

**AMENDMENT IN THE NATURE OF A SUBSTITUTE  
TO H.R. 1108  
OFFERED BY MR. PALLONE OF NEW JERSEY**

Strike all after the enacting clause and insert the following:

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

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

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

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

**TITLE I—AUTHORITY OF THE FOOD AND DRUG  
ADMINISTRATION**

- Sec. 101. Amendment of Federal Food, Drug, and Cosmetic Act.
- Sec. 102. Final rule.
- Sec. 103. Conforming and other amendments to general provisions.

**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.

1 **SEC. 2. FINDINGS.**

2 The Congress finds the following:

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

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

11 (3) Nicotine is an addictive drug.

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

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

18 (6) Because past efforts to restrict advertising  
19 and marketing of tobacco products have failed ade-  
20 quately to curb tobacco use by adolescents, com-  
21 prehensive restrictions on the sale, promotion, and  
22 distribution of such products are needed.

23 (7) Federal and State governments have lacked  
24 the legal and regulatory authority and resources  
25 they need to address comprehensively the public

1 health and societal problems caused by the use of to-  
2 bacco products.

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

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

11 (10) The sale, distribution, marketing, adver-  
12 tising, and use of tobacco products are activities in  
13 and substantially affecting interstate commerce be-  
14 cause they are sold, marketed, advertised, and dis-  
15 tributed in interstate commerce on a nationwide  
16 basis, and have a substantial effect on the Nation's  
17 economy.

18 (11) The sale, distribution, marketing, adver-  
19 tising, and use of such products substantially affect  
20 interstate commerce through the health care and  
21 other costs attributable to the use of tobacco prod-  
22 ucts.

23 (12) It is in the public interest for Congress to  
24 enact legislation that provides the Food and Drug  
25 Administration with the authority to regulate to-

1       bacco products and the advertising and promotion of  
2       such products. The benefits to the American people  
3       from enacting such legislation would be significant  
4       in human and economic terms.

5           (13) Tobacco use is the foremost preventable  
6       cause of premature death in America. It causes over  
7       400,000 deaths in the United States each year and  
8       approximately 8,600,000 Americans have chronic ill-  
9       nesses related to smoking.

10          (14) Reducing the use of tobacco by minors by  
11       50 percent would prevent well over 10,000,000 of to-  
12       day's children from becoming regular, daily smokers,  
13       saving over 3,000,000 of them from premature  
14       death due to tobacco induced disease. Such a reduc-  
15       tion in youth smoking would also result in approxi-  
16       mately \$75,000,000,000 in savings attributable to  
17       reduced health care costs.

18          (15) Advertising, marketing, and promotion of  
19       tobacco products have been especially directed to at-  
20       tract young persons to use tobacco products and  
21       these efforts have resulted in increased use of such  
22       products by youth. Past efforts to oversee these ac-  
23       tivities have not been successful in adequately pre-  
24       venting such increased use.

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

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

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

13           (19) Through advertisements during and spon-  
14 sorship of sporting events, tobacco has become  
15 strongly associated with sports and has become por-  
16 trayed as an integral part of sports and the healthy  
17 lifestyle associated with rigorous sporting activity.

18           (20) Children are exposed to substantial and  
19 unavoidable tobacco advertising that leads to favor-  
20 able beliefs about tobacco use, plays a role in leading  
21 young people to overestimate the prevalence of to-  
22 bacco use, and increases the number of young people  
23 who begin to use tobacco.

24           (21) The use of tobacco products in motion pic-  
25 tures and other mass media glamorizes its use for

1 young people and encourages them to use tobacco  
2 products.

3 (22) Tobacco advertising expands the size of  
4 the tobacco market by increasing consumption of to-  
5 bacco products including tobacco use by young peo-  
6 ple.

7 (23) Children are more influenced by tobacco  
8 marketing than adults: more than 80 percent of  
9 youth smoke three heavily marketed brands, while  
10 only 54 percent of adults, 26 and older, smoke these  
11 same brands.

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

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

21 (26) Restrictions on advertising are necessary  
22 to prevent unrestricted tobacco advertising from un-  
23 dermining legislation prohibiting access to young  
24 people and providing for education about tobacco  
25 use.

1           (27) International experience shows that adver-  
2           tising regulations that are stringent and comprehen-  
3           sive have a greater impact on overall tobacco use  
4           and young people's use than weaker or less com-  
5           prehensive ones.

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

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

13          (30) The final regulations promulgated by the  
14          Secretary of Health and Human Services in the Au-  
15          gust 28, 1996, issue of the Federal Register (61  
16          Fed. Reg. 44615–44618) for inclusion as part 897  
17          of title 21, Code of Federal Regulations, are con-  
18          sistent with the First Amendment to the United  
19          States Constitution and with the standards set forth  
20          in the amendments made by this subtitle for the reg-  
21          ulation of tobacco products by the Food and Drug  
22          Administration and the restriction on the sale and  
23          distribution, including access to and the advertising  
24          and promotion of, tobacco products contained in

1       such regulations are substantially related to accom-  
2       plishing the public health goals of this Act.

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

23           (32) The regulations described in paragraph  
24       (30) impose no more extensive restrictions on com-  
25      munication by tobacco manufacturers and sellers

1 than are necessary to reduce the number of children  
2 and adolescents who use cigarettes and smokeless to-  
3 bacco and to prevent the life-threatening health con-  
4 sequences associated with tobacco use. Such regula-  
5 tions are narrowly tailored to restrict those adver-  
6 tising and promotional practices which are most like-  
7 ly to be seen or heard by youth and most likely to  
8 entice them into tobacco use, while affording tobacco  
9 manufacturers and sellers ample opportunity to con-  
10 vey information about their products to adult con-  
11 sumers.

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

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

18 (35) Tobacco products have been used to facili-  
19 tate and finance criminal activities both domestically  
20 and internationally. Illicit trade of tobacco products  
21 has been linked to organized crime and terrorist  
22 groups.

23 (36) It is essential that the Food and Drug Ad-  
24 ministration review products sold or distributed for  
25 use to reduce risks or exposures associated with to-

1       bacco products and that it be empowered to review  
2       any advertising and labeling for such products. It is  
3       also essential that manufacturers, prior to marketing  
4       such products, be required to demonstrate that such  
5       products will meet a series of rigorous criteria, and  
6       will benefit the health of the population as a whole,  
7       taking into account both users of tobacco products  
8       and persons who do not currently use tobacco prod-  
9       ucts.

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

1       sands of unnecessary deaths and injuries and huge  
2       costs to our health care system.

3           (38) As the National Cancer Institute has  
4       found, many smokers mistakenly believe that “low  
5       tar” and “light” cigarettes cause fewer health prob-  
6       lems than other cigarettes. As the National Cancer  
7       Institute has also found, mistaken beliefs about the  
8       health consequences of smoking “low tar” and  
9       “light” cigarettes can reduce the motivation to quit  
10      smoking entirely and thereby lead to disease and  
11      death.

12          (39) Recent studies have demonstrated that  
13      there has been no reduction in risk on a population-  
14      wide basis from “low tar” and “light” cigarettes and  
15      such products may actually increase the risk of to-  
16      bacco use.

17          (40) The dangers of products sold or distrib-  
18      uted as modified risk tobacco products that do not  
19      in fact reduce risk are so high that there is a com-  
20      pelling governmental interest in insuring that state-  
21      ments about modified risk tobacco products are com-  
22      plete, accurate, and relate to the overall disease risk  
23      of the product.

24          (41) As the Federal Trade Commission has  
25      found, consumers have misinterpreted advertise-

1       ments in which one product is claimed to be less  
2       harmful than a comparable product, even in the  
3       presence of disclosures and advisories intended to  
4       provide clarification.

5           (42) Permitting manufacturers to make unsub-  
6       stantiated statements concerning modified risk to-  
7       bacco products, whether express or implied, even if  
8       accompanied by disclaimers would be detrimental to  
9       the public health.

10          (43) The only way to effectively protect the  
11       public health from the dangers of unsubstantiated  
12       modified risk tobacco products is to empower the  
13       Food and Drug Administration to require that prod-  
14       ucts that tobacco manufacturers sold or distributed  
15       for risk reduction be reviewed in advance of mar-  
16       keting, and to require that the evidence relied on to  
17       support claims be fully verified.

18          (44) The Food and Drug Administration is a  
19       regulatory agency with the scientific expertise to  
20       identify harmful substances in products to which  
21       consumers are exposed, to design standards to limit  
22       exposure to those substances, to evaluate scientific  
23       studies supporting claims about the safety of prod-  
24       ucts, and to evaluate the impact of labels, labeling,  
25       and advertising on consumer behavior in order to re-

1       duce the risk of harm and promote understanding of  
2       the impact of the product on health. In connection  
3       with its mandate to promote health and reduce the  
4       risk of harm, the Food and Drug Administration  
5       routinely makes decisions about whether and how  
6       products may be marketed in the United States.

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

19           (46) If manufacturers are permitted to state or  
20      imply in communications directed to consumers that  
21      a tobacco product is approved or inspected by the  
22      Food and Drug Administration or complies with  
23      Food and Drug Administration standards, con-  
24      sumers are likely to be confused and misled. Such a  
25      statement could result in consumers being misled

1 into believing that the product is endorsed by the  
2 Food and Drug Administration for use or in con-  
3 sumers being misled about the harmfulness of the  
4 product because of such regulation, inspection, or  
5 compliance.

6 (47) In August 2006 a United States District  
7 Court judge found that the major United States cig-  
8 arette companies continue to target and market to  
9 youth. *USA v Philip Morris, USA, Inc., et al.* (Civil  
10 Action No. 99-2496 (GK), August 17, 2006).

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

19 (49) In August 2006 a United States District  
20 Court judge found that the major United States cig-  
21 arette companies have designed their cigarettes to  
22 precisely control nicotine delivery levels and provide  
23 doses of nicotine sufficient to create and sustain ad-  
24 diction while also concealing much of their nicotine-  
25 related research. *USA v Philip Morris, USA, Inc., et*

1 al. (Civil Action No. 99–2496 (GK), August 17,  
2 2006).

3 **SEC. 3. PURPOSE.**

4 The purposes of this Act are—

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

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

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

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

1           (5) to vest the Food and Drug Administration  
2           with the authority to regulate the levels of tar, nico-  
3           tine, and other harmful components of tobacco prod-  
4           ucts;

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

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

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

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

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

22 **SEC. 4. SCOPE AND EFFECT.**

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

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

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

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

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

20          **SEC. 5. SEVERABILITY.**

21          If any provision of this Act, the amendments made  
22          by this Act, or the application of any provision of this Act  
23          to any person or circumstance is held to be invalid, the  
24          remainder of this Act, the amendments made by this Act,  
25          and the application of the provisions of this Act to any

1 other person or circumstance shall not be affected and  
2 shall continue to be enforced to the fullest extent possible.

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

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

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

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

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

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

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

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

3 (b) FDA AUTHORITY OVER TOBACCO PRODUCTS.—

4 The Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
5 301 et seq.) is amended—

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

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

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

11 **“CHAPTER IX—TOBACCO PRODUCTS**

12 **“SEC. 900. DEFINITIONS.**

13 “In this chapter:

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

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

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

8                   “(A) means a product that—

9                           “(i) is a tobacco product; and

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

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

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

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

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

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

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

1           “(9) INDIAN 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           “(10) 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           “(11) 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           “(12) 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           “(13) RETAILER.—The term ‘retailer’ means  
21 any person who sells tobacco products to individuals  
22 for personal consumption, or who operates a facility  
23 where self-service displays of tobacco products are  
24 permitted.

1           “(14) 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           “(15) SMOKE CONSTITUENT.—The term ‘smoke  
8           constituent’ means any chemical or chemical com-  
9           pound in mainstream or sidestream tobacco smoke  
10          that either transfers from any component of the cig-  
11          arette to the smoke or that is formed by the combus-  
12          tion or heating of tobacco, additives, or other compo-  
13          nent of the tobacco product.

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

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

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

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

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

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

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

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

19          “(b) APPLICABILITY.—This chapter shall apply to all  
20          cigarettes, cigarette tobacco, and smokeless tobacco and  
21          to any other tobacco products that the Secretary by regu-  
22          lation deems to be subject to this chapter.

