22 lished or known to, or which should reasonably  
23 be known to, the applicant, concerning inves-  
24 tigations which have been made to show the  
25 health risks of such tobacco product and wheth-

1 er such tobacco product presents less risk than  
2 other tobacco products;

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

7 “(C) a full description of the methods used  
8 in, and the facilities and controls used for, the  
9 manufacture, processing, and, when relevant,  
10 packing and installation of, such tobacco prod-  
11 uct;

12 “(D) an identifying reference to any to-  
13 bacco product standard under section 907  
14 which would be applicable to any aspect of such  
15 tobacco product, and either adequate informa-  
16 tion to show that such aspect of such tobacco  
17 product fully meets such tobacco product stand-  
18 ard or adequate information to justify any devi-  
19 ation from such standard;

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

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

1           “(G) such other information relevant to  
2           the subject matter of the application as the Sec-  
3           retary may require.

4           “(2) REFERRAL TO TOBACCO PRODUCTS SCI-  
5           ENTIFIC ADVISORY COMMITTEE.—Upon receipt of an  
6           application meeting the requirements set forth in  
7           paragraph (1), the Secretary—

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

10           “(B) may, upon the request of an appli-  
11           cant,

12           refer such application to the Tobacco Products Sci-  
13           entific Advisory Committee for reference and for  
14           submission (within such period as the Secretary may  
15           establish) of a report and recommendation respect-  
16           ing the application, together with all underlying data  
17           and the reasons or basis for the recommendation.

18           “(c) ACTION ON APPLICATION.—

19           “(1) DEADLINE.—

20           “(A) IN GENERAL.—As promptly as pos-  
21           sible, but in no event later than 180 days after  
22           the receipt of an application under subsection  
23           (b), the Secretary, after considering the report  
24           and recommendation submitted under sub-  
25           section (b)(2), shall—

1           “(i) issue an order that the new prod-  
2           uct may be introduced or delivered for in-  
3           troduction into interstate commerce if the  
4           Secretary finds that none of the grounds  
5           specified in paragraph (2) of this sub-  
6           section applies; or

7           “(ii) issue an order that the new prod-  
8           uct may not be introduced or delivered for  
9           introduction into interstate commerce if  
10          the Secretary finds (and sets forth the  
11          basis for such finding as part of or accom-  
12          panying such denial) that 1 or more  
13          grounds for denial specified in paragraph  
14          (2) of this subsection apply.

15          “(B) RESTRICTIONS ON SALE AND DIS-  
16          TRIBUTION.—An order under subparagraph  
17          (A)(i) may require that the sale and distribu-  
18          tion of the tobacco product be restricted but  
19          only to the extent that the sale and distribution  
20          of a tobacco product may be restricted under a  
21          regulation under section 906(d).

22          “(2) DENIAL OF APPLICATION.—The Secretary  
23          shall deny an application submitted under subsection  
24          (b) if, upon the basis of the information submitted  
25          to the Secretary as part of the application and any

1 other information before the Secretary with respect  
2 to such tobacco product, the Secretary finds that—

3 “(A) there is a lack of a showing that per-  
4 mitting such tobacco product to be marketed  
5 would be appropriate for the protection of the  
6 public health;

7 “(B) the methods used in, or the facilities  
8 or controls used for, the manufacture, proc-  
9 essing, or packing of such tobacco product do  
10 not conform to the requirements of section  
11 906(e);

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

15 “(D) such tobacco product is not shown to  
16 conform in all respects to a tobacco product  
17 standard in effect under section 907, and there  
18 is a lack of adequate information to justify the  
19 deviation from such standard.

20 “(3) DENIAL INFORMATION.—Any denial of an  
21 application shall, insofar as the Secretary determines  
22 to be practicable, be accompanied by a statement in-  
23 forming the applicant of the measures required to  
24 remove such application from deniable form (which  
25 measures may include further research by the appli-

1 cant in accordance with 1 or more protocols pre-  
2 scribed by the Secretary).

3 “(4) BASIS FOR FINDING.—For purposes of  
4 this section, the finding as to whether the marketing  
5 of a tobacco product for which an application has  
6 been submitted is appropriate for the protection of  
7 the public health shall be determined with respect to  
8 the risks and benefits to the population as a whole,  
9 including users and nonusers of the tobacco product,  
10 and taking into account—

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

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

17 “(5) BASIS FOR ACTION.—

18 “(A) INVESTIGATIONS.—For purposes of  
19 paragraph (2)(A), whether permitting a tobacco  
20 product to be marketed would be appropriate  
21 for the protection of the public health shall,  
22 when appropriate, be determined on the basis of  
23 well-controlled investigations, which may in-  
24 clude 1 or more clinical investigations by ex-

1           perts qualified by training and experience to  
2           evaluate the tobacco product.

3           “(B) OTHER EVIDENCE.—If the Secretary  
4           determines that there exists valid scientific evi-  
5           dence (other than evidence derived from inves-  
6           tigations described in subparagraph (A)) which  
7           is sufficient to evaluate the tobacco product, the  
8           Secretary may authorize that the determination  
9           for purposes of paragraph (2)(A) be made on  
10          the basis of such evidence.

11          “(d) WITHDRAWAL AND TEMPORARY SUSPENSION.—

12           “(1) IN GENERAL.—The Secretary shall, upon  
13           obtaining, where appropriate, advice on scientific  
14           matters from the Tobacco Products Scientific Advi-  
15           sory Committee, and after due notice and oppor-  
16           tunity for informal hearing for a tobacco product for  
17           which an order was issued under subsection  
18           (c)(1)(A)(i), issue an order withdrawing the order if  
19           the Secretary finds—

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

23           “(B) that the application contained or was  
24           accompanied by an untrue statement of a mate-  
25           rial fact;

1 “(C) that the applicant—

2 “(i) has failed to establish a system  
3 for maintaining records, or has repeatedly  
4 or deliberately failed to maintain records  
5 or to make reports, required by an applica-  
6 ble regulation under section 909;

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

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

12 “(D) on the basis of new information be-  
13 fore the Secretary with respect to such tobacco  
14 product, evaluated together with the evidence  
15 before the Secretary when the application was  
16 reviewed, that the methods used in, or the fa-  
17 cilities and controls used for, the manufacture,  
18 processing, packing, or installation of such to-  
19 bacco product do not conform with the require-  
20 ments of section 906(e) and were not brought  
21 into conformity with such requirements within a  
22 reasonable time after receipt of written notice  
23 from the Secretary of nonconformity;

24 “(E) on the basis of new information be-  
25 fore the Secretary, evaluated together with the

1 evidence before the Secretary when the applica-  
2 tion was reviewed, that the labeling of such to-  
3 bacco product, based on a fair evaluation of all  
4 material facts, is false or misleading in any par-  
5 ticular and was not corrected within a reason-  
6 able time after receipt of written notice from  
7 the Secretary of such fact; or

8 “(F) on the basis of new information be-  
9 fore the Secretary, evaluated together with the  
10 evidence before the Secretary when such order  
11 was issued, that such tobacco product is not  
12 shown to conform in all respects to a tobacco  
13 product standard which is in effect under sec-  
14 tion 907, compliance with which was a condi-  
15 tion to the issuance of an order relating to the  
16 application, and that there is a lack of adequate  
17 information to justify the deviation from such  
18 standard.

19 “(2) APPEAL.—The holder of an application  
20 subject to an order issued under paragraph (1) with-  
21 drawing an order issued pursuant to subsection  
22 (c)(1)(A)(i) may, by petition filed on or before the  
23 30th day after the date upon which such holder re-  
24 ceives notice of such withdrawal, obtain review there-  
25 of in accordance with section 912.

1           “(3) TEMPORARY SUSPENSION.—If, after pro-  
2           viding an opportunity for an informal hearing, the  
3           Secretary determines there is reasonable probability  
4           that the continuation of distribution of a tobacco  
5           product under an order would cause serious, adverse  
6           health consequences or death, that is greater than  
7           ordinarily caused by tobacco products on the market,  
8           the Secretary shall by order temporarily suspend the  
9           authority of the manufacturer to market the prod-  
10          uct. If the Secretary issues such an order, the Sec-  
11          retary shall proceed expeditiously under paragraph  
12          (1) to withdraw such application.

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

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

17                 “(2) by mailing the order by registered mail or  
18                 certified mail addressed to the applicant at the ap-  
19                 plicant’s last known address in the records of the  
20                 Secretary.

21          “(f) RECORDS.—

22                 “(1) ADDITIONAL INFORMATION.—In the case  
23                 of any tobacco product for which an order issued  
24                 pursuant to subsection (c)(1)(A)(i) for an applica-  
25                 tion filed under subsection (b) is in effect, the appli-

1       cant shall establish and maintain such records, and  
2       make such reports to the Secretary, as the Secretary  
3       may by regulation, or by order with respect to such  
4       application, prescribe on the basis of a finding that  
5       such records and reports are necessary in order to  
6       enable the Secretary to determine, or facilitate a de-  
7       termination of, whether there is or may be grounds  
8       for withdrawing or temporarily suspending such  
9       order.

10           “(2) ACCESS TO RECORDS.—Each person re-  
11       quired under this section to maintain records, and  
12       each person in charge of custody thereof, shall, upon  
13       request of an officer or employee designated by the  
14       Secretary, permit such officer or employee at all rea-  
15       sonable times to have access to and copy and verify  
16       such records.

17           “(g) INVESTIGATIONAL TOBACCO PRODUCT EXEMP-  
18       TION FOR INVESTIGATIONAL USE.—The Secretary may  
19       exempt tobacco products intended for investigational use  
20       from the provisions of this chapter under such conditions  
21       as the Secretary may by regulation prescribe.

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

23           “(a) IN GENERAL.—No person may introduce or de-  
24       liver for introduction into interstate commerce any modi-

1 fied risk tobacco product unless an order issued pursuant  
2 to subsection (g) is effective with respect to such product.

3 “(b) DEFINITIONS.—In this section:

4 “(1) MODIFIED RISK TOBACCO PRODUCT.—The  
5 term ‘modified risk tobacco product’ means any to-  
6 bacco product that is sold or distributed for use to  
7 reduce harm or the risk of tobacco-related disease  
8 associated with commercially marketed tobacco prod-  
9 ucts.

10 “(2) SOLD OR DISTRIBUTED.—

11 “(A) IN GENERAL.—With respect to a to-  
12 bacco product, the term ‘sold or distributed for  
13 use to reduce harm or the risk of tobacco-re-  
14 lated disease associated with commercially mar-  
15 keted tobacco products’ means a tobacco prod-  
16 uct—

17 “(i) the label, labeling, or advertising  
18 of which represents explicitly or implicitly  
19 that—

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

1                   “(II) the tobacco product or its  
2                   smoke contains a reduced level of a  
3                   substance or presents a reduced expo-  
4                   sure to a substance; or

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

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

11                  “(iii) the tobacco product manufac-  
12                  turer of which has taken any action di-  
13                  rected to consumers through the media or  
14                  otherwise, other than by means of the to-  
15                  bacco product’s label, labeling, or adver-  
16                  tising, after the date of enactment of the  
17                  Family Smoking Prevention and Tobacco  
18                  Control Act, respecting the product that  
19                  would be reasonably expected to result in  
20                  consumers believing that the tobacco prod-  
21                  uct or its smoke may present a lower risk  
22                  of disease or is less harmful than one or  
23                  more commercially marketed tobacco prod-  
24                  ucts, or presents a reduced exposure to, or

1           does not contain or is free of, a substance  
2           or substances.

3           “(B) LIMITATION.—No tobacco product  
4           shall be considered to be ‘sold or distributed for  
5           use to reduce harm or the risk of tobacco-re-  
6           lated disease associated with commercially mar-  
7           keted tobacco products’, except as described in  
8           subparagraph (A).

9           “(C) SMOKELESS TOBACCO PRODUCT.—No  
10          smokeless tobacco product shall be considered  
11          to be ‘sold or distributed for use to reduce harm  
12          or the risk of tobacco-related disease associated  
13          with commercially marketed tobacco products’  
14          solely because its label, labeling, or advertising  
15          uses the following phrases to describe such  
16          product and its use: ‘smokeless tobacco’,  
17          ‘smokeless tobacco product’, ‘not consumed by  
18          smoking’, ‘does not produce smoke’,  
19          ‘smokefree’, ‘smoke-free’, ‘without smoke’, ‘no  
20          smoke’, or ‘not smoke’.

21          “(3) EFFECTIVE DATE.—The provisions of  
22          paragraph (2)(A)(ii) shall take effect 12 months  
23          after the date of enactment of the Family Smoking  
24          Prevention and Tobacco Control Act for those prod-  
25          ucts whose label, labeling, or advertising contains

1 the terms described in such paragraph on such date  
2 of enactment. The effective date shall be with re-  
3 spect to the date of manufacture, provided that, in  
4 any case, beginning 30 days after such effective  
5 date, a manufacturer shall not introduce into the do-  
6 mestic commerce of the United States any product,  
7 irrespective of the date of manufacture, that is not  
8 in conformance with paragraph (2)(A)(ii).

9 “(c) TOBACCO DEPENDENCE PRODUCTS.—A product  
10 that is intended to be used for the treatment of tobacco  
11 dependence, including smoking cessation, is not a modified  
12 risk tobacco product under this section if it has been ap-  
13 proved as a drug or device by the Food and Drug Adminis-  
14 tration and is subject to the requirements of chapter V.

15 “(d) FILING.—Any person may file with the Sec-  
16 retary an application for a modified risk tobacco product.  
17 Such application shall include—

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

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

21 “(3) the formulation of the product;

22 “(4) sample product labels and labeling;

23 “(5) all documents (including underlying sci-  
24 entific information) relating to research findings  
25 conducted, supported, or possessed by the tobacco

1 product manufacturer relating to the effect of the  
2 product on tobacco-related diseases and health-re-  
3 lated conditions, including information both favor-  
4 able and unfavorable to the ability of the product to  
5 reduce risk or exposure and relating to human  
6 health;

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

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

11 “(e) PUBLIC AVAILABILITY.—The Secretary shall  
12 make the application described in subsection (d) publicly  
13 available (except matters in the application which are  
14 trade secrets or otherwise confidential, commercial infor-  
15 mation) and shall request comments by interested persons  
16 on the information contained in the application and on the  
17 label, labeling, and advertising accompanying such appli-  
18 cation.