23          “(c) SCOPE.—

24                  “(1) IN GENERAL.—Nothing in this chapter, or  
25          any policy issued or regulation promulgated there-

1 under, or in sections 101(a), 102, or 103 of title I,  
2 title II, or title III of the Family Smoking Preven-  
3 tion and Tobacco Control Act, shall be construed to  
4 affect, expand, or limit the Secretary's authority  
5 over (including the authority to determine whether  
6 products may be regulated), or the regulation of,  
7 products under this Act that are not tobacco prod-  
8 ucts under chapter V or any other chapter.

9 “(2) LIMITATION OF AUTHORITY.—

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

20 “(B) EXCEPTION.—Notwithstanding sub-  
21 paragraph (A), if a producer of tobacco leaf is  
22 also a tobacco product manufacturer or con-  
23 trolled by a tobacco product manufacturer, the  
24 producer shall be subject to this chapter in the  
25 producer's capacity as a manufacturer. The ex-

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

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

13          “(d) CENTER FOR TOBACCO PRODUCTS.—Not later  
14          than 90 days after the date of enactment of this chapter,  
15          the Secretary shall establish within the Food and Drug  
16          Administration the Center for Tobacco Products, which  
17          shall report to the Commissioner of Food and Drugs in  
18          the same manner as the other agency centers within the  
19          Food and Drug Administration. The Center shall be re-  
20          sponsible for the implementation of this chapter and re-  
21          lated matters assigned by the Commissioner.

22          “(e) OFFICE TO ASSIST SMALL TOBACCO PRODUCT  
23          MANUFACTURERS.—The Secretary shall establish within  
24          the Food and Drug Administration an identifiable office  
25          to provide technical and other nonfinancial assistance to

1 small tobacco product manufacturers to assist them in  
2 complying with the requirements of this Act.

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

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

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

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

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

18 “(4) the manufacturer or importer of the to-  
19 bacco product fails to pay a user fee assessed to  
20 such manufacturer or importer pursuant to section  
21 920 by the date specified in section 920 or by the  
22 30th day after final agency action on a resolution of  
23 any dispute as to the amount of such fee;

24 “(5) it is, or purports to be or is represented  
25 as, a tobacco product which is subject to a tobacco

1 product standard established under section 907 un-  
2 less such tobacco product is in all respects in con-  
3 formity with such standard;

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

7 “(B) it is in violation of an order under section  
8 910(c)(1)(A);

9 “(7) the methods used in, or the facilities or  
10 controls used for, its manufacture, packing, or stor-  
11 age are not in conformity with applicable require-  
12 ments under section 906(e)(1) or an applicable con-  
13 dition prescribed by an order under section  
14 906(e)(2); or

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

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

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

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

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

23 “(A) the name and place of business of the  
24 tobacco product manufacturer, packer, or dis-  
25 tributor;

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

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

8           “(D) the statement required under section  
9           921(a),  
10          except that under subparagraph (B) reasonable vari-  
11          ations shall be permitted, and exemptions as to  
12          small packages shall be established, by regulations  
13          prescribed by the Secretary;

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

22          “(4) if it has an established name, unless its  
23          label bears, to the exclusion of any other nonpropri-  
24          etary name, its established name prominently print-

1 ed in type as required by the Secretary by regula-  
2 tion;

3 “(5) if the Secretary has issued regulations re-  
4 quiring that its labeling bear adequate directions for  
5 use, or adequate warnings against use by children,  
6 that are necessary for the protection of users unless  
7 its labeling conforms in all respects to such regula-  
8 tions;

9 “(6) if it was manufactured, prepared, propa-  
10 gated, compounded, or processed in an establishment  
11 not duly registered under section 905(b), 905(c),  
12 905(d), or 905(h), if it was not included in a list re-  
13 quired by section 905(i), if a notice or other infor-  
14 mation respecting it was not provided as required by  
15 such section or section 905(j), or if it does not bear  
16 such symbols from the uniform system for identifica-  
17 tion of tobacco products prescribed under section  
18 905(e) as the Secretary by regulation requires;

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

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

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

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

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

11           “(B) a brief statement of—

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

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

1           “(9) if it is a tobacco product subject to a to-  
2           bacco product standard established under section  
3           907, unless it bears such labeling as may be pre-  
4           scribed in such tobacco product standard; or

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

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

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

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

11       The Secretary may, by regulation, require prior approval  
12       of statements made on the label of a tobacco product. No  
13       regulation issued under this subsection may require prior  
14       approval by the Secretary of the content of any advertise-  
15       ment, except for modified risk tobacco products as pro-  
16       vided in section 911. No advertisement of a tobacco prod-  
17       uct published after the date of enactment of the Family  
18       Smoking Prevention and Tobacco Control Act shall, with  
19       respect to the language of label statements as prescribed  
20       under section 4 of the Federal Cigarette Labeling and Ad-  
21       vertising Act and section 3 of the Comprehensive Smoke-  
22       less Tobacco Health Education Act of 1986 or the regula-  
23       tions issued under such sections, be subject to the provi-  
24       sions of sections 12 through 15 of the Federal Trade Com-  
25       mission Act.

1 **“SEC. 904. SUBMISSION OF HEALTH INFORMATION TO THE**  
2 **SECRETARY.**

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

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

14 “(2) A description of the content, delivery, and  
15 form of nicotine in each tobacco product measured  
16 in milligrams of nicotine in accordance with regula-  
17 tions promulgated by the Secretary in accordance  
18 with section 4(e) of the Federal Cigarette Labeling  
19 and Advertising Act.

20 “(3) Beginning 3 years after the date of enact-  
21 ment of this Act, a listing of all constituents, includ-  
22 ing smoke constituents as applicable, identified by  
23 the Secretary as harmful or potentially harmful to  
24 health in each tobacco product, and as applicable in  
25 the smoke of each tobacco product, by brand and by  
26 quantity in each brand and subbrand. Effective be-

1       ginning 3 years after the date of enactment of this  
2       chapter, the manufacturer, importer, or agent shall  
3       comply with regulations promulgated under section  
4       916 in reporting information under this paragraph,  
5       where applicable.

6               “(4) Beginning 6 months after the date of en-  
7       actment of the Family Smoking Prevention and To-  
8       bacco Control Act, all documents developed after the  
9       date of enactment of the Family Smoking Preven-  
10      tion and Tobacco Control Act that relate to health,  
11      toxicological, behavioral, or physiologic effects of  
12      current or future tobacco products, their constitu-  
13      ents (including smoke constituents), ingredients,  
14      components, and additives.

15              “(b) DATA SUBMISSION.—At the request of the Sec-  
16      retary, each tobacco product manufacturer or importer of  
17      tobacco products, or agents thereof, shall submit the fol-  
18      lowing:

19              “(1) Any or all documents (including under-  
20      lying scientific information) relating to research ac-  
21      tivities, and research findings, conducted, supported,  
22      or possessed by the manufacturer (or agents thereof)  
23      on the health, toxicological, behavioral, or physio-  
24      logic effects of tobacco products and their constitu-

1       ents (including smoke constituents), ingredients,  
2       components, and additives.

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

11          “(3) Any or all documents (including under-  
12      lying scientific or financial information) relating to  
13      marketing research involving the use of tobacco  
14      products or marketing practices and the effective-  
15      ness of such practices used by tobacco manufactur-  
16      ers and distributors.

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

20       “(c) TIME FOR SUBMISSION.—

21           “(1) IN GENERAL.—At least 90 days prior to  
22      the delivery for introduction into interstate com-  
23      merce of a tobacco product not on the market on the  
24      date of enactment of the Family Smoking Preven-  
25      tion and Tobacco Control Act, the manufacturer of

1 such product shall provide the information required  
2 under subsection (a).

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

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

19 “(d) DATA LIST.—

20 “(1) IN GENERAL.—Not later than 3 years  
21 after the date of enactment of the Family Smoking  
22 Prevention and Tobacco Control Act, and annually  
23 thereafter, the Secretary shall publish in a format  
24 that is understandable and not misleading to a lay  
25 person, and place on public display (in a manner de-

1       terminated by the Secretary) the list established under  
2       subsection (e).

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

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

24      **“SEC. 905. ANNUAL REGISTRATION.**

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

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

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

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

1           “(c) REGISTRATION OF NEW OWNERS AND OPERA-  
2 TORS.—Every person upon first engaging in the manufac-  
3 ture, preparation, compounding, or processing of a tobacco  
4 product or tobacco products in any establishment owned  
5 or operated in any State by that person shall immediately  
6 register with the Secretary that person’s name, place of  
7 business, and such establishment.

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

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

21           “(f) PUBLIC ACCESS TO REGISTRATION INFORMA-  
22 TION.—The Secretary shall make available for inspection,  
23 to any person so requesting, any registration filed under  
24 this section.

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

12           “(h) FOREIGN ESTABLISHMENTS SHALL REG-  
13 ISTER.—Any establishment within any foreign country en-  
14 gaged in the manufacture, preparation, compounding, or  
15 processing of a tobacco product or tobacco products, shall  
16 register under this section under regulations promulgated  
17 by the Secretary. Such regulations shall require such es-  
18 tablishment to provide the information required by sub-  
19 section (i) and shall include provisions for registration of  
20 any such establishment upon condition that adequate and  
21 effective means are available, by arrangement with the  
22 government of such foreign country or otherwise, to enable  
23 the Secretary to determine from time to time whether to-  
24 bacco products manufactured, prepared, compounded, or  
25 processed in such establishment, if imported or offered for

1 import into the United States, shall be refused admission  
2 on any of the grounds set forth in section 801(a).

3 “(i) REGISTRATION INFORMATION.—

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

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

24 “(B) in the case of any other tobacco prod-  
25 uct contained in an applicable list, a copy of all

1 consumer information and other labeling for  
2 such tobacco product, a representative sampling  
3 of advertisements for such tobacco product,  
4 and, upon request made by the Secretary for  
5 good cause, a copy of all advertisements for a  
6 particular tobacco product; and

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

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

22 “(3) BIENNIAL REPORT OF ANY CHANGE IN  
23 PRODUCT LIST.—Each person who registers with the  
24 Secretary under this section shall report to the Sec-  
25 retary once during the month of June of each year

1 and once during the month of December of each  
2 year the following:

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

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

21 “(C) If since the date the registrant re-  
22 ported under subparagraph (B) a notice of dis-  
23 continuance that person has resumed the manu-  
24 facture, preparation, compounding, or proc-  
25 essing for commercial distribution of the to-

1           bacco product with respect to which such notice  
2           of discontinuance was reported, notice of such  
3           resumption, the date of such resumption, the  
4           identity of such tobacco product by established  
5           name, and other information required by para-  
6           graph (1), unless the registrant has previously  
7           reported such resumption to the Secretary  
8           under this subparagraph.

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

12          “(j) REPORT PRECEDING INTRODUCTION OF CER-  
13          TAIN SUBSTANTIALLY-EQUIVALENT PRODUCTS INTO  
14          INTERSTATE COMMERCE.—

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

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

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

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

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

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

11          “(3) EXEMPTIONS.—

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

21                         “(i) such modification would be a  
22                         minor modification of a tobacco product  
23                         that can be sold under this Act;

24                         “(ii) a report under this subsection is  
25                         not necessary to ensure that permitting the

1 tobacco product to be marketed would be  
2 appropriate for protection of the public  
3 health; and

4 “(iii) an exemption is otherwise appro-  
5 priate.

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

11 **“SEC. 906. GENERAL PROVISIONS RESPECTING CONTROL**  
12 **OF TOBACCO PRODUCTS.**

13 “(a) IN GENERAL.—Any requirement established by  
14 or under section 902, 903, 905, or 909 applicable to a  
15 tobacco product shall apply to such tobacco product until  
16 the applicability of the requirement to the tobacco product  
17 has been changed by action taken under section 907, sec-  
18 tion 910, section 911, or subsection (d) of this section,  
19 and any requirement established by or under section 902,  
20 903, 905, or 909 which is inconsistent with a requirement  
21 imposed on such tobacco product under section 907, sec-  
22 tion 910, section 911, or subsection (d) of this section  
23 shall not apply to such tobacco product.

24 “(b) INFORMATION ON PUBLIC ACCESS AND COM-  
25 MENT.—Each notice of proposed rulemaking or other noti-

1 fication under section 907, 908, 909, 910, or 911 or under  
2 this section, any other notice which is published in the  
3 Federal Register with respect to any other action taken  
4 under any such section and which states the reasons for  
5 such action, and each publication of findings required to  
6 be made in connection with rulemaking under any such  
7 section shall set forth—

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

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

18          “(c) LIMITED CONFIDENTIALITY OF INFORMA-  
19          TION.—Any information reported to or otherwise obtained  
20          by the Secretary or the Secretary’s representative under  
21          section 903, 904, 907, 908, 909, 910, 911, or 704, or  
22          under subsection (e) or (f) of this section, which is exempt  
23          from disclosure under subsection (a) of section 552 of title  
24          5, United States Code, by reason of subsection (b)(4) of  
25          that section shall be considered confidential and shall not

1 be disclosed, except that the information may be disclosed  
2 to other officers or employees concerned with carrying out  
3 this chapter, or when relevant in any proceeding under  
4 this chapter.

5 “(d) RESTRICTIONS.—

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

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

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

4           No such regulation may require that the sale or dis-  
5           tribution of a tobacco product be limited to the writ-  
6           ten or oral authorization of a practitioner licensed  
7           by law to prescribe medical products.

8           “(2) LABEL STATEMENTS.—The label of a to-  
9           bacco product shall bear such appropriate state-  
10          ments of the restrictions required by a regulation  
11          under subsection (a) as the Secretary may in such  
12          regulation prescribe.

13          “(3) LIMITATIONS.—

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

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

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

22                 “(B) MATCHBOOKS.—For purposes of any  
23                 regulations issued by the Secretary, matchbooks  
24                 of conventional size containing not more than  
25                 20 paper matches, and which are customarily

1 given away for free with the purchase of to-  
2 bacco products shall be considered as adult  
3 written publications which shall be permitted to  
4 contain advertising. Notwithstanding the pre-  
5 ceeding sentence, if the Secretary finds that such  
6 treatment of matchbooks is not appropriate for  
7 the protection of the public health, the Sec-  
8 retary may determine by regulation that match-  
9 books shall not be considered adult written pub-  
10 lications.

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

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

15 “(A) IN GENERAL.—The Secretary may, in  
16 accordance with subparagraph (B), prescribe  
17 regulations (which may differ based on the type  
18 of tobacco product involved) requiring that the  
19 methods used in, and the facilities and controls  
20 used for, the manufacture, pre-production de-  
21 sign validation (including a process to assess  
22 the performance of a tobacco product), packing  
23 and storage of a tobacco product, conform to  
24 current good manufacturing practice, as pre-  
25 scribed in such regulations, to assure that the

1 public health is protected and that the tobacco  
2 product is in compliance with this chapter.  
3 Good manufacturing practices may include the  
4 testing of raw tobacco for pesticide chemical  
5 residues regardless of whether a tolerance for  
6 such chemical residues has been established.

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

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

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

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

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

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

10                   “(2) EXEMPTIONS; VARIANCES.—

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

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

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

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

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

21                 “(i) the date the petition was sub-  
22                 mitted to the Secretary under subpara-  
23                 graph (A); or

1                   “(ii) the day after the petition was re-  
2                   ferred to the Tobacco Products Scientific  
3                   Advisory Committee,  
4                   whichever occurs later, the Secretary shall by  
5                   order either deny the petition or approve it.

6                   “(C) APPROVAL.—The Secretary may ap-  
7                   prove—

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

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

24                  “(D) CONDITIONS.—An order of the Sec-  
25                  retary approving a petition for a variance shall

1           prescribe such conditions respecting the meth-  
2           ods used in, and the facilities and controls used  
3           for, the manufacture, packing, and storage of  
4           the tobacco product to be granted the variance  
5           under the petition as may be necessary to as-  
6           sure that the tobacco product will be in compli-  
7           ance with this chapter.

8           “(E) HEARING.—After the issuance of an  
9           order under subparagraph (B) respecting a pe-  
10          tition, the petitioner shall have an opportunity  
11          for an informal hearing on such order.

12          “(3) COMPLIANCE.—Compliance with require-  
13          ments under this subsection shall not be required be-  
14          fore the period ending—

15                 “(A) for small tobacco product manufac-  
16                 turers, 4 years after the date of enactment of  
17                 the Family Smoking Prevention and Tobacco  
18                 Control Act; and

19                 “(B) for other persons, 3 years after such  
20                 date of enactment.

21          “(f) RESEARCH AND DEVELOPMENT.—The Secretary  
22          may enter into contracts for research, testing, and dem-  
23          onstrations respecting tobacco products and may obtain  
24          tobacco products for research, testing, and demonstration  
25          purposes without regard to section 3324(a) and (b) of title

1 31, United States Code, and section 5 of title 41, United  
2 States Code.

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

4 “(a) IN GENERAL.—

5 “(1) SPECIAL RULE FOR CIGARETTES.—Begin-  
6 ning 3 months after the date of enactment of the  
7 Family Smoking Prevention and Tobacco Control  
8 Act, a cigarette or any of its component parts (in-  
9 cluding the tobacco, filter, or paper) shall not con-  
10 tain, as a constituent (including a smoke con-  
11 stituent) or additive, an artificial or natural flavor  
12 (other than tobacco or menthol) or an herb or spice,  
13 including strawberry, grape, orange, clove, cin-  
14 namon, pineapple, vanilla, coconut, licorice, cocoa,  
15 chocolate, cherry, or coffee, that is a characterizing  
16 flavor of the tobacco product or tobacco smoke.  
17 Nothing in this paragraph shall be construed to limit  
18 the Secretary’s authority to take action under this  
19 section or other sections of this Act applicable to  
20 menthol or any artificial or natural flavor, herb, or  
21 spice not specified in this paragraph.

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

1           “(3) TOBACCO PRODUCT STANDARDS.—

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

7           “(B) DETERMINATIONS.—

8           “(i) CONSIDERATIONS.—The finding  
9           described in subparagraph (A) shall be de-  
10          termined with respect to the risks and ben-  
11          efits to the population as a whole, includ-  
12          ing users and non-users of the tobacco  
13          product. In making such a finding, the  
14          Secretary shall consider scientific evidence  
15          concerning—

16                   “(I) the population impact of any  
17                   proposed standard;

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

22                   “(III) the increased or decreased  
23                   likelihood that those who do not use  
24                   tobacco products will start using such  
25                   products.

1                   “(ii) BURDEN.—Upon a determina-  
2                   tion by the Secretary that an additive, con-  
3                   stituent (including a smoke constituent), or  
4                   other component of the product that is the  
5                   subject of the proposed tobacco product  
6                   standard is harmful, it shall be the burden  
7                   of any party objecting to the proposed  
8                   standard to prove that the proposed stand-  
9                   ard will not reduce or eliminate the risk of  
10                  illness or injury.

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

14                  “(A) shall include provisions that are ap-  
15                  propriate for the protection of the public health,  
16                  including provisions, where appropriate—

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

18                  “(ii) for the reduction or elimination  
19                  of other constituents, including smoke con-  
20                  stituents, or harmful components of the  
21                  product; or

22                  “(iii) relating to any other require-  
23                  ment under subparagraph (B);

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

1           “(i) provisions respecting the con-  
2           struction, components, ingredients, addi-  
3           tives, constituents, including smoke con-  
4           stituents, and properties of the tobacco  
5           product;

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

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

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

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

1           “(C) shall, where appropriate, require the  
2           use and prescribe the form and content of label-  
3           ing for the proper use of the tobacco product.

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

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

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

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

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

1 cultural, or consumer organizations who in the  
2 Secretary's judgment can make a significant  
3 contribution.

4 “(b) ESTABLISHMENT OF STANDARDS.—

5 “(1) NOTICE.—

6 “(A) IN GENERAL.—The Secretary shall  
7 publish in the Federal Register a notice of pro-  
8 posed rulemaking for the establishment, amend-  
9 ment, or revocation of any tobacco product  
10 standard.

11 “(B) REQUIREMENTS OF NOTICE.—A no-  
12 tice of proposed rulemaking for the establish-  
13 ment or amendment of a tobacco product stand-  
14 ard for a tobacco product shall—

15 “(i) set forth a finding with sup-  
16 porting justification that the tobacco prod-  
17 uct standard is appropriate for the protec-  
18 tion of the public health;

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

23 “(iii) invite interested persons to sub-  
24 mit a draft or proposed tobacco product

1 standard for consideration by the Sec-  
2 retary.

3 “(C) FINDING.—A notice of proposed rule-  
4 making for the revocation of a tobacco product  
5 standard shall set forth a finding with sup-  
6 porting justification that the tobacco product  
7 standard is no longer appropriate for the pro-  
8 tection of the public health.

9 “(D) CONSIDERATION BY SECRETARY.—  
10 The Secretary shall consider all information  
11 submitted in connection with a proposed stand-  
12 ard, including information concerning the coun-  
13 tervailing effects of the tobacco product stand-  
14 ard on the health of adolescent tobacco users,  
15 adult tobacco users, or non-tobacco users, such  
16 as the creation of a significant demand for con-  
17 traband or other tobacco products that do not  
18 meet the requirements of this chapter and the  
19 significance of such demand, and shall issue the  
20 standard if the Secretary determines that the  
21 standard would be appropriate for the protec-  
22 tion of the public health.

23 “(E) COMMENT.—The Secretary shall pro-  
24 vide for a comment period of not less than 60  
25 days.

1           “(2) PROMULGATION.—

2                   “(A) IN GENERAL.—After the expiration of  
3 the period for comment on a notice of proposed  
4 rulemaking published under paragraph (1) re-  
5 specting a tobacco product standard and after  
6 consideration of such comments and any report  
7 from the Tobacco Products Scientific Advisory  
8 Committee, the Secretary shall—

9                   “(i) promulgate a regulation estab-  
10 lishing a tobacco product standard and  
11 publish in the Federal Register findings on  
12 the matters referred to in paragraph (1);  
13 or

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

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

1           dates shall be established so as to minimize,  
2           consistent with the public health, economic loss  
3           to, and disruption or dislocation of, domestic  
4           and international trade.

5           “(3) LIMITATION ON POWER GRANTED TO THE  
6           FOOD AND DRUG ADMINISTRATION.—Because of the  
7           importance of a decision of the Secretary to issue a  
8           regulation—

9                   “(A) banning all cigarettes, all smokeless  
10           tobacco products, all little cigars, all cigars  
11           other than little cigars, all pipe tobacco, or all  
12           roll-your-own tobacco products; or

13                   “(B) requiring the reduction of nicotine  
14           yields of a tobacco product to zero,  
15           the Secretary is prohibited from taking such actions  
16           under this Act.

17           “(4) AMENDMENT; REVOCATION.—

18                   “(A) AUTHORITY.—The Secretary, upon  
19           the Secretary’s own initiative or upon petition  
20           of an interested person may by a regulation,  
21           promulgated in accordance with the require-  
22           ments of paragraphs (1) and (2)(B), amend or  
23           revoke a tobacco product standard.

24                   “(B) EFFECTIVE DATE.—The Secretary  
25           may declare a proposed amendment of a to-

1           bacco product standard to be effective on and  
2           after its publication in the Federal Register and  
3           until the effective date of any final action taken  
4           on such amendment if the Secretary determines  
5           that making it so effective is in the public inter-  
6           est.

7           “(5) REFERRAL TO ADVISORY COMMITTEE.—

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

16                   “(B) INITIATION OF REFERRAL.—The Sec-  
17          retary may make a referral under this para-  
18          graph—

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

20                           or

21                           “(ii) upon the request of an interested  
22          person that—

23                                   “(I) demonstrates good cause for  
24          the referral; and

1                   “(II) is made before the expira-  
2                   tion of the period for submission of  
3                   comments on the proposed regulation.

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

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

21                  “(E) PUBLIC AVAILABILITY.—The Sec-  
22                  retary shall make a copy of each report and rec-  
23                  ommendation under subparagraph (D) publicly  
24                  available.