19 “(f) ADVISORY COMMITTEE.—

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

23 “(2) RECOMMENDATIONS.—Not later than 60  
24 days after the date an application is referred to the  
25 Tobacco Products Scientific Advisory Committee

1 under paragraph (1), the Advisory Committee shall  
2 report its recommendations on the application to the  
3 Secretary.

4 “(g) MARKETING.—

5 “(1) MODIFIED RISK PRODUCTS.—Except as  
6 provided in paragraph (2), the Secretary shall, with  
7 respect to an application submitted under this sec-  
8 tion, issue an order that a modified risk product  
9 may be commercially marketed only if the Secretary  
10 determines that the applicant has demonstrated that  
11 such product, as it is actually used by consumers,  
12 will—

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

16 “(B) benefit the health of the population  
17 as a whole taking into account both users of to-  
18 bacco products and persons who do not cur-  
19 rently use tobacco products.

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

21 “(A) IN GENERAL.—The Secretary may  
22 issue an order that a tobacco product may be  
23 introduced or delivered for introduction into  
24 interstate commerce, pursuant to an application  
25 under this section, with respect to a tobacco

1 product that may not be commercially marketed  
2 under paragraph (1) if the Secretary makes the  
3 findings required under this paragraph and de-  
4 termines that the applicant has demonstrated  
5 that—

6 “(i) such order would be appropriate  
7 to promote the public health;

8 “(ii) any aspect of the label, labeling,  
9 and advertising for such product that  
10 would cause the tobacco product to be a  
11 modified risk tobacco product under sub-  
12 section (b) is limited to an explicit or im-  
13 plicit representation that such tobacco  
14 product or its smoke does not contain or is  
15 free of a substance or contains a reduced  
16 level of a substance, or presents a reduced  
17 exposure to a substance in tobacco smoke;

18 “(iii) scientific evidence is not avail-  
19 able and, using the best available scientific  
20 methods, cannot be made available without  
21 conducting long-term epidemiological stud-  
22 ies for an application to meet the stand-  
23 ards set forth in paragraph (1); and

24 “(iv) the scientific evidence that is  
25 available without conducting long-term epi-

1           demiological studies demonstrates that a  
2           measurable and substantial reduction in  
3           morbidity or mortality among individual  
4           tobacco users is reasonably likely in subse-  
5           quent studies.

6           “(B) ADDITIONAL FINDINGS REQUIRED.—

7           To issue an order under subparagraph (A) the  
8           Secretary must also find that the applicant has  
9           demonstrated that—

10           “(i) the magnitude of the overall re-  
11           ductions in exposure to the substance or  
12           substances which are the subject of the ap-  
13           plication is substantial, such substance or  
14           substances are harmful, and the product as  
15           actually used exposes consumers to the  
16           specified reduced level of the substance or  
17           substances;

18           “(ii) the product as actually used by  
19           consumers will not expose them to higher  
20           levels of other harmful substances com-  
21           pared to the similar types of tobacco prod-  
22           ucts then on the market unless such in-  
23           creases are minimal and the reasonably  
24           likely overall impact of use of the product  
25           remains a substantial and measurable re-

1           duction in overall morbidity and mortality  
2           among individual tobacco users;

3           “(iii) testing of actual consumer per-  
4           ception shows that, as the applicant pro-  
5           poses to label and market the product, con-  
6           sumers will not be misled into believing  
7           that the product—

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

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

14           “(iv) issuance of an order with respect  
15           to the application is expected to benefit the  
16           health of the population as a whole taking  
17           into account both users of tobacco prod-  
18           ucts and persons who do not currently use  
19           tobacco products.

20           “(C) CONDITIONS OF MARKETING.—

21                   “(i) IN GENERAL.—Applications sub-  
22                   ject to an order under this paragraph shall  
23                   be limited to a term of not more than 5  
24                   years, but may be renewed upon a finding  
25                   by the Secretary that the requirements of

1 this paragraph continue to be satisfied  
2 based on the filing of a new application.

3 “(ii) AGREEMENTS BY APPLICANT.—

4 An order under this paragraph shall be  
5 conditioned on the applicant’s agreement  
6 to conduct postmarket surveillance and  
7 studies and to submit to the Secretary the  
8 results of such surveillance and studies to  
9 determine the impact of the order on con-  
10 sumer perception, behavior, and health and  
11 to enable the Secretary to review the accu-  
12 racy of the determinations upon which the  
13 order was based in accordance with a pro-  
14 tocol approved by the Secretary.

15 “(iii) ANNUAL SUBMISSION.—The re-

16 sults of such postmarket surveillance and  
17 studies described in clause (ii) shall be  
18 submitted annually.

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

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

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

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

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

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

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

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

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

25           “(h) ADDITIONAL CONDITIONS FOR MARKETING.—

1           “(1) MODIFIED RISK PRODUCTS.—The Sec-  
2           retary shall require for the marketing of a product  
3           under this section that any advertising or labeling  
4           concerning modified risk products enable the public  
5           to comprehend the information concerning modified  
6           risk and to understand the relative significance of  
7           such information in the context of total health and  
8           in relation to all of the diseases and health-related  
9           conditions associated with the use of tobacco prod-  
10          ucts.

11           “(2) COMPARATIVE CLAIMS.—

12           “(A) IN GENERAL.—The Secretary may re-  
13           quire for the marketing of a product under this  
14           subsection that a claim comparing a tobacco  
15           product to 1 or more other commercially mar-  
16           keted tobacco products shall compare the to-  
17           bacco product to a commercially marketed to-  
18           bacco product that is representative of that type  
19           of tobacco product on the market (for example  
20           the average value of the top 3 brands of an es-  
21           tablished regular tobacco product).

22           “(B) QUANTITATIVE COMPARISONS.—The  
23           Secretary may also require, for purposes of sub-  
24           paragraph (A), that the percent (or fraction) of  
25           change and identity of the reference tobacco

1 product and a quantitative comparison of the  
2 amount of the substance claimed to be reduced  
3 shall be stated in immediate proximity to the  
4 most prominent claim.

5 “(3) LABEL DISCLOSURE.—

6 “(A) IN GENERAL.—The Secretary may re-  
7 quire the disclosure on the label of other sub-  
8 stances in the tobacco product, or substances  
9 that may be produced by the consumption of  
10 that tobacco product, that may affect a disease  
11 or health-related condition or may increase the  
12 risk of other diseases or health-related condi-  
13 tions associated with the use of tobacco prod-  
14 ucts.

15 “(B) CONDITIONS OF USE.—If the condi-  
16 tions of use of the tobacco product may affect  
17 the risk of the product to human health, the  
18 Secretary may require the labeling of conditions  
19 of use.

20 “(4) TIME.—An order issued under subsection  
21 (g)(1) shall be effective for a specified period of  
22 time.

23 “(5) ADVERTISING.—The Secretary may re-  
24 quire, with respect to a product for which an appli-  
25 cant obtained an order under subsection (g)(1), that

1 the product comply with requirements relating to ad-  
2 vertising and promotion of the tobacco product.

3 “(i) POSTMARKET SURVEILLANCE AND STUDIES.—

4 “(1) IN GENERAL.—The Secretary shall re-  
5 quire, with respect to a product for which an appli-  
6 cant obtained an order under subsection (g)(1), that  
7 the applicant conduct postmarket surveillance and  
8 studies for such a tobacco product to determine the  
9 impact of the order issuance on consumer percep-  
10 tion, behavior, and health, to enable the Secretary to  
11 review the accuracy of the determinations upon  
12 which the order was based, and to provide informa-  
13 tion that the Secretary determines is otherwise nec-  
14 essary regarding the use or health risks involving  
15 the tobacco product. The results of postmarket sur-  
16 veillance and studies shall be submitted to the Sec-  
17 retary on an annual basis.

18 “(2) SURVEILLANCE PROTOCOL.—Each appli-  
19 cant required to conduct a surveillance of a tobacco  
20 product under paragraph (1) shall, within 30 days  
21 after receiving notice that the applicant is required  
22 to conduct such surveillance, submit, for the ap-  
23 proval of the Secretary, a protocol for the required  
24 surveillance. The Secretary, within 60 days of the  
25 receipt of such protocol, shall determine if the prin-

1        ciprocal investigator proposed to be used in the surveil-  
2        lance has sufficient qualifications and experience to  
3        conduct such surveillance and if such protocol will  
4        result in collection of the data or other information  
5        designated by the Secretary as necessary to protect  
6        the public health.

7        “(j) WITHDRAWAL OF AUTHORIZATION.—The Sec-  
8        retary, after an opportunity for an informal hearing, shall  
9        withdraw an order under subsection (g) if the Secretary  
10       determines that—

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

16                “(2) the application failed to include material  
17                information or included any untrue statement of ma-  
18                terial fact;

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

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

24                        “(B) an action is taken that affects the  
25                        risks presented by other commercially marketed

1 tobacco products that were compared to the  
2 product that is the subject of the application; or

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

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

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

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

14 “(l) IMPLEMENTING REGULATIONS OR GUIDANCE.—

15 “(1) SCIENTIFIC EVIDENCE.—Not later than 2  
16 years after the date of enactment of the Family  
17 Smoking Prevention and Tobacco Control Act, the  
18 Secretary shall issue regulations or guidance (or any  
19 combination thereof) on the scientific evidence re-  
20 quired for assessment and ongoing review of modi-  
21 fied risk tobacco products. Such regulations or guid-  
22 ance shall—

23 “(A) to the extent that adequate scientific  
24 evidence exists, establish minimum standards  
25 for scientific studies needed prior to issuing an

1 order under subsection (g) to show that a sub-  
2 stantial reduction in morbidity or mortality  
3 among individual tobacco users occurs for prod-  
4 ucts described in subsection (g)(1) or is reason-  
5 ably likely for products described in subsection  
6 (g)(2);

7 “(B) include validated biomarkers, inter-  
8 mediate clinical endpoints, and other feasible  
9 outcome measures, as appropriate;

10 “(C) establish minimum standards for  
11 postmarket studies, that shall include regular  
12 and long-term assessments of health outcomes  
13 and mortality, intermediate clinical endpoints,  
14 consumer perception of harm reduction, and the  
15 impact on quitting behavior and new use of to-  
16 bacco products, as appropriate;

17 “(D) establish minimum standards for re-  
18 quired postmarket surveillance, including ongo-  
19 ing assessments of consumer perception;

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

1           “(F) establish a reasonable timetable for  
2           the Secretary to review an application under  
3           this section.

4           “(2) CONSULTATION.—The regulations or guid-  
5           ance issued under paragraph (1) shall be developed  
6           in consultation with the Institute of Medicine, and  
7           with the input of other appropriate scientific and  
8           medical experts, on the design and conduct of such  
9           studies and surveillance.

10          “(3) REVISION.—The regulations or guidance  
11          under paragraph (1) shall be revised on a regular  
12          basis as new scientific information becomes avail-  
13          able.

14          “(4) NEW TOBACCO PRODUCTS.—Not later  
15          than 2 years after the date of enactment of the  
16          Family Smoking Prevention and Tobacco Control  
17          Act, the Secretary shall issue a regulation or guid-  
18          ance that permits the filing of a single application  
19          for any tobacco product that is a new tobacco prod-  
20          uct under section 910 and which the applicant seeks  
21          to commercially market under this section.

22          “(m) DISTRIBUTORS.—Except as provided in this  
23          section, no distributor may take any action, after the date  
24          of enactment of the Family Smoking Prevention and To-  
25          bacco Control Act, with respect to a tobacco product that

1 would reasonably be expected to result in consumers be-  
2 lieving that the tobacco product or its smoke may present  
3 a lower risk of disease or is less harmful than one or more  
4 commercially marketed tobacco products, or presents a re-  
5 duced exposure to, or does not contain or is free of, a sub-  
6 stance or substances.

7 **“SEC. 912. JUDICIAL REVIEW.**

8 “(a) RIGHT TO REVIEW.—

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

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

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

16 any person adversely affected by such regulation or  
17 denial may file a petition for judicial review of such  
18 regulation or denial with the United States Court of  
19 Appeals for the District of Columbia or for the cir-  
20 cuit in which such person resides or has their prin-  
21 cipal place of business.

22 “(2) REQUIREMENTS.—

23 “(A) COPY OF PETITION.—A copy of the  
24 petition filed under paragraph (1) shall be

1 transmitted by the clerk of the court involved to  
2 the Secretary.

3 “(B) RECORD OF PROCEEDINGS.—On re-  
4 ceipt of a petition under subparagraph (A), the  
5 Secretary shall file in the court in which such  
6 petition was filed—

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

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

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

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

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

20 “(iii) proceedings of any panel or ad-  
21 visory committee with respect to such reg-  
22 ulation or order;

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

1                   “(v) any other information identified  
2                   by the Secretary, in the administrative pro-  
3                   ceeding held with respect to such regula-  
4                   tion or order, as being relevant to such  
5                   regulation or order.

6           “(b) STANDARD OF REVIEW.—Upon the filing of the  
7 petition under subsection (a) for judicial review of a regu-  
8 lation or order, the court shall have jurisdiction to review  
9 the regulation or order in accordance with chapter 7 of  
10 title 5, United States Code, and to grant appropriate re-  
11 lief, including interim relief, as provided for in such chap-  
12 ter. A regulation or denial described in subsection (a) shall  
13 be reviewed in accordance with section 706(2)(A) of title  
14 5, United States Code.

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

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

24           “(e) REGULATIONS AND ORDERS MUST RECITE  
25 BASIS IN RECORD.—To facilitate judicial review, a regula-

1 tion or order issued under section 906, 907, 908, 909,  
2 910, or 916 shall contain a statement of the reasons for  
3 the issuance of such regulation or order in the record of  
4 the proceedings held in connection with its issuance.

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

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

11 **“SEC. 914. JURISDICTION OF AND COORDINATION WITH**  
12 **THE FEDERAL TRADE COMMISSION.**

13 “(a) JURISDICTION.—

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

20 “(2) ENFORCEMENT.—Any advertising that vio-  
21 lates this chapter or a provision of the regulations  
22 referred to in section 102 of the Family Smoking  
23 Prevention and Tobacco Control Act, is an unfair or  
24 deceptive act or practice under section 5(a) of the  
25 Federal Trade Commission Act and shall be consid-

1       ered a violation of a rule promulgated under section  
2       18 of that Act.