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

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

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

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

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

23 “(b) NO EXEMPTION FROM OTHER LIABILITY.—  
24 Compliance with an order issued under this section shall  
25 not relieve any person from liability under Federal or  
26 State law. In awarding damages for economic loss in an

1 action brought for the enforcement of any such liability,  
2 the value to the plaintiff in such action of any remedy  
3 provided under such order shall be taken into account.

4 “(c) RECALL AUTHORITY.—

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

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

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

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

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

19                 “(ii) shall provide for notice to per-  
20                 sons subject to the risks associated with  
21                 the use of such tobacco product.

22          In providing the notice required by clause (ii),  
23          the Secretary may use the assistance of retail-  
24          ers and other persons who distributed such to-  
25          bacco product. If a significant number of such

1 persons cannot be identified, the Secretary shall  
2 notify such persons under section 705(b).

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

6 **“SEC. 909. RECORDS AND REPORTS ON TOBACCO PROD-**  
7 **UCTS.**

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

16 “(1) may require a tobacco product manufac-  
17 turer or importer to report to the Secretary when-  
18 ever the manufacturer or importer receives or other-  
19 wise becomes aware of information that reasonably  
20 suggests that one of its marketed tobacco products  
21 may have caused or contributed to a serious unex-  
22 pected adverse experience associated with the use of  
23 the product or any significant increase in the fre-  
24 quency of a serious, expected adverse product experi-  
25 ence;

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

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

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

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

22          “(6) may not require that the identity of any  
23          patient or user be disclosed in records, reports, or  
24          information required under this subsection unless re-  
25          quired for the medical welfare of an individual, to

1 determine risks to public health of a tobacco prod-  
2 uct, or to verify a record, report, or information sub-  
3 mitted under this chapter.

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

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

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

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

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

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

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

11 **“SEC. 910. APPLICATION FOR REVIEW OF CERTAIN TO-  
12 BACCO PRODUCTS.**

13 “(a) IN GENERAL.—

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

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

21 “(B) any modification (including a change  
22 in design, any component, any part, or any con-  
23 stituent, including a smoke constituent, or in  
24 the content, delivery or form of nicotine, or any  
25 other additive or ingredient) of a tobacco prod-

1           uct where the modified product was commer-  
2           cially marketed in the United States after Feb-  
3           ruary 15, 2007.

4           “(2) PREMARKET REVIEW REQUIRED.—

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

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

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

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

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

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

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

9           “(ii) for which a report was submitted  
10          under section 905(j) within such 21-month  
11          period,

12          except that subparagraph (A) shall apply to the  
13          tobacco product if the Secretary issues an order  
14          that the tobacco product is not substantially  
15          equivalent.

16          “(3) SUBSTANTIALLY EQUIVALENT DEFINED.—

17                 “(A) IN GENERAL.—In this section and  
18                 section 905(j), the terms ‘substantially equiva-  
19                 lent’ or ‘substantial equivalence’ mean, with re-  
20                 spect to the tobacco product being compared to  
21                 the predicate tobacco product, that the Sec-  
22                 retary by order has found that the tobacco  
23                 product—

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

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

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

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

20          “(4) HEALTH INFORMATION.—

21          “(A) SUMMARY.—As part of a submission  
22          under section 905(j) respecting a tobacco prod-  
23          uct, the person required to file a premarket no-  
24          tification under such section shall provide an  
25          adequate summary of any health information

1 related to the tobacco product or state that  
2 such information will be made available upon  
3 request by any person.

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

13 “(b) APPLICATION.—

14 “(1) CONTENTS.—An application under this  
15 section shall contain—

16 “(A) full reports of all information, pub-  
17 lished or known to, or which should reasonably  
18 be known to, the applicant, concerning inves-  
19 tigation which have been made to show the  
20 health risks of such tobacco product and wheth-  
21 er such tobacco product presents less risk than  
22 other tobacco products;

23 “(B) a full statement of the components,  
24 ingredients, additives, and properties, and of

1 the principle or principles of operation, of such  
2 tobacco product;

3 “(C) a full description of the methods used  
4 in, and the facilities and controls used for, the  
5 manufacture, processing, and, when relevant,  
6 packing and installation of, such tobacco prod-  
7 uct;

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

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

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

21 “(G) such other information relevant to  
22 the subject matter of the application as the Sec-  
23 retary may require.

24 “(2) REFERRAL TO TOBACCO PRODUCTS SCI-  
25 ENTIFIC ADVISORY COMMITTEE.—Upon receipt of an

1 application meeting the requirements set forth in  
2 paragraph (1), the Secretary—

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

5 “(B) may, upon the request of an appli-  
6 cant,

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

13 “(c) ACTION ON APPLICATION.—

14 “(1) DEADLINE.—

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

21 “(i) issue an order that the new prod-  
22 uct may be introduced or delivered for in-  
23 troduction into interstate commerce if the  
24 Secretary finds that none of the grounds

1 specified in paragraph (2) of this sub-  
2 section applies; or

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

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

18 “(2) DENIAL OF APPLICATION.—The Secretary  
19 shall deny an application submitted under subsection  
20 (b) if, upon the basis of the information submitted  
21 to the Secretary as part of the application and any  
22 other information before the Secretary with respect  
23 to such tobacco product, the Secretary finds that—

24 “(A) there is a lack of a showing that per-  
25 mitting such tobacco product to be marketed

1 would be appropriate for the protection of the  
2 public health;

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

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

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

16 “(3) DENIAL INFORMATION.—Any denial of an  
17 application shall, insofar as the Secretary determines  
18 to be practicable, be accompanied by a statement in-  
19 forming the applicant of the measures required to  
20 remove such application from deniable form (which  
21 measures may include further research by the appli-  
22 cant in accordance with 1 or more protocols pre-  
23 scribed by the Secretary).

24 “(4) BASIS FOR FINDING.—For purposes of  
25 this section, the finding as to whether the marketing

1 of a tobacco product for which an application has  
2 been submitted is appropriate for the protection of  
3 the public health shall be determined with respect to  
4 the risks and benefits to the population as a whole,  
5 including users and nonusers of the tobacco product,  
6 and taking into account—

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

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

13 “(5) BASIS FOR ACTION.—

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

23 “(B) OTHER EVIDENCE.—If the Secretary  
24 determines that there exists valid scientific evi-  
25 dence (other than evidence derived from inves-

1           tigations described in subparagraph (A)) which  
2           is sufficient to evaluate the tobacco product the  
3           Secretary may authorize that the determination  
4           for purposes of paragraph (2)(A) be made on  
5           the basis of such evidence.

6           “(d) WITHDRAWAL AND TEMPORARY SUSPENSION.—

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

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

18                 “(B) that the application contained or was  
19                 accompanied by an untrue statement of a mate-  
20                 rial fact;

21                 “(C) that the applicant—

22                         “(i) has failed to establish a system  
23                         for maintaining records, or has repeatedly  
24                         or deliberately failed to maintain records

1 or to make reports, required by an applica-  
2 ble regulation under section 909;

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

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

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

20 “(E) on the basis of new information be-  
21 fore the Secretary, evaluated together with the  
22 evidence before the Secretary when the applica-  
23 tion was reviewed, that the labeling of such to-  
24 bacco product, based on a fair evaluation of all  
25 material facts, is false or misleading in any par-

1            ticular and was not corrected within a reason-  
2            able time after receipt of written notice from  
3            the Secretary of such fact; or

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

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

22           “(3) TEMPORARY SUSPENSION.—If, after pro-  
23           viding an opportunity for an informal hearing, the  
24           Secretary determines there is reasonable probability  
25           that the continuation of distribution of a tobacco

1 product under an order would cause serious, adverse  
2 health consequences or death, that is greater than  
3 ordinarily caused by tobacco products on the market,  
4 the Secretary shall by order temporarily suspend the  
5 authority of the manufacturer to market the prod-  
6 uct. If the Secretary issues such an order, the Sec-  
7 retary shall proceed expeditiously under paragraph  
8 (1) to withdraw such application.

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

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

13 “(2) by mailing the order by registered mail or  
14 certified mail addressed to the applicant at the ap-  
15 plicant’s last known address in the records of the  
16 Secretary.

17 “(f) RECORDS.—

18 “(1) ADDITIONAL INFORMATION.—In the case  
19 of any tobacco product for which an order issued  
20 pursuant to subsection (c)(1)(A)(i) for an applica-  
21 tion filed under subsection (b) is in effect, the appli-  
22 cant shall establish and maintain such records, and  
23 make such reports to the Secretary, as the Secretary  
24 may by regulation, or by order with respect to such  
25 application, prescribe on the basis of a finding that

1 such records and reports are necessary in order to  
2 enable the Secretary to determine, or facilitate a de-  
3 termination of, whether there is or may be grounds  
4 for withdrawing or temporarily suspending such  
5 order.

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

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

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

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

23 “(b) DEFINITIONS.—In this section:

24 “(1) MODIFIED RISK TOBACCO PRODUCT.—The  
25 term ‘modified risk tobacco product’ means any to-

1       bacco product that is sold or distributed for use to  
2       reduce harm or the risk of tobacco-related disease  
3       associated with commercially marketed tobacco prod-  
4       ucts.

5               “(2) SOLD OR DISTRIBUTED.—

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

12                               “(i) the label, labeling, or advertising  
13                               of which represents explicitly or implicitly  
14                               that—

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

20   “(II) the tobacco product or its  
21   smoke contains a reduced level of a  
22   substance or presents a reduced expo-  
23   sure to a substance; or

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

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

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

23                  “(B) LIMITATION.—No tobacco product  
24                  shall be considered to be ‘sold or distributed for  
25                  use to reduce harm or the risk of tobacco-re-

1           lated disease associated with commercially mar-  
2           keted tobacco products’, except as described in  
3           subparagraph (A).

4                   “(C) SMOKELESS TOBACCO PRODUCT.—No  
5           smokeless tobacco product shall be considered  
6           to be ‘sold or distributed for use to reduce harm  
7           or the risk of tobacco-related disease associated  
8           with commercially marketed tobacco products’  
9           solely because its label, labeling, or advertising  
10          uses the following phrases to describe such  
11          product and its use: ‘smokeless tobacco’,  
12          ‘smokeless tobacco product’, ‘not consumed by  
13          smoking’, or ‘does not produce smoke’.

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

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

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

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

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

13           “(3) the formulation of the product;

14           “(4) sample product labels and labeling;

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

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

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

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

11          “(f) ADVISORY COMMITTEE.—

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

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

21          “(g) MARKETING.—

22           “(1) MODIFIED RISK PRODUCTS.—Except as  
23           provided in paragraph (2), the Secretary shall ,with  
24           respect to an application submitted under this sec-  
25           tion, issue an order that a modified risk product

1       may be commercially marketed only if the Secretary  
2       determines that the applicant has demonstrated that  
3       such product, as it is actually used by consumers,  
4       will—

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

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

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

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

23                       “(i) such order would be appropriate  
24                       to promote the public health;

1           “(ii) any aspect of the label, labeling,  
2           and advertising for such product that  
3           would cause the tobacco product to be a  
4           modified risk tobacco product under sub-  
5           section (b) is limited to an explicit or im-  
6           plicit representation that such tobacco  
7           product or its smoke does not contain or is  
8           free of a substance or contains a reduced  
9           level of a substance, or presents a reduced  
10          exposure to a substance in tobacco smoke;

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

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

24          “(B) ADDITIONAL FINDINGS REQUIRED.—

25          To issue an order under subparagraph (A) the

1 Secretary must also find that the applicant has  
2 demonstrated that—

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

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

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

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

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

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

13                  “(C) CONDITIONS OF MARKETING.—

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

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

1 results of such surveillance and studies to  
2 determine the impact of the order on con-  
3 sumer perception, behavior, and health and  
4 to enable the Secretary to review the accu-  
5 racy of the determinations upon which the  
6 order was based in accordance with a pro-  
7 tocol approved by the Secretary.

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

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

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

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

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

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

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

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

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

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

18          “(h) ADDITIONAL CONDITIONS FOR MARKETING.—

19                 “(1) MODIFIED RISK PRODUCTS.—The Sec-  
20                 retary shall require for the marketing of a product  
21                 under this section that any advertising or labeling  
22                 concerning modified risk products enable the public  
23                 to comprehend the information concerning modified  
24                 risk and to understand the relative significance of  
25                 such information in the context of total health and

1 in relation to all of the diseases and health-related  
2 conditions associated with the use of tobacco prod-  
3 ucts.