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

7               “(1) the Chairman of the Federal Trade Com-  
8       mission shall coordinate with the Secretary con-  
9       cerning the enforcement of such Act as such enforce-  
10      ment relates to unfair or deceptive acts or practices  
11      in the advertising of cigarettes or smokeless tobacco;  
12      and

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

16   **“SEC. 915. REGULATION REQUIREMENT.**

17       “(a) TESTING, REPORTING, AND DISCLOSURE.—Not  
18      later than 36 months after the date of enactment of the  
19      Family Smoking Prevention and Tobacco Control Act, the  
20      Secretary shall promulgate regulations under this Act that  
21      meet the requirements of subsection (b).

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

24              “(1) shall require testing and reporting of to-  
25      bacco product constituents, ingredients, and addi-

1       tives, including smoke constituents, by brand and  
2       subbrand that the Secretary determines should be  
3       tested to protect the public health, provided that, for  
4       purposes of the testing requirements of this para-  
5       graph, tobacco products manufactured and sold by a  
6       single tobacco product manufacturer that are iden-  
7       tical in all respects except the labels, packaging de-  
8       sign, logo, trade dress, trademark, brand name, or  
9       any combination thereof, shall be considered as a  
10      single brand; and

11           “(2) may require that tobacco product manu-  
12      facturers, packagers, or importers make disclosures  
13      relating to the results of the testing of tar and nico-  
14      tine through labels or advertising or other appro-  
15      priate means, and make disclosures regarding the  
16      results of the testing of other constituents, including  
17      smoke constituents, ingredients, or additives, that  
18      the Secretary determines should be disclosed to the  
19      public to protect the public health and will not mis-  
20      lead consumers about the risk of tobacco-related dis-  
21      ease.

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

1       “(d) SMALL TOBACCO PRODUCT MANUFACTUR-  
2 ERS.—

3           “(1) FIRST COMPLIANCE DATE.—The initial  
4 regulations promulgated under subsection (a) shall  
5 not impose requirements on small tobacco product  
6 manufacturers before the later of—

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

9           “(B) the initial date set by the Secretary  
10 for compliance with such regulations by manu-  
11 facturers that are not small tobacco product  
12 manufacturers.

13       “(2) TESTING AND REPORTING INITIAL COM-  
14 PLIANCE PERIOD.—

15           “(A) 4-YEAR PERIOD.—The initial regula-  
16 tions promulgated under subsection (a) shall  
17 give each small tobacco product manufacturer a  
18 4-year period over which to conduct testing and  
19 reporting for all of its tobacco products. Subject  
20 to paragraph (1), the end of the first year of  
21 such 4-year period shall coincide with the initial  
22 date of compliance under this section set by the  
23 Secretary with respect to manufacturers that  
24 are not small tobacco product manufacturers or  
25 the end of the 2-year period following the final

1 promulgation of such regulations, as described  
2 in paragraph (1)(A). A small tobacco product  
3 manufacturer shall be required—

4 “(i) to conduct such testing and re-  
5 porting for 25 percent of its tobacco prod-  
6 ucts during each year of such 4-year pe-  
7 riod; and

8 “(ii) to conduct such testing and re-  
9 porting for its largest-selling tobacco prod-  
10 ucts (as determined by the Secretary) be-  
11 fore its other tobacco products, or in such  
12 other order of priority as determined by  
13 the Secretary.

14 “(B) CASE-BY-CASE DELAY.—Notwith-  
15 standing subparagraph (A), the Secretary may,  
16 on a case-by-case basis, delay the date by which  
17 an individual small tobacco product manufac-  
18 turer must conduct testing and reporting for its  
19 tobacco products under this section based upon  
20 a showing of undue hardship to such manufac-  
21 turer. Notwithstanding the preceding sentence,  
22 the Secretary shall not extend the deadline for  
23 a small tobacco product manufacturer to con-  
24 duct testing and reporting for all of its tobacco  
25 products beyond a total of 5 years after the ini-

1            tial date of compliance under this section set by  
2            the Secretary with respect to manufacturers  
3            that are not small tobacco product manufactur-  
4            ers.

5            “(3) SUBSEQUENT AND ADDITIONAL TESTING  
6            AND REPORTING.—The regulations promulgated  
7            under subsection (a) shall provide that, with respect  
8            to any subsequent or additional testing and report-  
9            ing of tobacco products required under this section,  
10           such testing and reporting by a small tobacco prod-  
11           uct manufacturer shall be conducted in accordance  
12           with the timeframes described in paragraph (2)(A),  
13           except that, in the case of a new product, or if there  
14           has been a modification described in section  
15           910(a)(1)(B) of any product of a small tobacco  
16           product manufacturer since the last testing and re-  
17           porting required under this section, the Secretary  
18           shall require that any subsequent or additional test-  
19           ing and reporting be conducted in accordance with  
20           the same timeframe applicable to manufacturers  
21           that are not small tobacco product manufacturers.

22           “(4) JOINT LABORATORY TESTING SERVICES.—  
23           The Secretary shall allow any 2 or more small to-  
24           bacco product manufacturers to join together to pur-  
25           chase laboratory testing services required by this

1 section on a group basis in order to ensure that such  
2 manufacturers receive access to, and fair pricing of,  
3 such testing services.

4 “(e) EXTENSIONS FOR LIMITED LABORATORY CA-  
5 PACITY.—

6 “(1) IN GENERAL.—The regulations promul-  
7 gated under subsection (a) shall provide that a small  
8 tobacco product manufacturer shall not be consid-  
9 ered to be in violation of this section before the  
10 deadline applicable under paragraphs (3) and (4),  
11 if—

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

15 “(B) the conditions described in paragraph  
16 (2) are met.

17 “(2) CONDITIONS.—Notwithstanding the re-  
18 quirements of this section, the Secretary may delay  
19 the date by which a small tobacco product manufac-  
20 turer must be in compliance with the testing and re-  
21 porting required by this section until such time as  
22 the testing is reported if, not later than 90 days be-  
23 fore the deadline for reporting in accordance with  
24 this section, a small tobacco product manufacturer

1 provides evidence to the Secretary demonstrating  
2 that—

3 “(A) the manufacturer has submitted the  
4 required products for testing to a laboratory  
5 and has done so sufficiently in advance of the  
6 deadline to create a reasonable expectation of  
7 completion by the deadline;

8 “(B) the products currently are awaiting  
9 testing by the laboratory; and

10 “(C) neither that laboratory nor any other  
11 laboratory is able to complete testing by the  
12 deadline at customary, nonexpedited testing  
13 fees.

14 “(3) EXTENSION.—The Secretary, taking into  
15 account the laboratory testing capacity that is avail-  
16 able to tobacco product manufacturers, shall review  
17 and verify the evidence submitted by a small tobacco  
18 product manufacturer in accordance with paragraph  
19 (2). If the Secretary finds that the conditions de-  
20 scribed in such paragraph are met, the Secretary  
21 shall notify the small tobacco product manufacturer  
22 that the manufacturer shall not be considered to be  
23 in violation of the testing and reporting require-  
24 ments of this section until the testing is reported or  
25 until 1 year after the reporting deadline has passed,

1       whichever occurs sooner. If, however, the Secretary  
2       has not made a finding before the reporting dead-  
3       line, the manufacturer shall not be considered to be  
4       in violation of such requirements until the Secretary  
5       finds that the conditions described in paragraph (2)  
6       have not been met, or until 1 year after the report-  
7       ing deadline, whichever occurs sooner.

8               “(4) ADDITIONAL EXTENSION.—In addition to  
9       the time that may be provided under paragraph (3),  
10      the Secretary may provide further extensions of  
11      time, in increments of no more than 1 year, for re-  
12      quired testing and reporting to occur if the Sec-  
13      retary determines, based on evidence properly and  
14      timely submitted by a small tobacco product manu-  
15      facturer in accordance with paragraph (2), that a  
16      lack of available laboratory capacity prevents the  
17      manufacturer from completing the required testing  
18      during the period described in paragraph (3).

19              “(f) RULE OF CONSTRUCTION.—Nothing in sub-  
20      section (d) or (e) shall be construed to authorize the exten-  
21      sion of any deadline, or to otherwise affect any timeframe,  
22      under any provision of this Act or the Family Smoking  
23      Prevention and Tobacco Control Act other than this sec-  
24      tion.

1 **“SEC. 916. PRESERVATION OF STATE AND LOCAL AUTHOR-**  
2 **ITY.**

3 “(a) IN GENERAL.—

4 “(1) PRESERVATION.—Except as provided in  
5 paragraph (2)(A), nothing in this chapter, or rules  
6 promulgated under this chapter, shall be construed  
7 to limit the authority of a Federal agency (including  
8 the Armed Forces), a State or political subdivision  
9 of a State, or the government of an Indian tribe to  
10 enact, adopt, promulgate, and enforce any law, rule,  
11 regulation, or other measure with respect to tobacco  
12 products that is in addition to, or more stringent  
13 than, requirements established under this chapter,  
14 including a law, rule, regulation, or other measure  
15 relating to or prohibiting the sale, distribution, pos-  
16 session, exposure to, access to, advertising and pro-  
17 motion of, or use of tobacco products by individuals  
18 of any age, information reporting to the State, or  
19 measures relating to fire safety standards for to-  
20 bacco products. No provision of this chapter shall  
21 limit or otherwise affect any State, Tribal, or local  
22 taxation of tobacco products.

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

25 “(A) IN GENERAL.—No State or political  
26 subdivision of a State may establish or continue

1 in effect with respect to a tobacco product any  
2 requirement which is different from, or in addi-  
3 tion to, any requirement under the provisions of  
4 this chapter relating to tobacco product stand-  
5 ards, premarket review, adulteration, mis-  
6 branding, labeling, registration, good manufac-  
7 turing standards, or modified risk tobacco prod-  
8 ucts.

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

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

1 **“SEC. 917. TOBACCO PRODUCTS SCIENTIFIC ADVISORY**  
2 **COMMITTEE.**

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

9 “(b) MEMBERSHIP.—

10 “(1) IN GENERAL.—

11 “(A) MEMBERS.—The Secretary shall ap-  
12 point as members of the Tobacco Products Sci-  
13 entific Advisory Committee individuals who are  
14 technically qualified by training and experience  
15 in medicine, medical ethics, science, or tech-  
16 nology involving the manufacture, evaluation, or  
17 use of tobacco products, who are of appro-  
18 priately diversified professional backgrounds.  
19 The committee shall be composed of—

20 “(i) 7 individuals who are physicians,  
21 dentists, scientists, or health care profes-  
22 sionals practicing in the area of oncology,  
23 pulmonology, cardiology, toxicology, phar-  
24 macology, addiction, or any other relevant  
25 specialty;

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

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

6           “(iv) 1 individual as a representative  
7           of the interests of the tobacco manufac-  
8           turing industry;

9           “(v) 1 individual as a representative  
10          of the interests of the small business to-  
11          bacco manufacturing industry, which posi-  
12          tion may be filled on a rotating, sequential  
13          basis by representatives of different small  
14          business tobacco manufacturers based on  
15          areas of expertise relevant to the topics  
16          being considered by the Advisory Com-  
17          mittee; and

18          “(vi) 1 individual as a representative  
19          of the interests of the tobacco growers.

20          “(B) NONVOTING MEMBERS.—The mem-  
21          bers of the committee appointed under clauses  
22          (iv), (v), and (vi) of subparagraph (A) shall  
23          serve as consultants to those described in  
24          clauses (i) through (iii) of subparagraph (A)  
25          and shall be nonvoting representatives.

1           “(C) CONFLICTS OF INTEREST.—No mem-  
2           bers of the committee, other than members ap-  
3           pointed pursuant to clauses (iv), (v), and (vi) of  
4           subparagraph (A) shall, during the member’s  
5           tenure on the committee or for the 18-month  
6           period prior to becoming such a member, re-  
7           ceive any salary, grants, or other payments or  
8           support from any business that manufactures,  
9           distributes, markets, or sells cigarettes or other  
10          tobacco products.

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

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

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

24                  “(1) as provided in this chapter;

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

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

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

9           “(d) COMPENSATION; SUPPORT; FACA.—

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



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

4           “(b) REPORT ON INNOVATIVE PRODUCTS.—

5           “(1) IN GENERAL.—Not later than 3 years  
6           after the date of enactment of the Family Smoking  
7           Prevention and Tobacco Control Act, the Secretary,  
8           after consultation with recognized scientific, medical,  
9           and public health experts (including both Federal  
10          agencies and nongovernmental entities, the Institute  
11          of Medicine of the National Academy of Sciences,  
12          and the Society for Research on Nicotine and To-  
13          bacco), shall submit to the Congress a report that  
14          examines how best to regulate, promote, and encour-  
15          age the development of innovative products and  
16          treatments (including nicotine-based and non-nico-  
17          tine-based products and treatments) to better  
18          achieve, in a manner that best protects and pro-  
19          motes the public health—

20                   “(A) total abstinence from tobacco use;

21                   “(B) reductions in consumption of tobacco;

22                   and

23                   “(C) reductions in the harm associated  
24                   with continued tobacco use.

1           “(2) RECOMMENDATIONS.—The report under  
2 paragraph (1) shall include the recommendations of  
3 the Secretary on how the Food and Drug Adminis-  
4 tration should coordinate and facilitate the exchange  
5 of information on such innovative products and  
6 treatments among relevant offices and centers within  
7 the Administration and within the National Insti-  
8 tutes of Health, the Centers for Disease Control and  
9 Prevention, and other relevant agencies.

10 **“SEC. 919. USER FEES.**

11           “(a) ESTABLISHMENT OF QUARTERLY FEE.—Begin-  
12 ning on the date of enactment of the Family Smoking Pre-  
13 vention and Tobacco Control Act, the Secretary shall in  
14 accordance with this section assess user fees on, and col-  
15 lect such fees from, each manufacturer and importer of  
16 tobacco products subject to this chapter. The fees shall  
17 be assessed and collected with respect to each quarter of  
18 each fiscal year, and the total amount assessed and col-  
19 lected for a fiscal year shall be the amount specified in  
20 subsection (b)(1) for such year, subject to subsection (c).

21           “(b) ASSESSMENT OF USER FEE.—

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

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

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

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

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

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

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

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

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

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

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

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

14          “(2) ALLOCATIONS OF ASSESSMENT BY CLASS  
15 OF TOBACCO PRODUCTS.—

16           “(A) IN GENERAL.—The total user fees as-  
17 sessed and collected under subsection (a) each  
18 fiscal year with respect to each class of tobacco  
19 products shall be an amount that is equal to  
20 the applicable percentage of each class for the  
21 fiscal year multiplied by the amount specified in  
22 paragraph (1) for the fiscal year.

23           “(B) APPLICABLE PERCENTAGE.—

24           “(i) IN GENERAL.—For purposes of  
25 subparagraph (A), the applicable percent-

1 age for a fiscal year for each of the fol-  
2 lowing classes of tobacco products shall be  
3 determined in accordance with clause (ii):

4 “(I) Cigarettes.

5 “(II) Cigars, including small ci-  
6 gars and cigars other than small ci-  
7 gars.

8 “(III) Snuff.

9 “(IV) Chewing tobacco.

10 “(V) Pipe tobacco.

11 “(VI) Roll-your-own tobacco.

12 “(ii) ALLOCATIONS.—The applicable  
13 percentage of each class of tobacco product  
14 described in clause (i) for a fiscal year  
15 shall be the percentage determined under  
16 section 625(c) of Public Law 108–357 for  
17 each such class of product for such fiscal  
18 year.

19 “(iii) REQUIREMENT OF REGULA-  
20 TIONS.—Notwithstanding clause (ii), no  
21 user fees shall be assessed on a class of to-  
22 bacco products unless such class of tobacco  
23 products is listed in section 901(b) or is  
24 deemed by the Secretary in a regulation

1 under section 901(b) to be subject to this  
2 chapter.

3 “(iv) REALLOCATIONS.—In the case  
4 of a class of tobacco products that is not  
5 listed in section 901(b) or deemed by the  
6 Secretary in a regulation under section  
7 901(b) to be subject to this chapter, the  
8 amount of user fees that would otherwise  
9 be assessed to such class of tobacco prod-  
10 ucts shall be reallocated to the classes of  
11 tobacco products that are subject to this  
12 chapter in the same manner and based on  
13 the same relative percentages otherwise de-  
14 termined under clause (ii).

15 “(3) DETERMINATION OF USER FEE BY COM-  
16 PANY.—

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

21 “(i) such manufacturer’s or importer’s  
22 percentage share as determined under  
23 paragraph (4); by

24 “(ii) the portion of the user fee  
25 amount for the current quarter to be as-

1           sessed on all manufacturers and importers  
2           of such class of tobacco products as deter-  
3           mined under paragraph (2).

4           “(B) NO FEE IN EXCESS OF PERCENTAGE  
5           SHARE.—No manufacturer or importer of to-  
6           bacco products shall be required to pay a user  
7           fee in excess of the percentage share of such  
8           manufacturer or importer.

9           “(4) ALLOCATION OF ASSESSMENT WITHIN  
10          EACH CLASS OF TOBACCO PRODUCT.—The percent-  
11          age share of each manufacturer or importer of a  
12          particular class of tobacco products of the total user  
13          fee to be paid by all manufacturers or importers of  
14          that class of tobacco products shall be the percent-  
15          age determined for purposes of allocations under  
16          subsections (e) through (h) of section 625 of Public  
17          Law 108–357.

18          “(5) ALLOCATION FOR CIGARS.—Notwith-  
19          standing paragraph (4), if a user fee assessment is  
20          imposed on cigars, the percentage share of each  
21          manufacturer or importer of cigars shall be based on  
22          the excise taxes paid by such manufacturer or im-  
23          porter during the prior fiscal year.

24          “(6) TIMING OF ASSESSMENT.—The Secretary  
25          shall notify each manufacturer and importer of to-

1       bacco products subject to this section of the amount  
2       of the quarterly assessment imposed on such manu-  
3       facturer or importer under this subsection for each  
4       quarter of each fiscal year. Such notifications shall  
5       occur not later than 30 days prior to the end of the  
6       quarter for which such assessment is made, and pay-  
7       ments of all assessments shall be made by the last  
8       day of the quarter involved.

9               “(7) MEMORANDUM OF UNDERSTANDING.—

10              “(A) IN GENERAL.—The Secretary shall  
11              request the appropriate Federal agency to enter  
12              into a memorandum of understanding that pro-  
13              vides for the regular and timely transfer from  
14              the head of such agency to the Secretary of the  
15              information described in paragraphs (2)(B)(ii)  
16              and (4) and all necessary information regarding  
17              all tobacco product manufacturers and import-  
18              ers required to pay user fees. The Secretary  
19              shall maintain all disclosure restrictions estab-  
20              lished by the head of such agency regarding the  
21              information provided under the memorandum of  
22              understanding.

23              “(B) ASSURANCES.—Beginning not later  
24              than fiscal year 2015, and for each subsequent  
25              fiscal year, the Secretary shall ensure that the

1 Food and Drug Administration is able to deter-  
2 mine the applicable percentages described in  
3 paragraph (2) and the percentage shares de-  
4 scribed in paragraph (4). The Secretary may  
5 carry out this subparagraph by entering into a  
6 contract with the head of the Federal agency  
7 referred to in subparagraph (A) to continue to  
8 provide the necessary information.

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

10 “(1) IN GENERAL.—Fees authorized under sub-  
11 section (a) shall be collected and available for obliga-  
12 tion only to the extent and in the amount provided  
13 in advance in appropriations Acts. Such fees are au-  
14 thorized to remain available until expended. Such  
15 sums as may be necessary may be transferred from  
16 the Food and Drug Administration salaries and ex-  
17 penses appropriation account without fiscal year lim-  
18 itation to such appropriation account for salaries  
19 and expenses with such fiscal year limitation.

20 “(2) AVAILABILITY.—

21 “(A) IN GENERAL.—Fees appropriated  
22 under paragraph (3) are available only for the  
23 purpose of paying the costs of the activities of  
24 the Food and Drug Administration related to  
25 the regulation of tobacco products under this

1 chapter and the Family Smoking Prevention  
2 and Tobacco Control Act. No fees collected  
3 under subsection (a) may be used for any other  
4 costs.

5 “(B) PROHIBITION AGAINST USE OF  
6 OTHER FUNDS.—

7 “(i) IN GENERAL.—Except as pro-  
8 vided in clause (ii), fees collected under  
9 subsection (a) are the only funds author-  
10 ized to be made available for the purpose  
11 described in subparagraph (A).

12 “(ii) STARTUP COSTS.—Clause (i)  
13 does not apply until the date on which the  
14 Secretary has collected fees under sub-  
15 section (a) for 2 fiscal year quarters. Until  
16 such date, other amounts available to the  
17 Food and Drug Administration (excluding  
18 fees collected under subsection (a)) are au-  
19 thorized to be made available to pay the  
20 costs described in subparagraph (A), pro-  
21 vided that such amounts are reimbursed  
22 through fees collected under subsection (a).

23 “(3) AUTHORIZATION OF APPROPRIATIONS.—

24 For fiscal year 2009 and each subsequent fiscal  
25 year, there is authorized to be appropriated for fees

1 under this section an amount equal to the amount  
2 specified in subsection (b)(1) for the fiscal year.

3 “(d) COLLECTION OF UNPAID FEES.—In any case  
4 where the Secretary does not receive payment of a fee as-  
5 sessed under subsection (a) within 30 days after it is due,  
6 such fee shall be treated as a claim of the United States  
7 Government subject to subchapter II of chapter 37 of title  
8 31, United States Code.

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

13 “(1) The Secretary shall determine the fees  
14 that would apply for a single quarter of such fiscal  
15 year according to the application of subsection (b) to  
16 the amount specified in paragraph (1)(A) of such  
17 subsection (referred to in this subsection as the  
18 ‘quarterly fee amounts’).

19 “(2) For the quarter in which such date of en-  
20 actment occurs, the amount of fees assessed shall be  
21 a pro rata amount, determined according to the  
22 number of days remaining in the quarter (including  
23 such date of enactment) and according to the daily  
24 equivalent of the quarterly fee amounts. Fees as-

1       sessed under the preceding sentence shall not be col-  
2       lected until the next quarter.

3               “(3) For the quarter following the quarter to  
4       which paragraph (2) applies, the full quarterly fee  
5       amounts shall be assessed and collected, in addition  
6       to collection of the pro rata fees assessed under  
7       paragraph (2).”.

8       **SEC. 102. FINAL RULE.**

9       (a) CIGARETTES AND SMOKELESS TOBACCO.—

10               (1) IN GENERAL.—On the first day of publica-  
11       tion of the Federal Register that is 180 days or  
12       more after the date of enactment of this Act, the  
13       Secretary of Health and Human Services shall pub-  
14       lish in the Federal Register a final rule regarding  
15       cigarettes and smokeless tobacco, which—

16               (A) is deemed to be issued under chapter  
17       9 of the Federal Food, Drug, and Cosmetic  
18       Act, as added by section 101 of this Act; and

19               (B) shall be deemed to be in compliance  
20       with all applicable provisions of chapter 5 of  
21       title 5, United States Code, and all other provi-  
22       sions of law relating to rulemaking procedures.

23               (2) CONTENTS OF RULE.—Except as provided  
24       in this subsection, the final rule published under  
25       paragraph (1), shall be identical in its provisions to

1 part 897 of the regulations promulgated by the Sec-  
2 retary of Health and Human Services in the August  
3 28, 1996, issue of the Federal Register (61 Fed.  
4 Reg., 44615–44618). Such rule shall—

5 (A) provide for the designation of jurisdic-  
6 tional authority that is in accordance with this  
7 subsection in accordance with this Act and the  
8 amendments made by this Act;

9 (B) strike Subpart C—Labels and section  
10 897.32(c);

11 (C) strike paragraphs (a), (b), and (i) of  
12 section 897.3 and insert definitions of the terms  
13 “cigarette”, “cigarette tobacco,” and “smoke-  
14 less tobacco” as defined in section 900 of the  
15 Federal Food, Drug, and Cosmetic Act;

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

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

22 (F) amend paragraph (d) of section 897.16  
23 to read as follows:

24 “(d)(1) Except as provided in subparagraph (2), no  
25 manufacturer, distributor, or retailer may distribute or

1 cause to be distributed any free samples of cigarettes,  
2 smokeless tobacco, or other tobacco products (as such  
3 term is defined in section 201 of the Federal Food, Drug,  
4 and Cosmetic Act).

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

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

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

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

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

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

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

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

7 “(v) is enclosed by a barrier that—

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

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

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

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

22 “(I) any tobacco product advertising;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

20 (4) in subsection (e)—

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

22 and

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

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

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

5           (7) in subsection (j)—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

15       “(tt) With respect to a tobacco product, any state-  
16 ment directed to consumers through the media or through  
17 the label, labeling, or advertising that would reasonably  
18 be expected to result in consumers believing that the prod-  
19 uct is regulated, inspected or approved by the Food and  
20 Drug Administration, or that the product complies with  
21 the requirements of the Food and Drug Administration,  
22 including a statement or implication in the label, labeling,  
23 or advertising of such product, and that could result in  
24 consumers believing that the product is endorsed for use  
25 by the Food and Drug Administration or in consumers

1 being misled about the harmfulness of the product because  
2 of such regulation, inspection, or compliance.”.

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

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

8 (2) in paragraph (5)—

9 (A) in subparagraph (A)—

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

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

18 (B) in subparagraph (B)—

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

22 (ii) by adding at the end the fol-  
23 lowing: “A no-tobacco-sale order perma-  
24 nently prohibiting an individual retail out-  
25 let from selling tobacco products shall in-

1           clude provisions that allow the outlet, after  
2           a specified period of time, to request that  
3           the Secretary compromise, modify, or ter-  
4           minate the order.”; and

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

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

9           (3) in paragraph (6)—

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

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

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

17           “(8) If the Secretary finds that a person has com-  
18           mitted repeated violations of restrictions promulgated  
19           under section 906(d) at a particular retail outlet then the  
20           Secretary may impose a no-tobacco-sale order on that per-  
21           son prohibiting the sale of tobacco products in that outlet.  
22           A no-tobacco-sale order may be imposed with a civil pen-  
23           alty under paragraph (1). Prior to the entry of a no-sale  
24           order under this paragraph, a person shall be entitled to  
25           a hearing pursuant to the procedures established through

1 regulations of the Food and Drug Administration for as-  
2 sessing civil money penalties, including at a retailer's re-  
3 quest a hearing by telephone, or at the nearest regional  
4 or field office of the Food and Drug Administration, or  
5 at a Federal, State, or county facility within 100 miles  
6 from the location of the retail outlet, if such a facility is  
7 available.”.

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

10 (1) in subsection (a)(2)—

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

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

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

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

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

22 (e) SECTION 505.—Section 505(n)(2) (21 U.S.C.  
23 355(n)(2)) is amended by striking “section 904” and in-  
24 serting “section 1004”.

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

4           (g) SECTION 702.—Section 702(a)(1) (U.S.C.  
5 372(a)(1)) is amended—

6                 (1) by striking “(a)(1)” and inserting  
7 “(a)(1)(A)”; and

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

9           “(B)(i) For a tobacco product, to the extent feasible,  
10 the Secretary shall contract with the States in accordance  
11 with this paragraph to carry out inspections of retailers  
12 within that State in connection with the enforcement of  
13 this Act.

14           “(ii) The Secretary shall not enter into any contract  
15 under clause (i) with the government of any of the several  
16 States to exercise enforcement authority under this Act  
17 on Indian country without the express written consent of  
18 the Indian tribe involved.”.

19           (h) SECTION 703.—Section 703 (21 U.S.C. 373) is  
20 amended—

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

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

1 (i) SECTION 704.—Section 704 (21 U.S.C. 374) is  
2 amended—

3 (1) in subsection (a)(1)—

4 (A) by striking “devices, or cosmetics”  
5 each place it appears and inserting “devices, to-  
6 bacco products, or cosmetics”;

7 (B) by striking “or restricted devices” each  
8 place it appears and inserting “restricted de-  
9 vices, or tobacco products”;

10 (C) by striking “and devices and subject  
11 to” and all that follows through “other drugs or  
12 devices” and inserting “devices, and tobacco  
13 products and subject to reporting and inspec-  
14 tion under regulations lawfully issued pursuant  
15 to section 505(i) or (k), section 519, section  
16 520(g), or chapter IX and data relating to  
17 other drugs, devices, or tobacco products”;

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

20 (3) in subsection (g)(13), by striking “section  
21 903(g)” and inserting “section 1003(g)”.