4 “(2) COMPARATIVE CLAIMS.—

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

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

23 “(3) LABEL DISCLOSURE.—

24 “(A) IN GENERAL.—The Secretary may re-  
25 quire the disclosure on the label of other sub-

1 stances in the tobacco product, or substances  
2 that may be produced by the consumption of  
3 that tobacco product, that may affect a disease  
4 or health-related condition or may increase the  
5 risk of other diseases or health-related condi-  
6 tions associated with the use of tobacco prod-  
7 ucts.

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

13 “(4) TIME.—An order issued under subsection  
14 (g)(1) shall be effective for a specified period of  
15 time.

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

21 “(i) POSTMARKET SURVEILLANCE AND STUDIES.—

22 “(1) IN GENERAL.—The Secretary shall re-  
23 quire, with respect to a product for which an appli-  
24 cant obtained an order under subsection (g)(1), that  
25 the applicant conduct postmarket surveillance and

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

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

1           “(j) WITHDRAWAL OF AUTHORIZATION.—The Sec-  
2 retary, after an opportunity for an informal hearing, shall  
3 withdraw an order under subsection (g) if the Secretary  
4 determines that—

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

10           “(2) the application failed to include material  
11 information or included any untrue statement of ma-  
12 terial fact;

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

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

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

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

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

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

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

9           “(l) IMPLEMENTING REGULATIONS OR GUIDANCE.—

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

18           “(A) to the extent that adequate scientific  
19 evidence exists, establish minimum standards  
20 for scientific studies needed prior to issuing an  
21 order under subsection (g) to show that a sub-  
22 stantial reduction in morbidity or mortality  
23 among individual tobacco users occurs for prod-  
24 ucts described in subsection (g)(1) or is reason-

1 ably likely for products described in subsection  
2 (g)(2);

3 “(B) include validated biomarkers, inter-  
4 mediate clinical endpoints, and other feasible  
5 outcome measures, as appropriate;

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

13 “(D) establish minimum standards for re-  
14 quired postmarket surveillance, including ongo-  
15 ing assessments of consumer perception; and

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

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

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

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

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

23          **“SEC. 912. JUDICIAL REVIEW.**

24          “(a) RIGHT TO REVIEW.—

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

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

6           “(B) a denial of an application under sec-  
7 tion 910(e),

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

14           “(2) REQUIREMENTS.—

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

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

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

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

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

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

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

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

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

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

21                  “(b) STANDARD OF REVIEW.—Upon the filing of the  
22                  petition under subsection (a) for judicial review of a regu-  
23                  lation or order, the court shall have jurisdiction to review  
24                  the regulation or order in accordance with chapter 7 of  
25                  title 5, United States Code, and to grant appropriate re-

1 lief, including interim relief, as provided for in such chap-  
2 ter. A regulation or denial described in subsection (a) shall  
3 be reviewed in accordance with section 706(2)(A) of title  
4 5, United States Code.

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

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

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

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

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

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

3 “(a) JURISDICTION.—

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

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

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

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

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

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

6 **“SEC. 915. CONGRESSIONAL REVIEW PROVISIONS.**

7 “In accordance with section 801 of title 5, United  
8 States Code, Congress shall review, and may disapprove,  
9 any rule under this chapter that is subject to section 801.  
10 This section and section 801 do not apply to the final rule  
11 referred to in paragraphs (1) and (2) of section 102(a)  
12 of the Family Smoking Prevention and Tobacco Control  
13 Act.

14 **“SEC. 916. REGULATION REQUIREMENT.**

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

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

23 “(1) shall require testing and reporting of to-  
24 bacco product constituents, ingredients, and addi-  
25 tives, including smoke constituents, by brand and

1 sub-brand that the Secretary determines should be  
2 tested to protect the public health; and

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

14 “(c) **AUTHORITY.**—The Commissioner of Food and  
15 Drugs shall have the authority under this chapter to con-  
16 duct or to require the testing, reporting, or disclosure of  
17 tobacco product constituents, including smoke constitu-  
18 ents.

19 **“SEC. 917. PRESERVATION OF STATE AND LOCAL AUTHOR-**  
20 **ITY.**

21 “(a) **IN GENERAL.**—

22 “(1) **PRESERVATION.**—Except as provided in  
23 paragraph (2)(A), nothing in this chapter, or rules  
24 promulgated under this chapter, shall be construed  
25 to limit the authority of a Federal agency (including

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

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

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

1 turing standards, or modified risk tobacco prod-  
2 ucts.

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

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

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

22 “(a) ESTABLISHMENT.—Not later than 1 year after  
23 the date of enactment of the Family Smoking Prevention  
24 and Tobacco Control Act, the Secretary shall establish a  
25 12-member advisory committee, to be known as the ‘To-

1 tobacco Products Scientific Advisory Committee’ (in this  
2 section referred to as the ‘Advisory Committee’).

3 “(b) MEMBERSHIP.—

4 “(1) IN GENERAL.—

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

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

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

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

1           “(iv) 1 individual as a representative  
2 of the interests of the tobacco manufac-  
3 turing industry;

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

13           “(vi) 1 individual as a representative  
14 of the interests of the tobacco growers.

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

21           “(C) CONFLICTS OF INTEREST.—No mem-  
22 bers of the committee, other than members ap-  
23 pointed pursuant to clauses (iv), (v), and (vi) of  
24 subparagraph (A) shall, during the member’s  
25 tenure on the committee or for the 18-month

1 period prior to becoming such a member, re-  
2 ceive any salary, grants, or other payments or  
3 support from any business that manufactures,  
4 distributes, markets, or sells cigarettes or other  
5 tobacco products.

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

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

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

19 “(1) as provided in this chapter;

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

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

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

4           “(d) COMPENSATION; SUPPORT; FACa.—

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

21           “(2) ADMINISTRATIVE SUPPORT.—The Sec-  
22 retary shall furnish the Advisory Committee clerical  
23 and other assistance.



1 “(b) REPORT ON INNOVATIVE PRODUCTS.—

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

17 “(A) total abstinence from tobacco use;

18 “(B) reductions in consumption of tobacco;

19 and

20 “(C) reductions in the harm associated  
21 with continued tobacco use.

22 “(2) RECOMMENDATIONS.—The report under  
23 paragraph (1) shall include the recommendations of  
24 the Secretary on how the Food and Drug Adminis-  
25 tration should coordinate and facilitate the exchange

1 of information on such innovative products and  
2 treatments among relevant offices and centers within  
3 the Administration and within the National Insti-  
4 tutes of Health, the Centers for Disease Control and  
5 Prevention, and other relevant agencies.

6 **“SEC. 920. USER FEE.**

7 “(a) ESTABLISHMENT OF QUARTERLY USER FEE.—  
8 The Secretary shall assess a quarterly user fee with re-  
9 spect to every quarter of each fiscal year commencing fis-  
10 cal year 2008, calculated in accordance with this section,  
11 upon each manufacturer and importer of tobacco products  
12 subject to this chapter.

13 “(b) FUNDING OF FDA REGULATION OF TOBACCO  
14 PRODUCTS.—

15 “(1) IN GENERAL.—The Secretary shall make  
16 all user fees collected pursuant to subsection  
17 (c)(1)(A) available solely to pay, in each fiscal year  
18 beginning with fiscal year 2008, for the costs of the  
19 activities of the Food and Drug Administration re-  
20 lated to the regulation of tobacco products under  
21 this chapter and the Family Smoking Prevention  
22 and Tobacco Control Act. No fees collected pursuant  
23 to subsection (c)(1)(A) may be used for any other  
24 costs.

1           “(2) AVAILABILITY.—Fees collected pursuant  
2 to subsection (c)(1)(A) shall be available to the Sec-  
3 retary without further appropriation only for the  
4 costs of the activities described in paragraph (1) and  
5 shall remain available until expended.

6           “(3) OFFSETTING RECEIPTS.—Fees collected  
7 pursuant to subparagraph (A) or (B) of subsection  
8 (c)(1) shall be recorded as offsetting receipts.

9           “(c) ASSESSMENT OF USER FEE.—

10           “(1) AMOUNT OF ASSESSMENT.—

11           “(A) IN GENERAL.—The assessment under  
12 this section for—

13           “(i) fiscal year 2008 shall be  
14 \$85,000,000;

15           “(ii) fiscal year 2009 shall be  
16 \$235,000,000;

17           “(iii) fiscal year 2010 shall be  
18 \$450,000,000;

19           “(iv) fiscal year 2011 shall be  
20 \$477,000,000;

21           “(v) fiscal year 2012 shall be  
22 \$505,000,000;

23           “(vi) fiscal year 2013 shall be  
24 \$534,000,000;

1                   “(vii) fiscal year 2014 shall be  
2                   \$566,000,000;

3                   “(viii) fiscal year 2015 shall be  
4                   \$599,000,000;

5                   “(ix) fiscal year 2016 shall be  
6                   \$635,000,000;

7                   “(x) fiscal year 2017 shall be  
8                   \$672,000,000; and

9                   “(xi) fiscal year 2018 and each subse-  
10                  quent fiscal year shall be \$712,000,000.

11                  “(B) ADJUSTMENT.—For each of fiscal  
12                  years 2008 through 2018, the assessment for  
13                  the fiscal year involved under subparagraph (A)  
14                  shall be adjusted upward by **【\_\_\_\_\_ percent】**  
15                  **【Explanation: The percentage is to be deter-**  
16                  **mined by the Congressional Budget Office at**  
17                  **the time the Family Smoking Prevention and**  
18                  **Tobacco Control Act is scored. It is intended to**  
19                  **defray any net loss to the Treasury attributable**  
20                  **to changes in revenue and spending resulting**  
21                  **from the enactment of the Family Smoking**  
22                  **Prevention and Tobacco Control Act, so that**  
23                  **such Act will have a deficit-neutral impact on**  
24                  **the Federal Budget.】** and the amounts gen-  
25                  erated by the adjustment under this subpara-

1 graph shall be deposited into the general fund  
2 of the Treasury.

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

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

11 “(B) APPLICABLE PERCENTAGE.—

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

17 “(I) Cigarettes.

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

21 “(III) Snuff.

22 “(IV) Chewing tobacco.

23 “(V) Pipe tobacco.

24 “(VI) Roll-your-own tobacco.

1           “(ii) ALLOCATIONS.—The applicable  
2           percentage of each class of tobacco product  
3           described in class (i) for a fiscal year shall  
4           be the percentage determined under section  
5           625(c) of the Fair and Equitable Tobacco  
6           Reform Act of 2004 for each such class of  
7           product for such fiscal year.

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

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

1           “(3) DETERMINATION OF USER FEE BY COM-  
2           PANY.—

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

7                   “(i) such manufacturer’s or importer’s  
8                   percentage share as determined under  
9                   paragraph (4); by

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

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

20           “(4) ALLOCATION OF ASSESSMENT WITHIN  
21           EACH CLASS OF TOBACCO PRODUCT.—The percent-  
22           age share of each manufacturer or importer of a  
23           particular class of tobacco products of the total user  
24           fee to be paid by all manufacturers or importers of  
25           that class of tobacco products shall be the percent-

1 age determined by the Secretary of Agriculture in  
2 making allocations in accordance with subsections  
3 (e) through (h) of section 625 of the Fair and Equi-  
4 table Tobacco Reform Act of 2004.

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

11 “(d) TIMING OF USER FEE ASSESSMENT.—The Sec-  
12 retary shall notify each manufacturer and importer of to-  
13 bacco products subject to this section of the amount of  
14 the quarterly assessment imposed on such manufacturer  
15 or importer under subsection (c) during each quarter of  
16 each fiscal year. Such notifications shall occur not later  
17 than 30 days prior to the end of the quarter for which  
18 such assessment is made, and payments of all assessments  
19 shall be made by the last day of the quarter involved.

20 “(e) MEMORANDUM OF UNDERSTANDING.—

21 “(1) IN GENERAL.—The Secretary and the Sec-  
22 retary of Agriculture shall enter into a memorandum  
23 of understanding that provides for the regular and  
24 timely transfer from the Secretary of Agriculture to  
25 the Secretary of the information described in para-

1 graphs (2)(B)(ii) and (4) of subsection (c) and all  
2 necessary information regarding all tobacco product  
3 manufacturers and importers required to pay user  
4 fees. The memorandum of understanding shall pro-  
5 vide that the Secretary will ensure that all disclosure  
6 restrictions established by the Secretary of Agri-  
7 culture regarding such information are maintained.

8 “(2) ASSURANCES.—Beginning not later than  
9 fiscal year 2015, and for each subsequent fiscal  
10 year, the Secretary shall ensure that the Food and  
11 Drug Administration is able to determine the appli-  
12 cable percentages described in subsection (c)(2) and  
13 the percentage shares described in subsection (c)(4).  
14 The Secretary may carry out this paragraph by en-  
15 tering into a contract with the Secretary of Agri-  
16 culture to continue to provide the necessary informa-  
17 tion.

18 “(f) EFFECTIVE DATE.—

19 “(1) IN GENERAL.—The user fees prescribed by  
20 this section shall be assessed in fiscal year 2008,  
21 and shall be assessed in each fiscal year thereafter.

22 “(2) SPECIAL RULE.—If the date of enactment  
23 of the Family Smoking Prevention and Tobacco  
24 Control Act occurs during a quarter of fiscal year  
25 2008, the user fees for the portion of the quarter

1 that occurs after such date of enactment shall be as-  
2 sessed during the next full quarter.”.

3 **SEC. 102. FINAL RULE.**

4 (a) CIGARETTES AND SMOKELESS TOBACCO.—

5 (1) IN GENERAL.—Not later than 30 days after  
6 the date of enactment of this Act, the Secretary of  
7 Health and Human Services shall publish in the  
8 Federal Register a final rule regarding cigarettes  
9 and smokeless tobacco, which—

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

13 (B) is deemed to be in compliance with  
14 chapter 5 of title 5, United States Code, and  
15 other applicable law.

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

23 (A) provide for the designation of jurisdic-  
24 tional authority that is in accordance with this

1 subsection in accordance with this Act and the  
2 amendments made by this Act;

3 (B) strike Subpart C—Labels and section  
4 897.32(c);

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

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

13 (E) become effective not later than 1 year  
14 after the date of enactment of this Act; and

15 (F) amend paragraph (d) of section 897.16  
16 to read as follows:

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

23 “(2)(A) Subparagraph (1) does not prohibit a manu-  
24 facturer, distributor, or retailer from distributing or caus-

1 ing to be distributed free samples of smokeless tobacco  
2 in a qualified adult-only facility.

3 “(B) This subparagraph does not affect the authority  
4 of a State or local government to prohibit or otherwise  
5 restrict the distribution of free samples of smokeless to-  
6 bacco.

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

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

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

18 “(iii) is not located adjacent to or immediately  
19 across from (in any direction) a space that is used  
20 primarily for youth-oriented marketing, promotional,  
21 or other activities;

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

1 “(v) is enclosed by a barrier that—

2 “(I) is constructed of, or covered with, an  
3 opaque material (except for entrances and  
4 exits);

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

11 “(III) prevents persons outside the quali-  
12 fied adult-only facility from seeing into the  
13 qualified adult-only facility, unless they make  
14 unreasonable efforts to do so; and

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

16 “(I) any tobacco product advertising;

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

20 “(III) any combination of words that  
21 would imply to a reasonable observer that the  
22 manufacturer, distributor, or retailer has a  
23 sponsorship that would violate section  
24 897.34(c).

1       “(D) Distribution of samples of smokeless tobacco  
2 under this subparagraph permitted to be taken out of the  
3 qualified adult-only facility shall be limited to 1 package  
4 per adult consumer containing no more than 0.53 ounces  
5 (15 grams) of smokeless tobacco. If such package of  
6 smokeless tobacco contains individual portions of smoke-  
7 less tobacco, the individual portions of smokeless tobacco  
8 shall not exceed 8 individual portions and the collective  
9 weight of such individual portions shall not exceed 0.53  
10 ounces (15 grams). Any manufacturer, distributor, or re-  
11 tailer who distributes or causes to be distributed free sam-  
12 ples also shall take reasonable steps to ensure that the  
13 above amounts are limited to one such package per adult  
14 consumer per day.

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

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

19       or

20               “(B) at any football, basketball, baseball, soc-  
21 cer, or hockey event or any other sporting or enter-  
22 tainment event determined by the Secretary to be  
23 covered by this subparagraph.

24       “(4) The Secretary shall implement a program to en-  
25 sure compliance with this paragraph and submit a report

1 to the Congress on such compliance not later than 18  
2 months after the date of enactment of the Family Smok-  
3 ing Prevention and Tobacco Control Act.”.

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

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

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

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

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

12           (3) The preamble to the final rule in the docu-  
13 ment titled “Regulations Restricting the Sale and  
14 Distribution of Cigarettes and Smokeless Tobacco to  
15 Protect Children and Adolescents” (61 Fed. Reg.  
16 44396–44615 (August 28, 1996)).

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

1 **SEC. 103. CONFORMING AND OTHER AMENDMENTS TO GEN-**  
2 **ERAL PROVISIONS.**

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

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

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

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

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

18 (4) in subsection (e)—

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

20 and

21 (B) by striking “or 761 or the refusal to  
22 permit access to” and inserting “761, 909, or  
23 921 or the refusal to permit access to”;

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

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

3           (7) in subsection (j)—

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

5                 (B) by striking “708, or 721” and insert-  
6           ing “708, 721, 904, 905, 906, 907, 908, 909,  
7           or 921(b)”;

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

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

12           “(p) The failure to register in accordance with section  
13           510 or 905, the failure to provide any information re-  
14           quired by section 510(j), 510(k), 905(i), or 905(j), or the  
15           failure to provide a notice required by section 510(j)(2)  
16           or 905(i)(3).”;

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

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

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

22                 “(B) to furnish any notification or other mate-  
23           rial or information required by or under section 519,  
24           520(g), 904, 909, or 921; or

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

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

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

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

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

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

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

20          “(2) Making, selling, disposing of, or keeping in pos-  
21          session, control, or custody, or concealing any punch, die,  
22          plate, stone, or other item that is designed to print, im-  
23          print, or reproduce the trademark, trade name, or other  
24          identifying mark, imprint, or device of another or any like-  
25          ness of any of the foregoing upon any tobacco product or

1 container or labeling thereof so as to render such tobacco  
2 product a counterfeit tobacco product.

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

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

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

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

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

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

6           (2) in paragraph (5)—

7           (A) in subparagraph (A)—

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

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

16           (B) in subparagraph (B)—

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

20           (ii) by adding at the end the fol-  
21           lowing: “A no-tobacco-sale order perma-  
22           nently prohibiting an individual retail out-  
23           let from selling tobacco products shall in-  
24           clude provisions that allow the outlet, after  
25           a specified period of time, to request that

1 the Secretary compromise, modify, or ter-  
2 minate the order.”; and

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

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

7 (3) in paragraph (6)—

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

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

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

15 “(8) If the Secretary finds that a person has  
16 committed repeated violations of restrictions promul-  
17 gated under section 906(d) at a particular retail out-  
18 let then the Secretary may impose a no-tobacco-sale  
19 order on that person prohibiting the sale of tobacco  
20 products in that outlet. A no-tobacco-sale order may  
21 be imposed with a civil penalty under paragraph (1).  
22 Prior to the entry of a no-sale order under this para-  
23 graph, a person shall be entitled to a hearing pursu-  
24 ant to the procedures established through regula-  
25 tions of the Food and Drug Administration for as-

1       sessing civil money penalties, including at a retailer’s  
2       request a hearing by telephone, or at the nearest re-  
3       gional or field office of the Food and Drug Adminis-  
4       tration, or at a Federal, State, or county facility  
5       within 100 miles from the location of the retail out-  
6       let, if such a facility is available.”.

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

9               (1) in subsection (a)(2)—

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

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

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

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

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

21       (e) SECTION 505.—Section 505(n)(2) (21 U.S.C.  
22       355(n)(2)) is amended by striking “section 904” and in-  
23       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) (21 U.S.C.  
5 372(a)) is amended by adding at the end of paragraph  
6 (1) the following: “For a tobacco product, to the extent  
7 feasible, the Secretary shall contract with the States in  
8 accordance with this paragraph to carry out inspections  
9 of retailers within that State in connection with the en-  
10 forcement of this Act.”.

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

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

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

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

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

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

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

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

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

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

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

12                 (1) in subsection (a)—

13                         (A) by inserting “tobacco products,” after  
14                         the term “devices,” the first time such term ap-  
15                         pears;

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

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

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

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

24                 “(p)(1) Not later than 36 months after the date of  
25                 enactment of the Family Smoking Prevention and To-

1   tobacco Control Act, and annually thereafter, the Secretary  
2 shall submit to the Committee on Health, Education,  
3 Labor, and Pensions of the Senate and the Committee on  
4 Energy and Commerce of the House of Representatives,  
5 a report regarding—

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

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

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

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

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

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

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

1           (n) SECTION 1009.—Section 1009(b) (as redesign-  
2 nated by section 101(b)) is amended by striking “section  
3 908” and inserting “section 1008”.

4           (o) SECTION 409 OF THE FEDERAL MEAT INSPEC-  
5 TION ACT.—Section 409(a) of the Federal Meat Inspec-  
6 tion Act (21 U.S.C. 679(a)) is amended by striking “sec-  
7 tion 902(b)” and inserting “section 1002(b)”.

8           (p) RULE OF CONSTRUCTION.—Nothing in this sec-  
9 tion is intended or shall be construed to expand, contract,  
10 or otherwise modify or amend the existing limitations on  
11 State government authority over tribal restricted fee or  
12 trust lands.

13           (q) GUIDANCE AND EFFECTIVE DATES.—

14               (1) IN GENERAL.—The Secretary of Health and  
15 Human Services shall issue guidance—

16                       (A) defining the term “repeated violation”,  
17 as used in section 303(f)(8) of the Federal  
18 Food, Drug, and Cosmetic Act (21 U.S.C.  
19 333(f)(8)) as amended by subsection (c), as in-  
20 cluding at least 5 violations of particular re-  
21 quirements over a 36-month period at a par-  
22 ticular retail outlet that constitute a repeated  
23 violation and providing for civil penalties in ac-  
24 cordance with paragraph (2);

1 (B) providing for timely and effective no-  
2 tice by certified or registered mail or personal  
3 delivery to the retailer of each alleged violation  
4 at a particular retail outlet prior to conducting  
5 a follow-up compliance check, such notice to be  
6 sent to the retailer's address of record or the  
7 retailer's registered agent if the retailer has  
8 provided such agent information to the Food  
9 and Drug Administration prior to the violation;

10 (C) providing for a hearing pursuant to the  
11 procedures established through regulations of  
12 the Food and Drug Administration for assess-  
13 ing civil money penalties, including at a retail-  
14 er's request a hearing by telephone or at the  
15 nearest regional or field office of the Food and  
16 Drug Administration, and providing for an ex-  
17 pedited procedure for the administrative appeal  
18 of an alleged violation;

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

24 (E) establishing that civil money penalties  
25 for multiple violations shall increase from one

1 violation to the next violation pursuant to para-  
2 graph (2) within the time periods provided for  
3 in such paragraph; and

4 (F) providing that good faith reliance on  
5 the presentation of a false government issued  
6 photographic identification that contains a date  
7 of birth does not constitute a violation of any  
8 minimum age requirement for the sale of to-  
9 bacco products if the retailer has taken effective  
10 steps to prevent such violations, including—

11 (i) adopting and enforcing a written  
12 policy against sales to minors;

13 (ii) informing its employees of all ap-  
14 plicable laws;

15 (iii) establishing disciplinary sanctions  
16 for employee noncompliance; and

17 (iv) requiring its employees to verify  
18 age by way of photographic identification  
19 or electronic scanning device.