22 (j) SECTION 705.—Section 705(b) (21 U.S.C.  
23 375(b)) is amended by inserting “tobacco products,” after  
24 “devices,”.

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

3 (l) SECTION 801.—Section 801 (21 U.S.C. 381) is  
4 amended—

5 (1) in subsection (a)—

6 (A) by inserting “tobacco products,” after  
7 the term “devices,”;

8 (B) by inserting “or section 905(h)” after  
9 “section 510”; and

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

13 (2) in subsection (e)(1)—

14 (A) by inserting “tobacco product” after  
15 “drug, device,”; and

16 (B) by inserting “, and a tobacco product  
17 intended for export shall not be deemed to be  
18 in violation of section 906(e), 907, 911, or  
19 920(a),” before “if it—”; and

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

21 “(p)(1) Not later than 36 months after the date of  
22 enactment of the Family Smoking Prevention and To-  
23 bacco Control Act, and annually thereafter, the Secretary  
24 shall submit to the Committee on Health, Education,  
25 Labor, and Pensions of the Senate and the Committee on

1 Energy and Commerce of the House of Representatives,  
2 a report regarding—

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

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

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

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

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

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

20 (2) inserting “, and tobacco products” after  
21 “devices”.

22 (n) SECTION 1009.—Section 1009(b) (as redesi-  
23 gnated by section 101(b)) is amended by striking “section  
24 908” and inserting “section 1008”.

1           (o) SECTION 409 OF THE FEDERAL MEAT INSPEC-  
2 TION ACT.—Section 409(a) of the Federal Meat Inspec-  
3 tion Act (21 U.S.C. 679(a)) is amended by striking “sec-  
4 tion 902(b)” and inserting “section 1002(b)”.

5           (p) RULE OF CONSTRUCTION.—Nothing in this sec-  
6 tion is intended or shall be construed to expand, contract,  
7 or otherwise modify or amend the existing limitations on  
8 State government authority over tribal restricted fee or  
9 trust lands.

10          (q) GUIDANCE AND EFFECTIVE DATES.—

11           (1) IN GENERAL.—The Secretary of Health and  
12 Human Services shall issue guidance—

13           (A) defining the term “repeated violation”,  
14 as used in section 303(f)(8) of the Federal  
15 Food, Drug, and Cosmetic Act (21 U.S.C.  
16 333(f)(8)) as amended by subsection (c), as in-  
17 cluding at least 5 violations of particular re-  
18 quirements over a 36-month period at a par-  
19 ticular retail outlet that constitute a repeated  
20 violation and providing for civil penalties in ac-  
21 cordance with paragraph (2);

22           (B) providing for timely and effective no-  
23 tice by certified or registered mail or personal  
24 delivery to the retailer of each alleged violation  
25 at a particular retail outlet prior to conducting

1 a followup compliance check, such notice to be  
2 sent to the location specified on the retailer's  
3 registration or to the retailer's registered agent  
4 if the retailer has provided such agent informa-  
5 tion to the Food and Drug Administration prior  
6 to the violation;

7 (C) providing for a hearing pursuant to the  
8 procedures established through regulations of  
9 the Food and Drug Administration for assess-  
10 ing civil money penalties, including at a retail-  
11 er's request a hearing by telephone or at the  
12 nearest regional or field office of the Food and  
13 Drug Administration, and providing for an ex-  
14 pedited procedure for the administrative appeal  
15 of an alleged violation;

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

21 (E) establishing that civil money penalties  
22 for multiple violations shall increase from one  
23 violation to the next violation pursuant to para-  
24 graph (2) within the time periods provided for  
25 in such paragraph;

1 (F) providing that good faith reliance on  
2 the presentation of a false government-issued  
3 photographic identification that contains a date  
4 of birth does not constitute a violation of any  
5 minimum age requirement for the sale of to-  
6 bacco products if the retailer has taken effective  
7 steps to prevent such violations, including—

8 (i) adopting and enforcing a written  
9 policy against sales to minors;

10 (ii) informing its employees of all ap-  
11 plicable laws;

12 (iii) establishing disciplinary sanctions  
13 for employee noncompliance; and

14 (iv) requiring its employees to verify  
15 age by way of photographic identification  
16 or electronic scanning device; and

17 (G) providing for the Secretary, in deter-  
18 mining whether to impose a no-tobacco-sale  
19 order and in determining whether to com-  
20 promise, modify, or terminate such an order, to  
21 consider whether the retailer has taken effective  
22 steps to prevent violations of the minimum age  
23 requirements for the sale of tobacco products,  
24 including the steps listed in subparagraph (F).

25 (2) PENALTIES FOR VIOLATIONS.—

1 (A) IN GENERAL.—The amount of the civil  
2 penalty to be applied for violations of restric-  
3 tions promulgated under section 906(d), as de-  
4 scribed in paragraph (1), shall be as follows:

5 (i) With respect to a retailer with an  
6 approved training program, the amount of  
7 the civil penalty shall not exceed—

8 (I) in the case of the first viola-  
9 tion, \$0.00 together with the issuance  
10 of a warning letter to the retailer;

11 (II) in the case of a second viola-  
12 tion within a 12-month period, \$250;

13 (III) in the case of a third viola-  
14 tion within a 24-month period, \$500;

15 (IV) in the case of a fourth viola-  
16 tion within a 24-month period,  
17 \$2,000;

18 (V) in the case of a fifth violation  
19 within a 36-month period, \$5,000;  
20 and

21 (VI) in the case of a sixth or sub-  
22 sequent violation within a 48-month  
23 period, \$10,000 as determined by the  
24 Secretary on a case-by-case basis.

1           (ii) With respect to a retailer that  
2           does not have an approved training pro-  
3           gram, the amount of the civil penalty shall  
4           not exceed—

5                   (I) in the case of the first viola-  
6                   tion, \$250;

7                   (II) in the case of a second viola-  
8                   tion within a 12-month period, \$500;

9                   (III) in the case of a third viola-  
10                  tion within a 24-month period,  
11                  \$1,000;

12                  (IV) in the case of a fourth viola-  
13                  tion within a 24-month period,  
14                  \$2,000;

15                  (V) in the case of a fifth violation  
16                  within a 36-month period, \$5,000;  
17                  and

18                  (VI) in the case of a sixth or sub-  
19                  sequent violation within a 48-month  
20                  period, \$10,000 as determined by the  
21                  Secretary on a case-by-case basis.

22           (B) TRAINING PROGRAM.—For purposes of  
23           subparagraph (A), the term “approved training  
24           program” means a training program that com-

1           plies with standards developed by the Food and  
2           Drug Administration for such programs.

3           (C) CONSIDERATION OF STATE PEN-  
4           ALTIES.—The Secretary shall coordinate with  
5           the States in enforcing the provisions of this  
6           Act and, for purposes of mitigating a civil pen-  
7           alty to be applied for a violation by a retailer  
8           of any restriction promulgated under section  
9           906(d), shall consider the amount of any pen-  
10          alties paid by the retailer to a State for the  
11          same violation.

12          (3) GENERAL EFFECTIVE DATE.—The amend-  
13          ments made by paragraphs (2), (3), and (4) of sub-  
14          section (c) shall take effect upon the issuance of  
15          guidance described in paragraph (1) of this sub-  
16          section.

17          (4) SPECIAL EFFECTIVE DATE.—The amend-  
18          ment made by subsection (c)(1) shall take effect on  
19          the date of enactment of this Act.

20          (5) PACKAGE LABEL REQUIREMENTS.—The  
21          package label requirements of paragraphs (2), (3),  
22          and (4) of section 903(a) of the Federal Food,  
23          Drug, and Cosmetic Act (as amended by this Act)  
24          shall take effect on the date that is 12 months after  
25          the date of enactment of this Act. The effective date

1 shall be with respect to the date of manufacture,  
2 provided that, in any case, beginning 30 days after  
3 such effective date, a manufacturer shall not intro-  
4 duce into the domestic commerce of the United  
5 States any product, irrespective of the date of manu-  
6 facture, that is not in conformance with section  
7 903(a)(2), (3), and (4) and section 920(a) of the  
8 Federal Food, Drug, and Cosmetic Act.

9 (6) ADVERTISING REQUIREMENTS.—The adver-  
10 tising requirements of section 903(a)(8) of the Fed-  
11 eral Food, Drug, and Cosmetic Act (as amended by  
12 this Act) shall take effect on the date that is 12  
13 months after the date of enactment of this Act.

14 **SEC. 104. STUDY ON RAISING THE MINIMUM AGE TO PUR-**  
15 **CHASE TOBACCO PRODUCTS.**

16 The Secretary of Health and Human Services shall—

17 (1) convene an expert panel to conduct a study  
18 on the public health implications of raising the min-  
19 imum age to purchase tobacco products; and

20 (2) not later than 5 years after the date of en-  
21 actment of this Act, submit a report to the Congress  
22 on the results of such study.

23 **SEC. 105. ENFORCEMENT ACTION PLAN FOR ADVERTISING**  
24 **AND PROMOTION RESTRICTIONS.**

25 (a) ACTION PLAN.—

1           (1) DEVELOPMENT.—Not later than 6 months  
2 after the date of enactment of this Act, the Sec-  
3 retary of Health and Human Services (in this sec-  
4 tion referred to as the “Secretary”) shall develop  
5 and publish an action plan to enforce restrictions  
6 adopted pursuant to section 906 of the Federal  
7 Food, Drug, and Cosmetic Act, as added by section  
8 101(b) of this Act, or pursuant to section 102(a) of  
9 this Act, on promotion and advertising of menthol  
10 and other cigarettes to youth.

11           (2) CONSULTATION.—The action plan required  
12 by paragraph (1) shall be developed in consultation  
13 with public health organizations and other stake-  
14 holders with demonstrated expertise and experience  
15 in serving minority communities.

16           (3) PRIORITY.—The action plan required by  
17 paragraph (1) shall include provisions designed to  
18 ensure enforcement of the restrictions described in  
19 paragraph (1) in minority communities.

20           (b) STATE AND LOCAL ACTIVITIES.—

21           (1) INFORMATION ON AUTHORITY.—Not later  
22 than 3 months after the date of enactment of this  
23 Act, the Secretary shall inform State, local, and trib-  
24 al governments of the authority provided to such en-  
25 tities under section 5(c) of the Federal Cigarette La-

1       beling and Advertising Act, as added by section 203  
 2       of this Act, or preserved by such entities under sec-  
 3       tion 916 of the Federal Food, Drug, and Cosmetic  
 4       Act, as added by section 101(b) of this Act.

5               (2) COMMUNITY ASSISTANCE.—At the request  
 6       of communities seeking assistance to prevent under-  
 7       age tobacco use, the Secretary shall provide such as-  
 8       sistance, including assistance with strategies to ad-  
 9       dress the prevention of underage tobacco use in com-  
 10      munities with a disproportionate use of menthol  
 11      cigarettes by minors.

12   **TITLE II—TOBACCO PRODUCT**  
 13       **WARNINGS;       CONSTITUENT**  
 14       **AND SMOKE       CONSTITUENT**  
 15       **DISCLOSURE**

16   **SEC. 201. CIGARETTE LABEL AND ADVERTISING WARNINGS.**

17       (a) AMENDMENT.—Section 4 of the Federal Ciga-  
 18      rette Labeling and Advertising Act (15 U.S.C. 1333) is  
 19      amended to read as follows:

20   **“SEC. 4. LABELING.**

21       “(a) LABEL REQUIREMENTS.—

22               “(1) IN GENERAL.—It shall be unlawful for any  
 23      person to manufacture, package, sell, offer to sell,  
 24      distribute, or import for sale or distribution within  
 25      the United States any cigarettes the package of

1 which fails to bear, in accordance with the require-  
2 ments of this section, one of the following labels:

3 “WARNING: Cigarettes are addictive.

4 “WARNING: Tobacco smoke can harm  
5 your children.

6 “WARNING: Cigarettes cause fatal lung  
7 disease.

8 “WARNING: Cigarettes cause cancer.

9 “WARNING: Cigarettes cause strokes and  
10 heart disease.

11 “WARNING: Smoking during pregnancy  
12 can harm your baby.

13 “WARNING: Smoking can kill you.

14 “WARNING: Tobacco smoke causes fatal  
15 lung disease in nonsmokers.

16 “WARNING: Quitting smoking now great-  
17 ly reduces serious risks to your health.

18 “(2) PLACEMENT; TYPOGRAPHY; ETC.—Each  
19 label statement required by paragraph (1) shall be  
20 located in the upper portion of the front and rear  
21 panels of the package, directly on the package un-  
22 derneath the cellophane or other clear wrapping.  
23 Each label statement shall comprise at least the top  
24 30 percent of the front and rear panels of the pack-  
25 age. The word ‘WARNING’ shall appear in capital

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

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

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

22 “(A) contains a warning label;

23 “(B) is supplied to the retailer by a  
24 license- or permit-holding tobacco product man-  
25 ufacturer, importer, or distributor; and

1           “(C) is not altered by the retailer in a way  
2           that is material to the requirements of this sub-  
3           section.