20 (2) PENALTIES FOR VIOLATIONS.—

21 (A) IN GENERAL.—The amount of the civil  
22 penalty to be applied for violations of restric-  
23 tions promulgated under section 906(d), as de-  
24 scribed in paragraph (1), shall be as follows:

1 (i) With respect to a retailer with an  
2 approved training program, the amount of  
3 the civil penalty shall not exceed—

4 (I) in the case of the first viola-  
5 tion, \$0.00 together with the issuance  
6 of a warning letter to the retailer;

7 (II) in the case of a second viola-  
8 tion within a 12-month period, \$250;

9 (III) in the case of a third viola-  
10 tion within a 24-month period, \$500;

11 (IV) in the case of a fourth viola-  
12 tion with a 24-month period, \$2,000

13 (V) in the case of a fifth violation  
14 with a 36-month period, \$5,000; and

15 (VI) in the case of a sixth or sub-  
16 sequent violation, \$10,000 as deter-  
17 mined by the Secretary on a case by  
18 case basis.

19 (ii) With respect to a retailer that  
20 does not have an approved training pro-  
21 gram, the amount of the civil penalty shall  
22 not exceed—

23 (I) in the case of the first viola-  
24 tion, \$250;

- 1 (II) in the case of a second viola-  
2 tion within a 12-month period, \$500;  
3 (III) in the case of a third viola-  
4 tion with a 24-month period, \$1,000  
5 (IV) in the case of a fourth viola-  
6 tion with a 24-month period, \$2,000;  
7 (V) in the case of a fifth violation  
8 with a 36-month period, \$5,000; and  
9 (VI) in the case of a sixth or sub-  
10 sequent violation, \$10,000 as deter-  
11 mined by the Secretary on a case by  
12 case basis.

13 (B) TRAINING PROGRAM.—For purposes of  
14 subparagraph (A), the term “approved training  
15 program” means a training program that com-  
16 plies with standards developed by the Food and  
17 Drug Administration for such programs.

18 (3) GENERAL EFFECTIVE DATE.—The amend-  
19 ments made by paragraphs (2), (3), and (4) of sub-  
20 section (c) shall take effect upon the issuance of  
21 guidance described in paragraph (1).

22 (4) SPECIAL EFFECTIVE DATE.—The amend-  
23 ment made by subsection (c)(1) shall take effect on  
24 the date of enactment of this Act.

1           (5) PACKAGE LABEL REQUIREMENTS.—The  
2 package label requirements of paragraphs (2), (3),  
3 and (4) of section 903(a) of the Federal Food,  
4 Drug, and Cosmetic Act (as amended by this Act)  
5 shall take effect on the date that is 12 months after  
6 the date of enactment of this Act. The effective date  
7 shall be with respect to the date of manufacture,  
8 provided that, in any case, 30 days after such effec-  
9 tive date, a manufacturer shall not introduce into  
10 the domestic commerce of the United States any  
11 product that is not in conformance with section  
12 903(a)(2), (3), and (4) and section 921(a) of the  
13 Federal Food, Drug, and Cosmetic Act.

14           (6) ADVERTISING REQUIREMENTS.—The adver-  
15 tising requirements of section 903(a)(8) of the Fed-  
16 eral Food, Drug, and Cosmetic Act (as amended by  
17 this Act) shall take effect on the date that is 12  
18 months after the date of enactment of this Act.

1 **TITLE II—TOBACCO PRODUCT**  
2 **WARNINGS; CONSTITUENT**  
3 **AND SMOKE CONSTITUENT**  
4 **DISCLOSURE**

5 **SEC. 201. CIGARETTE LABEL AND ADVERTISING WARNINGS.**

6 (a) AMENDMENT.—Section 4 of the Federal Ciga-  
7 rette Labeling and Advertising Act (15 U.S.C. 1333) is  
8 amended to read as follows:

9 **“SEC. 4. LABELING.**

10 “(a) LABEL REQUIREMENTS.—

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

17 “WARNING: Cigarettes are addictive.

18 “WARNING: Tobacco smoke can harm  
19 your children.

20 “WARNING: Cigarettes cause fatal lung  
21 disease.

22 “WARNING: Cigarettes cause cancer.

23 “WARNING: Cigarettes cause strokes and  
24 heart disease.

1           “WARNING: Smoking during pregnancy  
2           can harm your baby.

3           “WARNING: Smoking can kill you.

4           “WARNING: Tobacco smoke causes fatal  
5           lung disease in non-smokers.

6           “WARNING: Quitting smoking now great-  
7           ly reduces serious risks to your health.

8           “(2) PLACEMENT; TYPOGRAPHY; ETC.—Each  
9           label statement required by paragraph (1) shall be  
10          located in the upper portion of the front and rear  
11          panels of the package, directly on the package un-  
12          derneath the cellophane or other clear wrapping.  
13          Each label statement shall comprise at least the top  
14          30 percent of the front and rear panels of the pack-  
15          age. The word ‘WARNING’ shall appear in capital  
16          letters and all text shall be in conspicuous and leg-  
17          ible 17-point type, unless the text of the label state-  
18          ment would occupy more than 70 percent of such  
19          area, in which case the text may be in a smaller con-  
20          spicuous and legible type size, provided that at least  
21          60 percent of such area is occupied by required text.  
22          The text shall be black on a white background, or  
23          white on a black background, in a manner that con-  
24          trasts, by typography, layout, or color, with all other  
25          printed material on the package, in an alternating

1 fashion under the plan submitted under subsection  
2 (c).

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

9 “(4) APPLICABILITY TO RETAILERS.—A retailer  
10 of cigarettes shall not be in violation of this subsection for packaging that—

12 “(A) contains a warning label;

13 “(B) is supplied to the retailer by a tobacco product manufacturer, importer, or distributor; and

16 “(C) is not altered by the retailer in a way  
17 that is material to the requirements of this subsection.  
18

19 “(b) ADVERTISING REQUIREMENTS.—

20 “(1) IN GENERAL.—It shall be unlawful for any  
21 tobacco product manufacturer, importer, distributor,  
22 or retailer of cigarettes to advertise or cause to be  
23 advertised within the United States any cigarette  
24 unless its advertising bears, in accordance with the

1 requirements of this section, one of the labels speci-  
2 fied in subsection (a).

3 “(2) TYPOGRAPHY, ETC.—Each label statement  
4 required by subsection (a) in cigarette advertising  
5 shall comply with the standards set forth in this  
6 paragraph. For press and poster advertisements,  
7 each such statement and (where applicable) any re-  
8 quired statement relating to tar, nicotine, or other  
9 constituent (including a smoke constituent) yield  
10 shall comprise at least 20 percent of the area of the  
11 advertisement and shall appear in a conspicuous and  
12 prominent format and location at the top of each ad-  
13 vertisement within the trim area. The Secretary may  
14 revise the required type sizes in such area in such  
15 manner as the Secretary determines appropriate.  
16 The word ‘WARNING’ shall appear in capital let-  
17 ters, and each label statement shall appear in con-  
18 spicuous and legible type. The text of the label state-  
19 ment shall be black if the background is white and  
20 white if the background is black, under the plan sub-  
21 mitted under subsection (c). The label statements  
22 shall be enclosed by a rectangular border that is the  
23 same color as the letters of the statements and that  
24 is the width of the first downstroke of the capital  
25 ‘W’ of the word ‘WARNING’ in the label state-

1       ments. The text of such label statements shall be in  
2       a typeface pro rata to the following requirements:  
3       45-point type for a whole-page broadsheet newspaper  
4       advertisement; 39-point type for a half-page  
5       broadsheet newspaper advertisement; 39-point type  
6       for a whole-page tabloid newspaper advertisement;  
7       27-point type for a half-page tabloid newspaper ad-  
8       vertisement; 31.5-point type for a double page  
9       spread magazine or whole-page magazine advertise-  
10      ment; 22.5-point type for a 28 centimeter by 3 col-  
11      umn advertisement; and 15-point type for a 20 cen-  
12      timeter by 2 column advertisement. The label state-  
13      ments shall be in English, except that in the case  
14      of—

15               “(A) an advertisement that appears in a  
16               newspaper, magazine, periodical, or other publi-  
17               cation that is not in English, the statements  
18               shall appear in the predominant language of the  
19               publication; and

20               “(B) in the case of any other advertise-  
21               ment that is not in English, the statements  
22               shall appear in the same language as that prin-  
23               cipally used in the advertisement.

24               “(3) MATCHBOOKS.—Notwithstanding para-  
25               graph (2), for matchbooks (defined as containing not

1 more than 20 matches) customarily given away with  
2 the purchase of tobacco products, each label state-  
3 ment required by subsection (a) may be printed on  
4 the inside cover of the matchbook.

5 “(4) ADJUSTMENT BY SECRETARY.—The Sec-  
6 retary may, through a rulemaking under section 553  
7 of title 5, United States Code, adjust the format and  
8 type sizes for the label statements required by this  
9 section; the text, format, and type sizes of any re-  
10 quired tar, nicotine yield, or other constituent (in-  
11 cluding smoke constituent) disclosures; or the text,  
12 format, and type sizes for any other disclosures re-  
13 quired under the Federal Food, Drug, and Cosmetic  
14 Act. The text of any such label statements or disclo-  
15 sures shall be required to appear only within the 20  
16 percent area of cigarette advertisements provided by  
17 paragraph (2). The Secretary shall promulgate regu-  
18 lations which provide for adjustments in the format  
19 and type sizes of any text required to appear in such  
20 area to ensure that the total text required to appear  
21 by law will fit within such area.

22 “(c) MARKETING REQUIREMENTS.—

23 “(1) RANDOM DISPLAY.—The label statements  
24 specified in subsection (a)(1) shall be randomly dis-  
25 played in each 12-month period, in as equal a num-

1       ber of times as is possible on each brand of the  
2       product and be randomly distributed in all areas of  
3       the United States in which the product is marketed  
4       in accordance with a plan submitted by the tobacco  
5       product manufacturer, importer, distributor, or re-  
6       tailer and approved by the Secretary.

7               “(2) ROTATION.—The label statements speci-  
8       fied in subsection (a)(1) shall be rotated quarterly in  
9       alternating sequence in advertisements for each  
10      brand of cigarettes in accordance with a plan sub-  
11      mitted by the tobacco product manufacturer, im-  
12      porter, distributor, or retailer to, and approved by,  
13      the Secretary.

14              “(3) REVIEW.—The Secretary shall review each  
15      plan submitted under paragraph (2) and approve it  
16      if the plan—

17                      “(A) will provide for the equal distribution  
18                      and display on packaging and the rotation re-  
19                      quired in advertising under this subsection; and

20                      “(B) assures that all of the labels required  
21                      under this section will be displayed by the to-  
22                      bacco product manufacturer, importer, dis-  
23                      tributor, or retailer at the same time.

24              “(4) APPLICABILITY TO RETAILERS.—This sub-  
25      section and subsection (b) apply to a retailer only if

1 that retailer is responsible for or directs the label  
2 statements required under this section except that  
3 this paragraph shall not relieve a retailer of liability  
4 if the retailer displays, in a location open to the pub-  
5 lic, an advertisement that is not labeled in accord-  
6 ance with the requirements of subsection (b).”.

7 (b) **EFFECTIVE DATE.**—The amendments made by  
8 this title to section 4 of the Federal Cigarette Labeling  
9 and Advertising Act (15 U.S.C. 1333) shall take effect  
10 on the date that is 1 year after the date of enactment  
11 of the this Act.

12 **SEC. 202. AUTHORITY TO REVISE CIGARETTE WARNING**  
13 **LABEL STATEMENTS.**

14 Section 4 of the Federal Cigarette Labeling and Ad-  
15 vertising Act (15 U.S.C. 1333), as amended by section  
16 201, is further amended by adding at the end the fol-  
17 lowing:

18 “(d) **CHANGE IN REQUIRED STATEMENTS.**—The  
19 Secretary may, by a rulemaking conducted under section  
20 553 of title 5, United States Code, adjust the format, type  
21 size, and text of any of the label requirements, require  
22 color graphics to accompany the text, increase the re-  
23 quired label area from 30 percent up to 50 percent of the  
24 front and rear panels of the package, or establish the for-  
25 mat, type size, and text of any other disclosures required

1 under the Federal Food, Drug, and Cosmetic Act, if the  
2 Secretary finds that such a change would promote greater  
3 public understanding of the risks associated with the use  
4 of tobacco products.”.

5 **SEC. 203. STATE REGULATION OF CIGARETTE ADVER-**  
6 **TISING AND PROMOTION.**

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

10 “(c) EXCEPTION.—Notwithstanding subsection (b), a  
11 State or locality may enact statutes and promulgate regu-  
12 lations, based on smoking and health, that take effect  
13 after the effective date of the Family Smoking Prevention  
14 and Tobacco Control Act, imposing specific bans or re-  
15 strictions on the time, place, and manner, but not content,  
16 of the advertising or promotion of any cigarettes.”.

17 **SEC. 204. SMOKELESS TOBACCO LABELS AND ADVERTISING**  
18 **WARNINGS.**

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

22 **“SEC. 3. SMOKELESS TOBACCO WARNING.**

23 “(a) GENERAL RULE.—

24 “(1) It shall be unlawful for any person to man-  
25 ufacture, package, sell, offer to sell, distribute, or

1 import for sale or distribution within the United  
2 States any smokeless tobacco product unless the  
3 product package bears, in accordance with the re-  
4 quirements of this Act, one of the following labels:

5 “WARNING: This product can cause  
6 mouth cancer.

7 “WARNING: This product can cause gum  
8 disease and tooth loss.

9 “WARNING: This product is not a safe al-  
10 ternative to cigarettes.

11 “WARNING: Smokeless tobacco is addict-  
12 ive.

13 “(2) Each label statement required by para-  
14 graph (1) shall be—

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

19 “(B) in 17-point conspicuous and legible  
20 type and in black text on a white background,  
21 or white text on a black background, in a man-  
22 ner that contrasts by typography, layout, or  
23 color, with all other printed material on the  
24 package, in an alternating fashion under the  
25 plan submitted under subsection (b)(3), except

1           that if the text of a label statement would oc-  
2           cupy more than 70 percent of the area specified  
3           by subparagraph (A), such text may appear in  
4           a smaller type size, so long as at least 60 per-  
5           cent of such warning area is occupied by the  
6           label statement.

7           “(3) The label statements required by para-  
8           graph (1) shall be introduced by each tobacco prod-  
9           uct manufacturer, packager, importer, distributor, or  
10          retailer of smokeless tobacco products concurrently  
11          into the distribution chain of such products.

12          “(4) The provisions of this subsection do not  
13          apply to a tobacco product manufacturer or dis-  
14          tributor of any smokeless tobacco product that does  
15          not manufacture, package, or import smokeless to-  
16          bacco products for sale or distribution within the  
17          United States.

18          “(5) A retailer of smokeless tobacco products  
19          shall not be in violation of this subsection for pack-  
20          aging that is supplied to the retailer by a tobacco  
21          products manufacturer, importer, or distributor and  
22          that is not altered by the retailer unless the retailer  
23          offers for sale, sells, or distributes a smokeless to-  
24          bacco product that is not labeled in accordance with  
25          this subsection.

1 “(b) REQUIRED LABELS.—

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

9 “(2) Each label statement required by sub-  
10 section (a) in smokeless tobacco advertising shall  
11 comply with the standards set forth in this para-  
12 graph. For press and poster advertisements, each  
13 such statement and (where applicable) any required  
14 statement relating to tar, nicotine, or other con-  
15 stituent yield shall—

16 “(A) comprise at least 20 percent of the  
17 area of the advertisement, and the warning area  
18 shall be delineated by a dividing line of con-  
19 trasting color from the advertisement; and

20 “(B) the word ‘WARNING’ shall appear in  
21 capital letters and each label statement shall  
22 appear in conspicuous and legible type. The text  
23 of the label statement shall be black on a white  
24 background, or white on a black background, in

1 an alternating fashion under the plan submitted  
2 under paragraph (3).

3 “(3)(A) The label statements specified in sub-  
4 section (a)(1) shall be randomly displayed in each  
5 12-month period, in as equal a number of times as  
6 is possible on each brand of the product and be ran-  
7 domly distributed in all areas of the United States  
8 in which the product is marketed in accordance with  
9 a plan submitted by the tobacco product manufac-  
10 turer, importer, distributor, or retailer and approved  
11 by the Secretary.

12 “(B) The label statements specified in sub-  
13 section (a)(1) shall be rotated quarterly in alter-  
14 nating sequence in advertisements for each brand of  
15 smokeless tobacco product in accordance with a plan  
16 submitted by the tobacco product manufacturer, im-  
17 porter, distributor, or retailer to, and approved by,  
18 the Secretary.

19 “(C) The Secretary shall review each plan sub-  
20 mitted under subparagraphs (A) and (B) and ap-  
21 prove it if the plan—

22 “(i) will provide for the equal distribution  
23 and display on packaging and the rotation re-  
24 quired in advertising under this subsection; and



1       “(d) **AUTHORITY TO REVISE WARNING LABEL**  
2 **STATEMENTS.**—The Secretary may, by a rulemaking con-  
3 ducted under section 553 of title 5, United States Code,  
4 adjust the format, type size, and text of any of the label  
5 requirements, require color graphics to accompany the  
6 text, increase the required label area from 30 percent up  
7 to 50 percent of the front and rear panels of the package,  
8 or establish the format, type size, and text of any other  
9 disclosures required under the Federal Food, Drug, and  
10 Cosmetic Act, if the Secretary finds that such a change  
11 would promote greater public understanding of the risks  
12 associated with the use of smokeless tobacco products.”.

13       (b) **PREEMPTION.**—Section 7(a) of the Comprehen-  
14 sive Smokeless Tobacco Health Education Act of 1986 (15  
15 U.S.C. 4406(a)) is amended by striking “No” and insert-  
16 ing “Except as provided in the Family Smoking Preven-  
17 tion and Tobacco Control Act (and the amendments made  
18 by that Act), no”.

19 **SEC. 206. TAR, NICOTINE, AND OTHER SMOKE CON-**  
20 **STITUENT DISCLOSURE TO THE PUBLIC.**

21       Section 4 of the Federal Cigarette Labeling and Ad-  
22 vertising Act (15 U.S.C. 1333), as amended by sections  
23 201 and 202, is further amended by adding at the end  
24 the following:

1       “(e) TAR, NICOTINE, AND OTHER SMOKE CON-  
2   STITUENT DISCLOSURE.—

3               “(1) IN GENERAL.—The Secretary shall, by a  
4   rulemaking conducted under section 553 of title 5,  
5   United States Code, determine (in the Secretary’s  
6   sole discretion) whether cigarette and other tobacco  
7   product manufacturers shall be required to include  
8   in the area of each cigarette advertisement specified  
9   by subsection (b) of this section, or on the package  
10   label, or both, the tar and nicotine yields of the ad-  
11   vertised or packaged brand. Any such disclosure  
12   shall be in accordance with the methodology estab-  
13   lished under such regulations, shall conform to the  
14   type size requirements of subsection (b) of this sec-  
15   tion, and shall appear within the area specified in  
16   subsection (b) of this section.

17               “(2) RESOLUTION OF DIFFERENCES.—Any dif-  
18   ferences between the requirements established by the  
19   Secretary under paragraph (1) and tar and nicotine  
20   yield reporting requirements established by the Fed-  
21   eral Trade Commission shall be resolved by a memo-  
22   randum of understanding between the Secretary and  
23   the Federal Trade Commission.

24               “(3) CIGARETTE AND OTHER TOBACCO PROD-  
25   UCT CONSTITUENTS.—In addition to the disclosures

1 required by paragraph (1), the Secretary may, under  
2 a rulemaking conducted under section 553 of title 5,  
3 United States Code, prescribe disclosure require-  
4 ments regarding the level of any cigarette or other  
5 tobacco product constituent including any smoke  
6 constituent. Any such disclosure may be required if  
7 the Secretary determines that disclosure would be of  
8 benefit to the public health, or otherwise would in-  
9 crease consumer awareness of the health con-  
10 sequences of the use of tobacco products, except that  
11 no such prescribed disclosure shall be required on  
12 the face of any cigarette package or advertisement.  
13 Nothing in this section shall prohibit the Secretary  
14 from requiring such prescribed disclosure through a  
15 cigarette or other tobacco product package or adver-  
16 tisement insert, or by any other means under the  
17 Federal Food, Drug, and Cosmetic Act.

18 “(4) RETAILERS.—This subsection applies to a  
19 retailer only if that retailer is responsible for or di-  
20 rects the label statements required under this sec-  
21 tion.”.

1 **TITLE III—PREVENTION OF IL-**  
2 **LICIT TRADE IN TOBACCO**  
3 **PRODUCTS**

4 **SEC. 301. LABELING, RECORDKEEPING, RECORDS INSPEC-**  
5 **TION.**

6 Chapter IX of the Federal Food, Drug, and Cosmetic  
7 Act, as added by section 101, is further amended by add-  
8 ing at the end the following:

9 **“SEC. 921. LABELING, RECORDKEEPING, RECORDS INSPEC-**  
10 **TION.**

11 “(a) **ORIGIN LABELING.**—Beginning 1 year after the  
12 date of enactment of the Family Smoking Prevention and  
13 Tobacco Control Act, the label, packaging, and shipping  
14 containers of tobacco products for introduction or delivery  
15 for introduction into interstate commerce in the United  
16 States shall bear the statement ‘sale only allowed in the  
17 United States’.

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

20 “(1) **IN GENERAL.**—The Secretary shall pro-  
21 mulgate regulations regarding the establishment and  
22 maintenance of records by any person who manufac-  
23 tures, processes, transports, distributes, receives,  
24 packages, holds, exports, or imports tobacco prod-  
25 ucts.

1           “(2) INSPECTION.—In promulgating the regula-  
2           tions described in paragraph (1), the Secretary shall  
3           consider which records are needed for inspection to  
4           monitor the movement of tobacco products from the  
5           point of manufacture through distribution to retail  
6           outlets to assist in investigating potential illicit  
7           trade, smuggling, or counterfeiting of tobacco prod-  
8           ucts.

9           “(3) CODES.—The Secretary may require codes  
10          on the labels of tobacco products or other designs or  
11          devices for the purpose of tracking or tracing the to-  
12          bacco product through the distribution system.

13          “(4) SIZE OF BUSINESS.—The Secretary shall  
14          take into account the size of a business in promul-  
15          gating regulations under this section.

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

20          “(c) RECORDS INSPECTION.—If the Secretary has a  
21          reasonable belief that a tobacco product is part of an illicit  
22          trade or smuggling or is a counterfeit product, each person  
23          who manufactures, processes, transports, distributes, re-  
24          ceives, holds, packages, exports, or imports tobacco prod-  
25          ucts shall, at the request of an officer or employee duly

1 designated by the Secretary, permit such officer or em-  
2 ployee, at reasonable times and within reasonable limits  
3 and in a reasonable manner, upon the presentation of ap-  
4 propriate credentials and a written notice to such person,  
5 to have access to and copy all records (including financial  
6 records) relating to such article that are needed to assist  
7 the Secretary in investigating potential illicit trade, smug-  
8 gling, or counterfeiting of tobacco products.

9 “(d) KNOWLEDGE OF ILLEGAL TRANSACTION.—

10 “(1) NOTIFICATION.—If the manufacturer or  
11 distributor of a tobacco product has knowledge  
12 which reasonably supports the conclusion that a to-  
13 bacco product manufactured or distributed by such  
14 manufacturer or distributor that has left the control  
15 of such person may be or has been—

16 “(A) imported, exported, distributed, or of-  
17 fered for sale in interstate commerce by a per-  
18 son without paying duties or taxes required by  
19 law; or

20 “(B) imported, exported, distributed, or di-  
21 verted for possible illicit marketing,  
22 the manufacturer or distributor shall promptly no-  
23 tify the Attorney General and the Secretary of the  
24 Treasury of such knowledge.

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

4                   “(A) the actual knowledge that the manu-  
5 facturer or distributor had; or

6                   “(B) the knowledge which a reasonable  
7 person would have had under like circumstances  
8 or which would have been obtained upon the ex-  
9 ercise of due care.”.

10 **SEC. 302. STUDY AND REPORT.**

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

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

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

1           (b) REPORT.—Not later than 18 months after the  
2 date of enactment of this Act, the Comptroller General  
3 of the United States shall submit to the Committee on  
4 Health, Education, Labor, and Pensions of the Senate and  
5 the Committee on Energy and Commerce of the House  
6 of Representatives a report on the study described in sub-  
7 section (a).