4           “(b) ADVERTISING REQUIREMENTS.—

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

12          “(2) TYPOGRAPHY, ETC.—Each label statement  
13          required by subsection (a) in cigarette advertising  
14          shall comply with the standards set forth in this  
15          paragraph. For press and poster advertisements,  
16          each such statement and (where applicable) any re-  
17          quired statement relating to tar, nicotine, or other  
18          constituent (including a smoke constituent) yield  
19          shall comprise at least 20 percent of the area of the  
20          advertisement and shall appear in a conspicuous and  
21          prominent format and location at the top of each ad-  
22          vertisement within the trim area. The Secretary may  
23          revise the required type sizes in such area in such  
24          manner as the Secretary determines appropriate.  
25          The word ‘WARNING’ shall appear in capital let-

1       ters, and each label statement shall appear in con-  
2       spicuous and legible type. The text of the label state-  
3       ment shall be black if the background is white and  
4       white if the background is black, under the plan sub-  
5       mitted under subsection (c). The label statements  
6       shall be enclosed by a rectangular border that is the  
7       same color as the letters of the statements and that  
8       is the width of the first downstroke of the capital  
9       ‘W’ of the word ‘WARNING’ in the label state-  
10      ments. The text of such label statements shall be in  
11      a typeface pro rata to the following requirements:  
12      45-point type for a whole-page broadsheet newspaper  
13      advertisement; 39-point type for a half-page  
14      broadsheet newspaper advertisement; 39-point type  
15      for a whole-page tabloid newspaper advertisement;  
16      27-point type for a half-page tabloid newspaper ad-  
17      vertisement; 31.5-point type for a double page  
18      spread magazine or whole-page magazine advertise-  
19      ment; 22.5-point type for a 28 centimeter by 3 col-  
20      umn advertisement; and 15-point type for a 20 cen-  
21      timeter by 2 column advertisement. The label state-  
22      ments shall be in English, except that—

23                   “(A) in the case of an advertisement that  
24                   appears in a newspaper, magazine, periodical,  
25                   or other publication that is not in English, the

1 statements shall appear in the predominant lan-  
2 guage of the publication; and

3 “(B) in the case of any other advertise-  
4 ment that is not in English, the statements  
5 shall appear in the same language as that prin-  
6 cipally used in the advertisement.

7 “(3) MATCHBOOKS.—Notwithstanding para-  
8 graph (2), for matchbooks (defined as containing not  
9 more than 20 matches) customarily given away with  
10 the purchase of tobacco products, each label state-  
11 ment required by subsection (a) may be printed on  
12 the inside cover of the matchbook.

13 “(4) ADJUSTMENT BY SECRETARY.—The Sec-  
14 retary may, through a rulemaking under section 553  
15 of title 5, United States Code, adjust the format and  
16 type sizes for the label statements required by this  
17 section; the text, format, and type sizes of any re-  
18 quired tar, nicotine yield, or other constituent (in-  
19 cluding smoke constituent) disclosures; or the text,  
20 format, and type sizes for any other disclosures re-  
21 quired under the Federal Food, Drug, and Cosmetic  
22 Act. The text of any such label statements or disclo-  
23 sures shall be required to appear only within the 20  
24 percent area of cigarette advertisements provided by  
25 paragraph (2). The Secretary shall promulgate regu-

1 lations which provide for adjustments in the format  
2 and type sizes of any text required to appear in such  
3 area to ensure that the total text required to appear  
4 by law will fit within such area.

5 “(c) MARKETING REQUIREMENTS.—

6 “(1) RANDOM DISPLAY.—The label statements  
7 specified in subsection (a)(1) shall be randomly dis-  
8 played in each 12-month period, in as equal a num-  
9 ber of times as is possible on each brand of the  
10 product and be randomly distributed in all areas of  
11 the United States in which the product is marketed  
12 in accordance with a plan submitted by the tobacco  
13 product manufacturer, importer, distributor, or re-  
14 tailer and approved by the Secretary.

15 “(2) ROTATION.—The label statements speci-  
16 fied in subsection (a)(1) shall be rotated quarterly in  
17 alternating sequence in advertisements for each  
18 brand of cigarettes in accordance with a plan sub-  
19 mitted by the tobacco product manufacturer, im-  
20 porter, distributor, or retailer to, and approved by,  
21 the Secretary.

22 “(3) REVIEW.—The Secretary shall review each  
23 plan submitted under paragraph (2) and approve it  
24 if the plan—

1           “(A) will provide for the equal distribution  
2           and display on packaging and the rotation re-  
3           quired in advertising under this subsection; and

4           “(B) assures that all of the labels required  
5           under this section will be displayed by the to-  
6           bacco product manufacturer, importer, dis-  
7           tributor, or retailer at the same time.

8           “(4) APPLICABILITY TO RETAILERS.—This sub-  
9           section and subsection (b) apply to a retailer only if  
10          that retailer is responsible for or directs the label  
11          statements required under this section except that  
12          this paragraph shall not relieve a retailer of liability  
13          if the retailer displays, in a location open to the pub-  
14          lic, an advertisement that does not contain a warn-  
15          ing label or has been altered by the retailer in a way  
16          that is material to the requirements of this sub-  
17          section and subsection (b).”.

18          (b) EFFECTIVE DATE.—The amendment made by  
19          subsection (a) shall take effect 12 months after the date  
20          of enactment of this Act. Such effective date shall be with  
21          respect to the date of manufacture, provided that, in any  
22          case, beginning 30 days after such effective date, a manu-  
23          facturer shall not introduce into the domestic commerce  
24          of the United States any product, irrespective of the date  
25          of manufacture, that is not in conformance with section

1 4 of the Federal Cigarette Labeling and Advertising Act  
2 (15 U.S.C. 1333), as amended by subsection (a).

3 **SEC. 202. AUTHORITY TO REVISE CIGARETTE WARNING**  
4 **LABEL STATEMENTS.**

5 (a) PREEMPTION.—Section 5(a) of the Federal Ciga-  
6 rette Labeling and Advertising Act (15 U.S.C. 1334(a))  
7 is amended by striking “No” and inserting “Except to the  
8 extent the Secretary requires additional or different state-  
9 ments on any cigarette package by a regulation, by an  
10 order, by a standard, by an authorization to market a  
11 product, or by a condition of marketing a product, pursu-  
12 ant to the Family Smoking Prevention and Tobacco Con-  
13 trol Act (and the amendments made by that Act), or as  
14 required under section 903(a)(2) or section 920(a) of the  
15 Federal Food, Drug, and Cosmetic Act, no”.

16 (b) CHANGE IN REQUIRED STATEMENTS.—Section 4  
17 of the Federal Cigarette Labeling and Advertising Act (15  
18 U.S.C. 1333), as amended by section 201, is further  
19 amended by adding at the end the following:

20 “(d) CHANGE IN REQUIRED STATEMENTS.—The  
21 Secretary may, by a rulemaking conducted under section  
22 553 of title 5, United States Code, adjust the format, type  
23 size, and text of any of the label requirements, require  
24 color graphics to accompany the text, increase the re-  
25 quired label area from 30 percent up to 50 percent of the

1 front and rear panels of the package, or establish the for-  
2 mat, type size, and text of any other disclosures required  
3 under the Federal Food, Drug, and Cosmetic Act, if the  
4 Secretary finds that such a change would promote greater  
5 public understanding of the risks associated with the use  
6 of tobacco products.”.

7 **SEC. 203. STATE REGULATION OF CIGARETTE ADVER-**  
8 **TISING AND PROMOTION.**

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

12 “(c) EXCEPTION.—Notwithstanding subsection (b), a  
13 State or locality may enact statutes and promulgate regu-  
14 lations, based on smoking and health, that take effect  
15 after the effective date of the Family Smoking Prevention  
16 and Tobacco Control Act, imposing specific bans or re-  
17 strictions on the time, place, and manner, but not content,  
18 of the advertising or promotion of any cigarettes.”.

19 **SEC. 204. SMOKELESS TOBACCO LABELS AND ADVERTISING**  
20 **WARNINGS.**

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

24 **“SEC. 3. SMOKELESS TOBACCO WARNING.**

25 “(a) GENERAL RULE.—

1           “(1) It shall be unlawful for any person to man-  
2           ufacture, package, sell, offer to sell, distribute, or  
3           import for sale or distribution within the United  
4           States any smokeless tobacco product unless the  
5           product package bears, in accordance with the re-  
6           quirements of this Act, one of the following labels:

7                   “WARNING: This product can cause  
8                   mouth cancer.

9                   “WARNING: This product can cause gum  
10                  disease and tooth loss.

11                  “WARNING: This product is not a safe al-  
12                  ternative to cigarettes.

13                  “WARNING: Smokeless tobacco is addict-  
14                  ive.

15           “(2) Each label statement required by para-  
16           graph (1) shall be—

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

21                   “(B) in 17-point conspicuous and legible  
22                   type and in black text on a white background,  
23                   or white text on a black background, in a man-  
24                   ner that contrasts by typography, layout, or  
25                   color, with all other printed material on the

1 package, in an alternating fashion under the  
2 plan submitted under subsection (b)(3), except  
3 that if the text of a label statement would oc-  
4 cupy more than 70 percent of the area specified  
5 by subparagraph (A), such text may appear in  
6 a smaller type size, so long as at least 60 per-  
7 cent of such warning area is occupied by the  
8 label statement.

9 “(3) The label statements required by para-  
10 graph (1) shall be introduced by each tobacco prod-  
11 uct manufacturer, packager, importer, distributor, or  
12 retailer of smokeless tobacco products concurrently  
13 into the distribution chain of such products.

14 “(4) The provisions of this subsection do not  
15 apply to a tobacco product manufacturer or dis-  
16 tributor of any smokeless tobacco product that does  
17 not manufacture, package, or import smokeless to-  
18 bacco products for sale or distribution within the  
19 United States.

20 “(5) A retailer of smokeless tobacco products  
21 shall not be in violation of this subsection for pack-  
22 aging that—

23 “(A) contains a warning label;

1           “(B) is supplied to the retailer by a  
2           license- or permit-holding tobacco product man-  
3           ufacturer, importer, or distributor; and

4           “(C) is not altered by the retailer in a way  
5           that is material to the requirements of this sub-  
6           section.

7           “(b) REQUIRED LABELS.—

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

15          “(2)(A) Each label statement required by sub-  
16          section (a) in smokeless tobacco advertising shall  
17          comply with the standards set forth in this para-  
18          graph.

19          “(B) For press and poster advertisements, each  
20          such statement and (where applicable) any required  
21          statement relating to tar, nicotine, or other con-  
22          stituent yield shall comprise at least 20 percent of  
23          the area of the advertisement.

1           “(C) The word ‘WARNING’ shall appear in  
2 capital letters, and each label statement shall appear  
3 in conspicuous and legible type.

4           “(D) The text of the label statement shall be  
5 black on a white background, or white on a black  
6 background, in an alternating fashion under the  
7 plan submitted under paragraph (3).

8           “(E) The label statements shall be enclosed by  
9 a rectangular border that is the same color as the  
10 letters of the statements and that is the width of the  
11 first downstroke of the capital ‘W’ of the word  
12 ‘WARNING’ in the label statements.

13           “(F) The text of such label statements shall be  
14 in 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.

1           “(G) The label statements shall be in English,  
2           except that—

3                   “(i) in the case of an advertisement that  
4                   appears in a newspaper, magazine, periodical,  
5                   or other publication that is not in English, the  
6                   statements shall appear in the predominant lan-  
7                   guage of the publication; and

8                   “(ii) in the case of any other advertisement  
9                   that is not in English, the statements shall ap-  
10                  pear in the same language as that principally  
11                  used in the advertisement.

12               “(3)(A) The label statements specified in sub-  
13               section (a)(1) shall be randomly displayed in each  
14               12-month period, in as equal a number of times as  
15               is possible on each brand of the product and be ran-  
16               domly distributed in all areas of the United States  
17               in which the product is marketed in accordance with  
18               a plan submitted by the tobacco product manufac-  
19               turer, importer, distributor, or retailer and approved  
20               by the Secretary.

21               “(B) The label statements specified in sub-  
22               section (a)(1) shall be rotated quarterly in alter-  
23               nating sequence in advertisements for each brand of  
24               smokeless tobacco product in accordance with a plan  
25               submitted by the tobacco product manufacturer, im-

1 porter, distributor, or retailer to, and approved by,  
2 the Secretary.

3 “(C) The Secretary shall review each plan sub-  
4 mitted under subparagraphs (A) and (B) and ap-  
5 prove it if the plan—

6 “(i) will provide for the equal distribution  
7 and display on packaging and the rotation re-  
8 quired in advertising under this subsection; and

9 “(ii) assures that all of the labels required  
10 under this section will be displayed by the to-  
11 bacco product manufacturer, importer, dis-  
12 tributor, or retailer at the same time.

13 “(D) This paragraph applies to a retailer only  
14 if that retailer is responsible for or directs the label  
15 statements under this section, unless the retailer dis-  
16 plays, in a location open to the public, an advertise-  
17 ment that does not contain a warning label or has  
18 been altered by the retailer in a way that is material  
19 to the requirements of this subsection.

20 “(4) The Secretary may, through a rulemaking  
21 under section 553 of title 5, United States Code, ad-  
22 just the format and type sizes for the label state-  
23 ments required by this section; the text, format, and  
24 type sizes of any required tar, nicotine yield, or  
25 other constituent disclosures; or the text, format,

1 and type sizes for any other disclosures required  
2 under the Federal Food, Drug, and Cosmetic Act.  
3 The text of any such label statements or disclosures  
4 shall be required to appear only within the 20 per-  
5 cent area of advertisements provided by paragraph  
6 (2). The Secretary shall promulgate regulations  
7 which provide for adjustments in the format and  
8 type sizes of any text required to appear in such  
9 area to ensure that the total text required to appear  
10 by law will fit within such area.

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

15 (b) EFFECTIVE DATE.—The amendment made by  
16 subsection (a) shall take effect 12 months after the date  
17 of enactment of this Act. Such effective date shall be with  
18 respect to the date of manufacture, provided that, in any  
19 case, beginning 30 days after such effective date, a manu-  
20 facturer shall not introduce into the domestic commerce  
21 of the United States any product, irrespective of the date  
22 of manufacture, that is not in conformance with section  
23 3 of the Comprehensive Smokeless Tobacco Health Edu-  
24 cation Act of 1986 (15 U.S.C. 4402), as amended by sub-  
25 section (a).

1 **SEC. 205. AUTHORITY TO REVISE SMOKELESS TOBACCO**  
2 **PRODUCT WARNING LABEL STATEMENTS.**

3 (a) IN GENERAL.—Section 3 of the Comprehensive  
4 Smokeless Tobacco Health Education Act of 1986 (15  
5 U.S.C. 4402), as amended by section 204, is further  
6 amended by adding at the end the following:

7 “(d) AUTHORITY TO REVISE WARNING LABEL  
8 STATEMENTS.—The Secretary may, by a rulemaking con-  
9 ducted under section 553 of title 5, United States Code,  
10 adjust the format, type size, and text of any of the label  
11 requirements, require color graphics to accompany the  
12 text, increase the required label area from 30 percent up  
13 to 50 percent of the front and rear panels of the package,  
14 or establish the format, type size, and text of any other  
15 disclosures required under the Federal Food, Drug, and  
16 Cosmetic Act, if the Secretary finds that such a change  
17 would promote greater public understanding of the risks  
18 associated with the use of smokeless tobacco products.”.

19 (b) PREEMPTION.—Section 7(a) of the Comprehen-  
20 sive Smokeless Tobacco Health Education Act of 1986 (15  
21 U.S.C. 4406(a)) is amended by striking “No” and insert-  
22 ing “Except as provided in the Family Smoking Preven-  
23 tion and Tobacco Control Act (and the amendments made  
24 by that Act), no”.

1 **SEC. 206. TAR, NICOTINE, AND OTHER SMOKE CON-**  
2 **STITUENT DISCLOSURE TO THE PUBLIC.**

3 Section 4 of the Federal Cigarette Labeling and Ad-  
4 vertising Act (15 U.S.C. 1333), as amended by sections  
5 201 and 202, is further amended by adding at the end  
6 the following:

7 “(e) **TAR, NICOTINE, AND OTHER SMOKE CON-**  
8 **STITUENT DISCLOSURE.—**

9 “(1) **IN GENERAL.—**The Secretary shall, by a  
10 rulemaking conducted under section 553 of title 5,  
11 United States Code, determine (in the Secretary’s  
12 sole discretion) whether cigarette and other tobacco  
13 product manufacturers shall be required to include  
14 in the area of each cigarette advertisement specified  
15 by subsection (b) of this section, or on the package  
16 label, or both, the tar and nicotine yields of the ad-  
17 vertised or packaged brand. Any such disclosure  
18 shall be in accordance with the methodology estab-  
19 lished under such regulations, shall conform to the  
20 type size requirements of subsection (b) of this sec-  
21 tion, and shall appear within the area specified in  
22 subsection (b) of this section.

23 “(2) **RESOLUTION OF DIFFERENCES.—**Any dif-  
24 ferences between the requirements established by the  
25 Secretary under paragraph (1) and tar and nicotine  
26 yield reporting requirements established by the Fed-

1       eral Trade Commission shall be resolved by a memo-  
2       randum of understanding between the Secretary and  
3       the Federal Trade Commission.

4               “(3) CIGARETTE AND OTHER TOBACCO PROD-  
5       UCT CONSTITUENTS.—In addition to the disclosures  
6       required by paragraph (1), the Secretary may, under  
7       a rulemaking conducted under section 553 of title 5,  
8       United States Code, prescribe disclosure require-  
9       ments regarding the level of any cigarette or other  
10      tobacco product constituent including any smoke  
11      constituent. Any such disclosure may be required if  
12      the Secretary determines that disclosure would be of  
13      benefit to the public health, or otherwise would in-  
14      crease consumer awareness of the health con-  
15      sequences of the use of tobacco products, except that  
16      no such prescribed disclosure shall be required on  
17      the face of any cigarette package or advertisement.  
18      Nothing in this section shall prohibit the Secretary  
19      from requiring such prescribed disclosure through a  
20      cigarette or other tobacco product package or adver-  
21      tisement insert, or by any other means under the  
22      Federal Food, Drug, and Cosmetic Act.

23              “(4) RETAILERS.—This subsection applies to a  
24      retailer only if that retailer is responsible for or di-



1        factorer shall not introduce into the domestic com-  
2        merce of the United States any product, irrespective  
3        of the date of manufacture, that is not in conform-  
4        ance with such paragraph.

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

7               “(1) IN GENERAL.—The Secretary shall pro-  
8        mulgate regulations regarding the establishment and  
9        maintenance of records by any person who manufac-  
10       tures, processes, transports, distributes, receives,  
11       packages, holds, exports, or imports tobacco prod-  
12       ucts.

13              “(2) INSPECTION.—In promulgating the regula-  
14       tions described in paragraph (1), the Secretary shall  
15       consider which records are needed for inspection to  
16       monitor the movement of tobacco products from the  
17       point of manufacture through distribution to retail  
18       outlets to assist in investigating potential illicit  
19       trade, smuggling, or counterfeiting of tobacco prod-  
20       ucts.

21              “(3) CODES.—The Secretary may require codes  
22       on the labels of tobacco products or other designs or  
23       devices for the purpose of tracking or tracing the to-  
24       bacco product through the distribution system.

1           “(4) SIZE OF BUSINESS.—The Secretary shall  
2           take into account the size of a business in promul-  
3           gating regulations under this section.

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

8           “(c) RECORDS INSPECTION.—If the Secretary has a  
9           reasonable belief that a tobacco product is part of an illicit  
10          trade or smuggling or is a counterfeit product, each person  
11          who manufactures, processes, transports, distributes, re-  
12          ceives, holds, packages, exports, or imports tobacco prod-  
13          ucts shall, at the request of an officer or employee duly  
14          designated by the Secretary, permit such officer or em-  
15          ployee, at reasonable times and within reasonable limits  
16          and in a reasonable manner, upon the presentation of ap-  
17          propriate credentials and a written notice to such person,  
18          to have access to and copy all records (including financial  
19          records) relating to such article that are needed to assist  
20          the Secretary in investigating potential illicit trade, smug-  
21          gling, or counterfeiting of tobacco products. The Secretary  
22          shall not authorize an officer or employee of the govern-  
23          ment of any of the several States to exercise authority  
24          under the preceding sentence on Indian country without  
25          the express written consent of the Indian tribe involved.

1 “(d) KNOWLEDGE OF ILLEGAL TRANSACTION.—

2 “(1) NOTIFICATION.—If the manufacturer or  
3 distributor of a tobacco product has knowledge  
4 which reasonably supports the conclusion that a to-  
5 bacco product manufactured or distributed by such  
6 manufacturer or distributor that has left the control  
7 of such person may be or has been—

8 “(A) imported, exported, distributed, or of-  
9 fered for sale in interstate commerce by a per-  
10 son without paying duties or taxes required by  
11 law; or

12 “(B) imported, exported, distributed, or di-  
13 verted for possible illicit marketing,  
14 the manufacturer or distributor shall promptly no-  
15 tify the Attorney General and the Secretary of the  
16 Treasury of such knowledge.

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

20 “(A) the actual knowledge that the manu-  
21 facturer or distributor had; or

22 “(B) the knowledge which a reasonable  
23 person would have had under like circumstances  
24 or which would have been obtained upon the ex-  
25 ercise of due care.

1       “(e) CONSULTATION.—In carrying out this section,  
2 the Secretary shall consult with the Attorney General of  
3 the United States and the Secretary of the Treasury, as  
4 appropriate.”.

5 **SEC. 302. STUDY AND REPORT.**

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

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

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

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

1           (A) the illicit trade of tobacco products  
2           and the trade of counterfeit tobacco products;  
3           and

4           (B) the differing tax rates applicable to to-  
5           bacco products.

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

13          (c) DEFINITION.—In this section:

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

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

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

1                   **DIVISION B—FEDERAL**  
 2                   **RETIREMENT REFORM ACT**

3 **SEC. 100. SHORT TITLE; TABLE OF CONTENTS.**

4           (a) **SHORT TITLE.**—This division may be cited as the  
 5 “Federal Retirement Reform Act of 2009”.

6           (b) **TABLE OF CONTENTS.**—The table of contents for  
 7 this division is as follows:

DIVISION B—FEDERAL RETIREMENT REFORM ACT

Sec. 100. Short title; table of contents.

TITLE I—PROVISIONS RELATING TO FEDERAL EMPLOYEES  
 RETIREMENT

Subtitle A—Thrift Savings Plan Enhancement

- Sec. 101. Short title.
- Sec. 102. Automatic enrollments.
- Sec. 103. Qualified Roth contribution program.
- Sec. 104. Authority to establish self-directed investment window.
- Sec. 105. Reporting requirements.
- Sec. 106. Acknowledgement of risk.

Subtitle B—Other Retirement-Related Provisions

- Sec. 111. Credit for unused sick leave.
- Sec. 112. Exemption of certain CSRS repayments from the requirement that they be made with interest.
- Sec. 113. Computation of certain annuities based on part-time service.
- Sec. 114. Treatment of members of the uniformed services under the Thrift Savings Plan.
- Sec. 115. Authority to deposit refunds under FERS.
- Sec. 116. Retirement credit for service of certain employees transferred from District of Columbia service to Federal service.

TITLE II—SPECIAL SURVIVOR INDEMNITY ALLOWANCE FOR  
 SURVIVING SPOUSES OF ARMED FORCES MEMBERS

- Sec. 201. Increase in monthly amount of special survivor indemnity allowance for widows and widowers of deceased members of the Armed Forces affected by required Survivor Benefit Plan annuity offset for dependency and indemnity compensation.

1 **TITLE I—PROVISIONS RELATING**  
2 **TO FEDERAL EMPLOYEES RE-**  
3 **TIREMENT**

4 **Subtitle A—Thrift Savings Plan**  
5 **Enhancement**

6 **SEC. 101. SHORT TITLE.**

7 This subtitle may be cited as the “Thrift Savings  
8 Plan Enhancement Act of 2009”.

9 **SEC. 102. AUTOMATIC ENROLLMENTS.**

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

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

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

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

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

4           “(ii) decline automatic enrollment altogether.

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

11          “(E)(i) Subject to clause (ii), sections 8351(a)(1),  
12          8440a(a)(1), 8440b(a)(1), 8440c(a)(1), 8440d(a)(1), and  
13          8440e(a)(1) shall be applied in a manner consistent with  
14          the purposes of this paragraph.

15          “(ii) The Secretary concerned may, with respect to  
16          members of the uniformed services under the authority of  
17          such Secretary, establish such special rules as such Sec-  
18          retary considers necessary for the administration of this  
19          subparagraph, including rules in accordance with which  
20          such Secretary may—

21                 “(I) provide for delayed automatic enrollment;

22                 or

23                 “(II) preclude or suspend the application of  
24                 automatic enrollment.”.

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

4 **SEC. 103. QUALIFIED ROTH CONTRIBUTION PROGRAM.**

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

8 **“§ 8432d. Qualified Roth contribution program**

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

10 “(1) the term ‘qualified Roth contribution pro-  
11 gram’ means a program described in paragraph (1)  
12 of section 402A(b) of the Internal Revenue Code of  
13 1986 which meets the requirements of paragraph (2)  
14 of such section; and

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

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

23 “(c) REQUIRED PROVISIONS.—The regulations under  
24 subsection (b) shall include—

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

3           “(A) by any individual who is eligible to  
4 make contributions under section 8351,  
5 8432(a), 8440a, 8440b, 8440c, 8440d, or  
6 8440e; and

7           “(B) by any individual, not described in  
8 subparagraph (A), who is otherwise eligible to  
9 make elective deferrals under the Thrift Sav-  
10 ings Plan;

11           “(2) any provisions which may, as a result of  
12 enactment of this section, be necessary in order to  
13 clarify the meaning of any reference to an ‘account’  
14 made in section 8432(f), 8433, 8434(d), 8435,  
15 8437, or any other provision of law; and

16           “(3) any other provisions which may be nec-  
17 essary to carry out this section.”.

18           (b) CLERICAL AMENDMENT.—The analysis for chap-  
19 ter 84 of title 5, United States Code, is amended by insert-  
20 ing after the item relating to section 8432c the following:

“8432d. Qualified Roth contribution program.”.

21 **SEC. 104. AUTHORITY TO ESTABLISH SELF-DIRECTED IN-**  
22 **VESTMENT WINDOW.**

23           (a) IN GENERAL.—Section 8438(b)(1) of title 5,  
24 United States Code, is amended—

1           (1) in subparagraph (D), by striking “and” at  
2 the end;

3           (2) in subparagraph (E), by striking the period  
4 and inserting “; and”; and

5           (3) by adding after subparagraph (E) the fol-  
6 lowing:

7                   “(F) a self-directed investment window, if  
8 the Board authorizes such window under para-  
9 graph (5).”.

10       (b) REQUIREMENTS.—Section 8438(b) of title 5,  
11 United States Code, is amended by adding at the end the  
12 following:

13           “(5)(A) The Board may authorize the addition of a  
14 self-directed investment window under the Thrift Savings  
15 Plan if the Board determines that such addition would be  
16 in the best interests of participants.

17           “(B) The self-directed investment window shall be  
18 limited to—

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

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

24           “(C) The Board shall ensure that any administrative  
25 expenses related to use of the self-directed investment win-

1 dow are borne solely by the participants who use such win-  
2 dow.

3 “(D) The Board may establish such other terms and  
4 conditions for the self-directed investment window as the  
5 Board considers appropriate to protect the interests of  
6 participants, including requirements relating to risk dis-  
7 closure.

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

11 **SEC. 105. REPORTING REQUIREMENTS.**

12 (a) ANNUAL REPORT.—The Board shall, not later  
13 than June 30 of each year, submit to Congress an annual  
14 report on the operations of the Thrift Savings Plan. Such  
15 report shall include, for the prior calendar year, informa-  
16 tion on the number of participants as of the last day of  
17 such prior calendar year, the median balance in partici-  
18 pants’ accounts as of such last day, demographic informa-  
19 tion on participants, the percentage allocation of amounts  
20 among investment funds or options, the status of the de-  
21 velopment and implementation of the self-directed invest-  
22 ment window, the diversity demographics of any company,  
23 investment adviser, or other entity retained to invest and  
24 manage the assets of the Thrift Savings Fund, and such  
25 other information as the Board considers appropriate. A

1 copy of each annual report under this subsection shall be  
2 made available to the public through an Internet website.

3 (b) REPORTING OF FEES AND OTHER INFORMA-  
4 TION.—

5 (1) IN GENERAL.—The Board shall include in  
6 the periodic statements provided to participants  
7 under section 8439(c) of title 5, United States Code,  
8 the amount of the investment management fees, ad-  
9 ministrative expenses, and any other fees or ex-  
10 penses paid with respect to each investment fund  
11 and option under the Thrift Savings Plan. Any such  
12 statement shall also provide a statement notifying  
13 participants as to how they may access the annual  
14 report described in subsection (a), as well as any  
15 other information concerning the Thrift Savings  
16 Plan that might be useful.

17 (2) USE OF ESTIMATES.—For purposes of pro-  
18 viding the information required under this sub-  
19 section, the Executive Director may provide a rea-  
20 sonable and representative estimate of any fees or  
21 expenses described in paragraph (1) and shall indi-  
22 cate any such estimate as being such an estimate.  
23 Any such estimate shall be based on the previous  
24 year's experience.

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

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

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

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

9 **SEC. 106. ACKNOWLEDGEMENT OF RISK.**

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

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

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

19       (b) COORDINATION WITH PROVISIONS RELATING TO  
20 FIDUCIARY RESPONSIBILITIES, LIABILITIES, AND PEN-  
21 ALTIES.—Section 8477(e)(1)(C) of title 5, United States  
22 Code, is amended—

23           (1) by redesignating subparagraph (C) as sub-  
24 paragraph (C)(i); and

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

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

4 “(I) for providing for the automatic enrollment  
5 of a participant in accordance with section  
6 8432(b)(2)(A);

7 “(II) for enrolling a participant in a default in-  
8 vestment fund in accordance with section  
9 8438(c)(2); or

10 “(III) for allowing a participant to invest  
11 through the self-directed investment window or for  
12 establishing restrictions applicable to participants’  
13 ability to invest through the self-directed investment  
14 window.”.

## 15 **Subtitle B—Other Retirement-** 16 **Related Provisions**

### 17 **SEC. 111. CREDIT FOR UNUSED SICK LEAVE.**

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

20 (1) by redesignating the second subsection (k)  
21 and subsection (l) as subsections (l) and (m), respec-  
22 tively; and

23 (2) in subsection (l) (as so redesignated by  
24 paragraph (1))—

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

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

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

17 (b) EXCEPTION FROM DEPOSIT REQUIREMENT.—  
18 Section 8422(d)(2) of title 5, United States Code, is  
19 amended by striking “section 8415(k)” and inserting  
20 “paragraph (1) or (2) of section 8415(l)”.

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

1 **SEC. 112. EXEMPTION OF CERTAIN CSRS REPAYMENTS**  
2 **FROM THE REQUIREMENT THAT THEY BE**  
3 **MADE WITH INTEREST.**

4 (a) IN GENERAL.—Section 8334(d)(1) of title 5,  
5 United States Code, is amended—

6 (1) by striking “(d)(1)” and inserting  
7 “(d)(1)(A)”; and

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

9 “(B) No interest under subparagraph (A) shall be re-  
10 quired in the case of any deposit to the extent that it rep-  
11 resents the amount of any refund that was made to an  
12 employee or Member during the period beginning on Octo-  
13 ber 1, 1990, and ending on February 28, 1991.”.

14 (b) APPLICABILITY.—The amendments made by sub-  
15 section (a) shall be effective with respect to any annuity,  
16 entitlement to which is based on a separation from service  
17 occurring on or after the date of enactment of this Act.

18 **SEC. 113. COMPUTATION OF CERTAIN ANNUITIES BASED**  
19 **ON PART-TIME SERVICE.**

20 (a) IN GENERAL.—Section 8339(p) of title 5, United  
21 States Code, is amended by adding at the end the fol-  
22 lowing:

23 “(3) In the administration of paragraph (1)—

24 “(A) subparagraph (A) of such paragraph shall  
25 apply with respect to service performed before, on,  
26 or after April 7, 1986; and

1 “(B) subparagraph (B) of such paragraph—

2 “(i) shall apply with respect to that portion  
3 of any annuity which is attributable to service  
4 performed on or after April 7, 1986; and

5 “(ii) shall not apply with respect to that  
6 portion of any annuity which is attributable to  
7 service performed before April 7, 1986.”.

8 (b) APPLICABILITY.—The amendment made by sub-  
9 section (a) shall be effective with respect to any annuity,  
10 entitlement to which is based on a separation from service  
11 occurring on or after the date of enactment of this Act.

12 **SEC. 114. TREATMENT OF MEMBERS OF THE UNIFORMED**  
13 **SERVICES UNDER THE THRIFT SAVINGS**  
14 **PLAN.**

15 (a) SENSE OF CONGRESS.—It is the sense of Con-  
16 gress that—

17 (1) members of the uniformed services should  
18 have a retirement system that is at least as generous  
19 as the one which is available to Federal civilian em-  
20 ployees; and

21 (2) Federal civilian employees receive matching  
22 contributions from their employing agencies for their  
23 contributions to the Thrift Savings Fund, but the  
24 costs of requiring such a matching contribution from  
25 the Department of Defense could be significant.

1 (b) REPORTING REQUIREMENT.—Not later than 180  
2 days after the date of the enactment of this Act, the Sec-  
3 retary of Defense shall report to Congress on—

4 (1) the cost to the Department of Defense of  
5 providing a matching payment with respect to con-  
6 tributions made to the Thrift Savings Fund by  
7 members of the Armed Forces;

8 (2) the effect that requiring such a matching  
9 payment would have on recruitment and retention;  
10 and

11 (3) any other information that the Secretary of  
12 Defense considers appropriate.

13 **SEC. 115. AUTHORITY TO DEPOSIT REFUNDS UNDER FERS.**

14 (a) DEPOSIT AUTHORITY.—Section 8422 of title 5,  
15 United States Code, is amended by adding at the end the  
16 following:

17 “(i)(1) Each employee or Member who has received  
18 a refund of retirement deductions under this or any other  
19 retirement system established for employees of the Gov-  
20 ernment covering service for which such employee or Mem-  
21 ber may be allowed credit under this chapter may deposit  
22 the amount received, with interest. Credit may not be al-  
23 lowed for the service covered by the refund until the de-  
24 posit is made.

1       “(2) Interest under this subsection shall be computed  
2 in accordance with paragraphs (2) and (3) of section  
3 8334(e) and regulations prescribed by the Office. The op-  
4 tion under the third sentence of section 8334(e)(2) to  
5 make a deposit in one or more installments shall apply  
6 to deposits under this subsection.

7       “(3) For the purpose of survivor annuities, deposits  
8 authorized by this subsection may also be made by a sur-  
9 vivor of an employee or Member.”.

10       (b) TECHNICAL AND CONFORMING AMENDMENTS.—

11           (1) DEFINITIONAL AMENDMENT.—Section  
12 8401(19)(C) of title 5, United States Code, is  
13 amended by striking “8411(f);” and inserting  
14 “8411(f) or 8422(i);”.

15           (2) CREDITING OF DEPOSITS.—Section 8422(c)  
16 of title 5, United States Code, is amended by adding  
17 at the end the following: “Deposits made by an em-  
18 ployee, Member, or survivor also shall be credited to  
19 the Fund.”.

20           (3) SECTION HEADING.—(A) The heading for  
21 section 8422 of title 5, United States Code, is  
22 amended to read as follows:

1 **“§ 8422. Deductions from pay; contributions for other**  
2 **service; deposits”.**

3 (B) The analysis for chapter 84 of title 5,  
4 United States Code, is amended by striking the item  
5 relating to section 8422 and inserting the following:

“8422. Deductions from pay; contributions for other service; deposits.”.

6 (4) RESTORATION OF ANNUITY RIGHTS.—The  
7 last sentence of section 8424(a) of title 5, United  
8 States Code, is amended by striking “based.” and  
9 inserting “based, until the employee or Member is  
10 reemployed in the service subject to this chapter.”.

11 **SEC. 116. RETIREMENT CREDIT FOR SERVICE OF CERTAIN**  
12 **EMPLOYEES TRANSFERRED FROM DISTRICT**  
13 **OF COLUMBIA SERVICE TO FEDERAL SERV-**  
14 **ICE.**

15 (a) RETIREMENT CREDIT.—

16 (1) IN GENERAL.—Any individual who is treat-  
17 ed as an employee of the Federal Government for  
18 purposes of chapter 83 or chapter 84 of title 5,  
19 United States Code, on or after the date of enact-  
20 ment of this Act who performed qualifying District  
21 of Columbia service shall be entitled to have such  
22 service included in calculating the individual’s cred-  
23 itable service under sections 8332 or 8411 of title 5,  
24 United States Code, but only for purposes of the fol-  
25 lowing provisions of such title:

1 (A) Sections 8333 and 8410 (relating to  
2 eligibility for annuity).

3 (B) Sections 8336 (other than subsections  
4 (d), (h), and (p) thereof) and 8412 (relating to  
5 immediate retirement).

6 (C) Sections 8338 and 8413 (relating to  
7 deferred retirement).

8 (D) Sections 8336(d), 8336(h), 8336(p),  
9 and 8414 (relating to early retirement).

10 (E) Section 8341 and subchapter IV of  
11 chapter 84 (relating to survivor annuities).

12 (F) Section 8337 and subchapter V of  
13 chapter 84 (relating to disability benefits).

14 (2) TREATMENT OF DETENTION OFFICER SERV-  
15 ICE AS LAW ENFORCEMENT OFFICER SERVICE.—Any  
16 portion of an individual's qualifying District of Co-  
17 lumbia service which consisted of service as a deten-  
18 tion officer under section 2604(2) of the District of  
19 Columbia Government Comprehensive Merit Per-  
20 sonnel Act of 1978 (sec. 1–626.04(2), D.C. Official  
21 Code) shall be treated as service as a law enforce-  
22 ment officer under sections 8331(20) or 8401(17) of  
23 title 5, United States Code, for purposes of applying  
24 paragraph (1) with respect to the individual.

1           (3) SERVICE NOT INCLUDED IN COMPUTING  
2 AMOUNT OF ANY ANNUITY.—Qualifying District of  
3 Columbia service shall not be taken into account for  
4 purposes of computing the amount of any benefit  
5 payable out of the Civil Service Retirement and Dis-  
6 ability Fund.

7           (b) QUALIFYING DISTRICT OF COLUMBIA SERVICE  
8 DEFINED.—In this section, “qualifying District of Colum-  
9 bia service” means any of the following:

10           (1) Service performed by an individual as a  
11 nonjudicial employee of the District of Columbia  
12 courts—

13                   (A) which was performed prior to the ef-  
14 fective date of the amendments made by section  
15 11246(b) of the Balanced Budget Act of 1997;  
16 and

17                   (B) for which the individual did not ever  
18 receive credit under the provisions of sub-  
19 chapter III of chapter 83 or chapter 84 of title  
20 5, United States Code (other than by virtue of  
21 section 8331(1)(iv) of such title).

22           (2) Service performed by an individual as an  
23 employee of an entity of the District of Columbia  
24 government whose functions were transferred to the  
25 Pretrial Services, Parole, Adult Supervision, and Of-

1 fender Supervision Trustee under section 11232 of  
2 the Balanced Budget Act of 1997—

3 (A) which was performed prior to the ef-  
4 fective date of the individual's coverage as an  
5 employee of the Federal Government under sec-  
6 tion 11232(f) of such Act; and

7 (B) for which the individual did not ever  
8 receive credit under the provisions of sub-  
9 chapter III of chapter 83 or chapter 84 of title  
10 5, United States Code (other than by virtue of  
11 section 8331(1)(iv) of such title).

12 (3) Service performed by an individual as an  
13 employee of the District of Columbia Public De-  
14 fender Service—

15 (A) which was performed prior to the ef-  
16 fective date of the amendments made by section  
17 7(e) of the District of Columbia Courts and  
18 Justice Technical Corrections Act of 1998; and

19 (B) for which the individual did not ever  
20 receive credit under the provisions of sub-  
21 chapter III of chapter 83 or chapter 84 of title  
22 5, United States Code (other than by virtue of  
23 section 8331(1)(iv) of such title).

24 (4) In the case of an individual who was an em-  
25 ployee of the District of Columbia Department of

1 Corrections who was separated from service as a re-  
2 sult of the closing of the Lorton Correctional Com-  
3 plex and who was appointed to a position with the  
4 Bureau of Prisons, the District of Columbia courts,  
5 the Pretrial Services, Parole, Adult Supervision, and  
6 Offender Supervision Trustee, the United States Pa-  
7 role Commission, or the District of Columbia Public  
8 Defender Service, service performed by the indi-  
9 vidual as an employee of the District of Columbia  
10 Department of Corrections—

11 (A) which was performed prior to the ef-  
12 fective date of the individual's coverage as an  
13 employee of the Federal Government; and

14 (B) for which the individual did not ever  
15 receive credit under the provisions of sub-  
16 chapter III of chapter 83 or chapter 84 of title  
17 5, United States Code (other than by virtue of  
18 section 8331(1)(iv) of such title).

19 (c) CERTIFICATION OF SERVICE.—The Office of Per-  
20 sonnel Management shall accept the certification of the  
21 appropriate personnel official of the government of the  
22 District of Columbia or other independent employing enti-  
23 ty concerning whether an individual performed qualifying  
24 District of Columbia service and the length of the period  
25 of such service the individual performed.

1 **TITLE II—SPECIAL SURVIVOR**  
2 **INDEMNITY ALLOWANCE FOR**  
3 **SURVIVING SPOUSES OF**  
4 **ARMED FORCES MEMBERS**

5 **SEC. 201. INCREASE IN MONTHLY AMOUNT OF SPECIAL**  
6 **SURVIVOR INDEMNITY ALLOWANCE FOR WID-**  
7 **OWS AND WIDOWERS OF DECEASED MEM-**  
8 **BERS OF THE ARMED FORCES AFFECTED BY**  
9 **REQUIRED SURVIVOR BENEFIT PLAN ANNU-**  
10 **ITY OFFSET FOR DEPENDENCY AND INDEM-**  
11 **NITY COMPENSATION.**

12 Section 1450(m)(2) of title 10, United States Code,  
13 is amended—

14 (1) in subparagraph (B), by striking “\$60” and  
15 inserting “\$95”;

16 (2) in subparagraph (C), by striking “\$70” and  
17 inserting “\$105”;

18 (3) in subparagraph (D), by striking “\$80” and  
19 inserting “\$120”;

20 (4) in subparagraph (E), by striking “\$90;  
21 and” and inserting “\$130;” and

22 (5) by striking subparagraph (F) and inserting  
23 the following new subparagraphs:

24 “(F) for months during fiscal year 2014,  
25 \$330;

1           “(G) for months during fiscal year 2015,  
2           \$335; and

3           “(H) for months during fiscal year 2016  
4           ending before the termination date specified in  
5           paragraph (6), \$345.”.

Passed the House of Representatives April 2, 2009.

Attest:

*Clerk.*



111<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION

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**H. R. 1256**

**AN ACT**

To protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes.