

109TH CONGRESS
1ST SESSION

H. R. 1376

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

IN THE HOUSE OF REPRESENTATIVES

MARCH 17, 2005

Mr. TOM DAVIS of Virginia (for himself, Mr. WAXMAN, Mr. PLATTS, Mr. ABERCROMBIE, Mr. TIBERI, Mr. RUPPERSBERGER, Mr. RAMSTAD, Mrs. CAPPS, Mr. LAHOOD, Mrs. CHRISTENSEN, Mr. TERRY, Mr. JACKSON of Illinois, Mr. LEACH, Ms. ZOE LOFGREN of California, Mr. SHAYS, Mr. McDERMOTT, Ms. PRYCE of Ohio, Mr. FILNER, Mr. KIRK, Mr. HINCHAY, Mrs. MILLER of Michigan, Ms. LEE, Mr. MORAN of Virginia, Mr. SHERMAN, Mr. VAN HOLLEN, Mr. RUSH, Mr. WYNN, and Mrs. MALONEY) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

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

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

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

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

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

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

TITLE I—AUTHORITY OF THE FOOD AND DRUG
 ADMINISTRATION

- Sec. 101. Amendment of Federal Food, Drug, and Cosmetic act.
- Sec. 102. Interim 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.

3 **SEC. 2. FINDINGS.**

4 The Congress finds the following:

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

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

1 (3) Nicotine is an addictive drug.

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

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

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

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

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

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

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

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

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

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

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

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

16 (16) In 2002, the tobacco industry spent more
17 than \$12,466,000,000 to attract new users, retain
18 current users, increase current consumption, and
19 generate favorable long-term attitudes toward smok-
20 ing and tobacco use.

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

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

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

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

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

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

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

22 (23) Children are more influenced by tobacco
23 advertising than adults, they smoke the most adver-
24 tised brands.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

9 **SEC. 3. PURPOSE.**

10 The purposes of this Act are—

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

18 (2) to ensure that the Food and Drug Adminis-
19 tration has the authority to address issues of par-
20 ticular concern to public health officials, especially
21 the use of tobacco by young people and dependence
22 on tobacco;

23 (3) to authorize the Food and Drug Adminis-
24 tration to set national standards controlling the
25 manufacture of tobacco products and the identity,

1 public disclosure, and amount of ingredients used in
2 such products;

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

7 (5) to vest the Food and Drug Administration
8 with the authority to regulate the levels of tar, nico-
9 tine, and other harmful components of tobacco prod-
10 ucts;

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

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

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

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

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

3 **SEC. 4. SCOPE AND EFFECT.**

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

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

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

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

19 **SEC. 5. SEVERABILITY.**

20 If any provision of this Act, the amendments made
21 by this Act, or the application of any provision of this Act
22 to any person or circumstance is held to be invalid, the
23 remainder of this Act, the amendments made by this Act,
24 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 “(m)(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—

19 “(A) a product in the form of conventional food
20 (including water and chewing gum), a product rep-
21 resented for use as or for use in a conventional food,
22 or a product that is intended for ingestion in cap-
23 sule, tablet, softgel, or liquid form; or

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

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

5 “(4) A tobacco product may not be marketed in com-
 6 bination with any other article or product regulated under
 7 this Act (including a drug, biologic, food, cosmetics, med-
 8 ical device, or a dietary supplement).”.

9 (b) FDA AUTHORITY OVER TOBACCO PRODUCTS.—
 10 The Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 11 301 et seq.) is amended—

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

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

15 (3) by inserting after section 803 the following:

16 **“CHAPTER IX—TOBACCO**
 17 **PRODUCTS**

18 **“SEC. 900. DEFINITIONS.**

19 “In this chapter:

20 “(1) ADDITIVE.—The term ‘additive’ means
 21 any substance the intended use of which results or
 22 may reasonably be expected to result, directly or in-
 23 directly, in its becoming a component or otherwise
 24 affecting the characteristic of any tobacco product
 25 (including any substances intended for use as a fla-

1 voring, coloring or in producing, manufacturing,
2 packing, processing, preparing, treating, packaging,
3 transporting, or holding), except that such term does
4 not include tobacco or a pesticide chemical residue
5 in or on raw tobacco or a pesticide chemical.

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

12 “(3) CIGARETTE.—The term ‘cigarette’ has the
13 meaning given that term by section 3(1) of the Fed-
14 eral Cigarette Labeling and Advertising Act (15
15 U.S.C. 1332(1)), but also includes tobacco, in any
16 form, that is functional in the product, which, be-
17 cause of its appearance, the type of tobacco used in
18 the filler, or its packaging and labeling, is likely to
19 be offered to, or purchased by, consumers as a ciga-
20 rette or as roll-your-own tobacco.

21 “(4) CIGARETTE TOBACCO.—The term ‘ciga-
22 rette tobacco’ means any product that consists of
23 loose tobacco that is intended for use by consumers
24 in a cigarette. Unless otherwise stated, the require-

1 ments for cigarettes shall also apply to cigarette to-
2 bacco.

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

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

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

23 “(8) ILLICIT TRADE.—The term ‘illicit trade’
24 means any practice or conduct prohibited by law
25 which relates to production, shipment, receipt, pos-

1 session, distribution, sale, or purchase of tobacco
2 products including any practice or conduct intended
3 to facilitate such activity.

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

8 “(10) LITTLE CIGAR.—The term ‘little cigar’
9 has the meaning given that term by section 3(7) of
10 the Federal Cigarette Labeling and Advertising Act
11 (15 U.S.C. 1332(7)).

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

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

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

1 “(14) ROLL-YOUR-OWN TOBACCO.—The term
2 ‘roll-your-own tobacco’ means any tobacco which, be-
3 cause of its appearance, type, packaging, or labeling,
4 is suitable for use and likely to be offered to, or pur-
5 chased by, consumers as tobacco for making ciga-
6 rettes.

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.—The term ‘State’ means any
20 State of the United States and, for purposes of this
21 chapter, includes the District of Columbia, the Com-
22 monwealth of Puerto Rico, Guam, the Virgin Is-
23 lands, American Samoa, Wake Island, Midway Is-
24 lands, Kingman Reef, Johnston Atoll, the Northern

1 Mariana Islands, and any other trust territory or
2 possession of the United States.

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

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

8 “(B) imports a finished cigarette or
9 smokeless tobacco product for sale or distribu-
10 tion in the United States.

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

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

20 “(a) IN GENERAL.—Tobacco products shall be regu-
21 lated by the Secretary under this chapter and shall not
22 be subject to the provisions of chapter V, unless—

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

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

3 “(2) a claim is made for such products under
4 section 201(g)(1)(C) or 201(h)(3);
5 other than modified risk tobacco products approved
6 in accordance with section 911.

7 “(b) APPLICABILITY.—This chapter shall apply to all
8 tobacco products subject to the regulations referred to in
9 section 102 of the Family Smoking Prevention and To-
10 bacco Control Act, and to any other tobacco products that
11 the Secretary by regulation deems to be subject to this
12 chapter.

13 “(c) SCOPE.—

14 “(1) IN GENERAL.—Nothing in this chapter, or
15 any policy issued or regulation promulgated there-
16 under, or the Family Smoking Prevention and To-
17 bacco Control Act, shall be construed to affect the
18 Secretary’s authority over, or the regulation of,
19 products under this Act that are not tobacco prod-
20 ucts under chapter V or any other chapter.

21 “(2) LIMITATION OF AUTHORITY.—

22 “(A) IN GENERAL.—The provisions of this
23 chapter shall not apply to tobacco leaf that is
24 not in the possession of a manufacturer of to-
25 bacco products, or to the producers of tobacco

1 leaf, including tobacco growers, tobacco ware-
2 houses, and tobacco grower cooperatives, nor
3 shall any employee of the Food and Drug Ad-
4 ministration have any authority to enter onto a
5 farm owned by a producer of tobacco leaf with-
6 out the written consent of such producer.

7 “(B) EXCEPTION.—Notwithstanding any
8 other provision of this subparagraph, if a pro-
9 ducer of tobacco leaf is also a tobacco product
10 manufacturer or controlled by a tobacco prod-
11 uct manufacturer, the producer shall be subject
12 to this chapter in the producer’s capacity as a
13 manufacturer.

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

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

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

24 “(1) it consists in whole or in part of any filthy,
25 putrid, or decomposed substance, or is otherwise

1 contaminated by any added poisonous or added dele-
2 terious substance that may render the product inju-
3 rious to health;

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

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

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

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

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

21 “(6) the methods used in, or the facilities or
22 controls used for, its manufacture, packing or stor-
23 age are not in conformity with applicable require-
24 ments under section 906(e)(1) or an applicable con-

1 dition prescribed by an order under section
2 906(e)(2); or

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

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

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

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

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

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

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

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

21 “(D) the statement required under section
22 921(a),

23 except that under subparagraph (B) reasonable vari-
24 ations shall be permitted, and exemptions as to

1 small packages shall be established, by regulations
2 prescribed by the Secretary;

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

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

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

22 “(6) if it was manufactured, prepared, propa-
23 gated, compounded, or processed in any State in an
24 establishment not duly registered under section
25 905(b), 905(c), 905(d), or 905(h), if it was not in-

1 cluded in a list required by section 905(i), if a notice
2 or other information respecting it was not provided
3 as required by such section or section 905(j), or if
4 it does not bear such symbols from the uniform sys-
5 tem for identification of tobacco products prescribed
6 under section 905(e) as the Secretary by regulation
7 requires;

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

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

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

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

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

24 “(B) a brief statement of—

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

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

15 “(9) if it is a tobacco product subject to a to-
16 bacco product standard established under section
17 907, unless it bears such labeling as may be pre-
18 scribed in such tobacco product standard; or

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

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

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

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

25 The Secretary may, by regulation, require prior approval

1 of statements made on the label of a tobacco product. No
2 regulation issued under this subsection may require prior
3 approval by the Secretary of the content of any advertise-
4 ment, except for modified risk tobacco products as pro-
5 vided in section 911. No advertisement of a tobacco prod-
6 uct published after the date of enactment of the Family
7 Smoking Prevention and Tobacco Control Act shall, with
8 respect to the language of label statements as prescribed
9 under section 4 of the Cigarette Labeling and Advertising
10 Act and section 3 of the Comprehensive Smokeless To-
11 bacco Health Education Act of 1986 or the regulations
12 issued under such sections, be subject to the provisions
13 of sections 12 through 15 of the Federal Trade Commis-
14 sion Act (15 U.S.C. 52 through 55).

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

17 “(a) REQUIREMENT.—Not later than 6 months after
18 the date of enactment of the Family Smoking Prevention
19 and Tobacco Control Act, each tobacco product manufac-
20 turer or importer, or agents thereof, shall submit to the
21 Secretary the following information:

22 “(1) A listing of all ingredients, including to-
23 bacco, substances, compounds, and additives that
24 are, as of such date, added by the manufacturer to
25 the tobacco, paper, filter, or other part of each to-

1 tobacco product by brand and by quantity in each
2 brand and subbrand.

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

9 “(3) A listing of all constituents, including
10 smoke constituents as applicable, identified by the
11 Secretary as harmful or potentially harmful to
12 health in each tobacco product, and as applicable in
13 the smoke of each tobacco product, by brand and by
14 quantity in each brand and subbrand. Effective be-
15 ginning 2 years after the date of enactment of this
16 chapter, the manufacturer, importer, or agent shall
17 comply with regulations promulgated under section
18 916 in reporting information under this paragraph,
19 where applicable.

20 “(4) All documents developed after the date of
21 enactment of the Family Smoking Prevention and
22 Tobacco Control Act that relate to health, toxi-
23 cological, behavioral, or physiologic effects of current
24 or future tobacco products, their constituents (in-

1 including smoke constituents), ingredients, compo-
2 nents, and additives.

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

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

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

23 “(3) Any or all documents (including under-
24 lying scientific or financial information) relating to
25 marketing research involving the use of tobacco

1 products or marketing practices and the effective-
2 ness of such practices used by tobacco manufactur-
3 ers and distributors.

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

7 “(c) TIME FOR SUBMISSION.—

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

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

22 “(3) DISCLOSURE OF OTHER ACTIONS.—If at
23 any time a tobacco product manufacturer eliminates
24 or decreases an existing additive, or adds or in-
25 creases an additive that has by regulation been des-

1 ignated by the Secretary as an additive that is not
2 a human or animal carcinogen, or otherwise harmful
3 to health under intended conditions of use, the man-
4 ufacturer shall within 60 days of such action so ad-
5 vise the Secretary in writing.

6 “(d) DATA LIST.—

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

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

1 “(e) DATA COLLECTION.—Not later than 12 months
2 after the date of enactment of the Family Smoking Pre-
3 vention and Tobacco Control Act, the Secretary shall es-
4 tablish a list of harmful and potentially harmful constitu-
5 ents, including smoke constituents, to health in each to-
6 bacco product by brand and by quantity in each brand
7 and subbrand. The Secretary shall publish a public notice
8 requesting the submission by interested persons of sci-
9 entific and other information concerning the harmful and
10 potentially harmful constituents in tobacco products and
11 tobacco smoke.

12 **“SEC. 905. ANNUAL REGISTRATION.**

13 “(a) DEFINITIONS.—In this section:

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

23 “(2) NAME.—The term ‘name’ shall include in
24 the case of a partnership the name of each partner
25 and, in the case of a corporation, the name of each

1 corporate officer and director, and the State of in-
2 corporation.

3 “(b) REGISTRATION BY OWNERS AND OPERATORS.—

4 On or before December 31 of each year every person who
5 owns or operates any establishment in any State engaged
6 in the manufacture, preparation, compounding, or proc-
7 essing of a tobacco product or tobacco products shall reg-
8 ister with the Secretary the name, places of business, and
9 all such establishments of that person.

10 “(c) REGISTRATION OF NEW OWNERS AND OPERA-

11 TORS.—Every person upon first engaging in the manufac-
12 ture, preparation, compounding, or processing of a tobacco
13 product or tobacco products in any establishment owned
14 or operated in any State by that person shall immediately
15 register with the Secretary that person’s name, place of
16 business, and such establishment.

17 “(d) REGISTRATION OF ADDED ESTABLISHMENTS.—

18 Every person required to register under subsection (b) or
19 (c) shall immediately register with the Secretary any addi-
20 tional establishment which that person owns or operates
21 in any State and in which that person begins the manufac-
22 ture, preparation, compounding, or processing of a tobacco
23 product or tobacco products.

24 “(e) UNIFORM PRODUCT IDENTIFICATION SYS-

25 TEM.—The Secretary may by regulation prescribe a uni-

1 form system for the identification of tobacco products and
2 may require that persons who are required to list such
3 tobacco products under subsection (i) shall list such to-
4 bacco products in accordance with such system.

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

9 “(g) BIENNIAL INSPECTION OF REGISTERED ESTAB-
10 LISHMENTS.—Every establishment in any State registered
11 with the Secretary under this section shall be subject to
12 inspection under section 704, and every such establish-
13 ment engaged in the manufacture, compounding, or proc-
14 essing of a tobacco product or tobacco products shall be
15 so inspected by 1 or more officers or employees duly des-
16 igned by the Secretary at least once in the 2-year period
17 beginning with the date of registration of such establish-
18 ment under this section and at least once in every succes-
19 sive 2-year period thereafter.

20 “(h) FOREIGN ESTABLISHMENTS SHALL REG-
21 ISTER.—Any establishment within any foreign country en-
22 gaged in the manufacture, preparation, compounding, or
23 processing of a tobacco product or tobacco products, shall
24 register under this section under regulations promulgated
25 by the Secretary. Such regulations shall require such es-

1 establishment to provide the information required by sub-
2 section (i) of this section and shall include provisions for
3 registration of any such establishment upon condition that
4 adequate and effective means are available, by arrange-
5 ment with the government of such foreign country or oth-
6 erwise, to enable the Secretary to determine from time to
7 time whether tobacco products manufactured, prepared,
8 compounded, or processed in such establishment, if im-
9 ported or offered for import into the United States, shall
10 be refused admission on any of the grounds set forth in
11 section 801(a).

12 “(i) REGISTRATION INFORMATION.—

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

1 “(A) in the case of a tobacco product con-
2 tained in the applicable list with respect to
3 which a tobacco product standard has been es-
4 tablished under section 907 or which is subject
5 to section 910, a reference to the authority for
6 the marketing of such tobacco product and a
7 copy of all labeling for such tobacco product;

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

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

24 “(2) BIENNIAL REPORT OF ANY CHANGE IN
25 PRODUCT LIST.—Each person who registers with the

1 Secretary under this section shall report to the Sec-
2 retary once during the month of June of each year
3 and once during the month of December of each
4 year the following:

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

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

23 “(C) If since the date the registrant re-
24 ported under subparagraph (B) a notice of dis-
25 continuance that person has resumed the manu-

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

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

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

17 “(1) IN GENERAL.—Each person who is re-
18 quired to register under this section and who pro-
19 poses to begin the introduction or delivery for intro-
20 duction into interstate commerce for commercial dis-
21 tribution of a tobacco product intended for human
22 use that was not commercially marketed (other than
23 for test marketing) in the United States as of June
24 1, 2003, shall, at least 90 days prior to making such
25 introduction or delivery, report to the Secretary (in

1 such form and manner as the Secretary shall pre-
2 scribe)—

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

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

13 “(2) APPLICATION TO CERTAIN POST JUNE 1,
14 2003 PRODUCTS.—A report under this subsection for
15 a tobacco product that was first introduced or deliv-
16 ered for introduction into interstate commerce for
17 commercial distribution in the United States after
18 June 1, 2003, and prior to the date that is 15
19 months after the date of enactment of the Family
20 Smoking Prevention and Tobacco Control Act shall
21 be submitted to the Secretary not later than 15
22 months after such date of enactment.

23 “(3) EXEMPTIONS.—

24 “(A) IN GENERAL.—The Secretary may by
25 regulation, exempt from the requirements of

1 this subsection tobacco products that are modi-
2 fied by adding or deleting a tobacco additive, or
3 increasing or decreasing the quantity of an ex-
4 isting tobacco additive, if the Secretary deter-
5 mines that—

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

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

14 “(iii) an exemption is otherwise appro-
15 priate.

16 “(B) REGULATIONS.—Not later than 9
17 months after the date of enactment of the Fam-
18 ily Smoking Prevention and Tobacco Control
19 Act, the Secretary shall issue regulations to im-
20 plement this paragraph.

21 **“SEC. 906. GENERAL PROVISIONS RESPECTING CONTROL**
22 **OF TOBACCO PRODUCTS.**

23 “(a) IN GENERAL.—Any requirement established by
24 or under section 902, 903, 905, or 909 applicable to a
25 tobacco product shall apply to such tobacco product until

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

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

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

21 “(2) the period within which interested persons
22 may present their comments on the notice or find-
23 ings (including the need therefore) orally or in writ-
24 ing, which period shall be at least 60 days but may
25 not exceed 90 days unless the time is extended by

1 the Secretary by a notice published in the Federal
2 Register stating good cause therefore.

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

15 “(d) RESTRICTIONS.—

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

1 the Constitution. The finding as to whether such
2 regulation would be 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 non-users of the tobacco prod-
6 uct, 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 No such regulation may require that the sale or dis-
14 tribution of a tobacco product be limited to the writ-
15 ten or oral authorization of a practitioner licensed
16 by law to prescribe medical products.

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

22 “(3) LIMITATIONS.—

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

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

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

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

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

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

1 “(A) IN GENERAL.—The Secretary may, in
2 accordance with subparagraph (B), prescribe
3 regulations (which may differ based on the type
4 of tobacco product involved) requiring that the
5 methods used in, and the facilities and controls
6 used for, the manufacture, pre-production de-
7 sign validation (including a process to assess
8 the performance of a tobacco product), packing
9 and storage of a tobacco product, conform to
10 current good manufacturing practice, as pre-
11 scribed in such regulations, to assure that the
12 public health is protected and that the tobacco
13 product is in compliance with this chapter.
14 Good manufacturing practices may include the
15 testing of raw tobacco for pesticide chemical
16 residues regardless of whether a tolerance for
17 such chemical residues has been established.

18 “(B) REQUIREMENTS.—The Secretary
19 shall—

20 “(i) before promulgating any regula-
21 tion under subparagraph (A), afford the
22 Tobacco Products Scientific Advisory Com-
23 mittee an opportunity to submit rec-
24 ommendations with respect to the regula-
25 tion proposed to be promulgated;

1 “(ii) before promulgating any regula-
2 tion under subparagraph (A), afford oppor-
3 tunity for an oral hearing;

4 “(iii) provide the advisory committee a
5 reasonable time to make its recommenda-
6 tion with respect to proposed regulations
7 under subparagraph (A); and

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

20 “(2) EXEMPTIONS; VARIANCES.—

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

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

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

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

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

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

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

4 Within 60 days after—

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

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

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

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

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

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

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

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

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

19 “(3) COMPLIANCE.—Compliance with require-
20 ments under this subsection shall not be required be-
21 fore the period ending 3 years after the date of en-
22 actment of the Family Smoking Prevention and To-
23 bacco Control Act.

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

1 onstrations respecting tobacco products and may obtain
2 tobacco products for research, testing, and demonstration
3 purposes without regard to section 3324(a) and (b) of title
4 31, United States Code, and section 5 of title 41, United
5 States Code.

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

7 “(a) IN GENERAL.—

8 “(1) SPECIAL RULE FOR CIGARETTES.—A ciga-
9 rette or any of its component parts (including the
10 tobacco, filter, or paper) shall not contain, as a con-
11 stituent (including a smoke constituent) or additive,
12 an artificial or natural flavor (other than tobacco or
13 menthol) or an herb or spice, including strawberry,
14 grape, orange, clove, cinnamon, pineapple, vanilla,
15 coconut, licorice, cocoa, chocolate, cherry, or coffee,
16 that is a characterizing flavor of the tobacco product
17 or tobacco smoke. Nothing in this subparagraph
18 shall be construed to limit the Secretary’s authority
19 to take action under this section or other sections of
20 this Act applicable to menthol or any artificial or
21 natural flavor, herb, or spice not specified in this
22 paragraph.

23 “(2) REVISION OF TOBACCO PRODUCT STAND-
24 ARDS.—The Secretary may revise the tobacco prod-

1 uct standards in paragraph (1) in accordance with
2 subsection (b).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 “(B) consult with other Federal agencies
2 concerned with standard-setting and other na-
3 tionally or internationally recognized standard-
4 setting entities; and

5 “(C) invite appropriate participation,
6 through joint or other conferences, workshops,
7 or other means, by informed persons represent-
8 ative of scientific, professional, industry, agri-
9 cultural, or consumer organizations who in the
10 Secretary’s judgment can make a significant
11 contribution.

12 “(b) ESTABLISHMENT OF STANDARDS.—

13 “(1) NOTICE.—

14 “(A) IN GENERAL.—The Secretary shall
15 publish in the Federal Register a notice of pro-
16 posed rulemaking for the establishment, amend-
17 ment, or revocation of any tobacco product
18 standard.

19 “(B) REQUIREMENTS OF NOTICE.—A no-
20 tice of proposed rulemaking for the establish-
21 ment or amendment of a tobacco product stand-
22 ard for a tobacco product shall—

23 “(i) set forth a finding with sup-
24 porting justification that the tobacco prod-

1 uct standard is appropriate for the protec-
2 tion of the public health;

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

7 “(iii) invite interested persons to sub-
8 mit an existing tobacco product standard
9 for the tobacco product, including a draft
10 or proposed tobacco product standard, for
11 consideration by the Secretary.

12 “(C) STANDARD.—Upon a determination
13 by the Secretary that an additive, constituent
14 (including smoke constituent), or other compo-
15 nent of the product that is the subject of the
16 proposed tobacco product standard is harmful,
17 it shall be the burden of any party challenging
18 the proposed standard to prove that the pro-
19 posed standard will not reduce or eliminate the
20 risk of illness or injury.

21 “(D) FINDING.—A notice of proposed rule-
22 making for the revocation of a tobacco product
23 standard shall set forth a finding with sup-
24 porting justification that the tobacco product

1 standard is no longer appropriate for the pro-
2 tection of the public health.

3 “(E) CONSIDERATION BY SECRETARY.—

4 The Secretary shall consider all information
5 submitted in connection with a proposed stand-
6 ard, including information concerning the coun-
7 tervailing effects of the tobacco product stand-
8 ard on the health of adolescent tobacco users,
9 adult tobacco users, or non-tobacco users, such
10 as the creation of a significant demand for con-
11 traband or other tobacco products that do not
12 meet the requirements of this chapter and the
13 significance of such demand, and shall issue the
14 standard if the Secretary determines that the
15 standard would be appropriate for the protec-
16 tion of the public health.

17 “(F) COMMENT.—The Secretary shall pro-
18 vide for a comment period of not less than 60
19 days.

20 “(2) PROMULGATION.—

21 “(A) IN GENERAL.—After the expiration of
22 the period for comment on a notice of proposed
23 rulemaking published under paragraph (1) re-
24 specting a tobacco product standard and after
25 consideration of such comments and any report

1 from the Tobacco Products Scientific Advisory
2 Committee, the Secretary shall—

3 “(i) promulgate a regulation estab-
4 lishing a tobacco product standard and
5 publish in the Federal Register findings on
6 the matters referred to in paragraph (1);
7 or

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

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

24 “(3) POWER RESERVED TO CONGRESS.—Be-
25 cause of the importance of a decision of the Sec-

1 retary to issue a regulation establishing a tobacco
2 product standard—

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

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

10 “(4) AMENDMENT; REVOCATION.—

11 “(A) AUTHORITY.—The Secretary, upon
12 the Secretary’s own initiative or upon petition
13 of an interested person may by a regulation,
14 promulgated in accordance with the require-
15 ments of paragraphs (1) and (2)(B), amend or
16 revoke a tobacco product standard.

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

1 “(5) REFERENCE TO ADVISORY COMMITTEE.—

2 The Secretary may—

3 “(A) on the Secretary’s own initiative,
4 refer a proposed regulation for the establish-
5 ment, amendment, or revocation of a tobacco
6 product standard; or

7 “(B) upon the request of an interested per-
8 son which demonstrates good cause for referral
9 and which is made before the expiration of the
10 period for submission of comments on such pro-
11 posed regulation,

12 refer such proposed regulation to the Tobacco Products
13 Scientific Advisory Committee, for a report and rec-
14 ommendation with respect to any matter involved in the
15 proposed regulation which requires the exercise of sci-
16 entific judgment. If a proposed regulation is referred
17 under this paragraph to the Tobacco Products Scientific
18 Advisory Committee, the Secretary shall provide the advi-
19 sory committee with the data and information on which
20 such proposed regulation is based. The Tobacco Products
21 Scientific Advisory Committee shall, within 60 days after
22 the referral of a proposed regulation and after inde-
23 pendent study of the data and information furnished to
24 it by the Secretary and other data and information before
25 it, submit to the Secretary a report and recommendation

1 respecting such regulation, together with all underlying
2 data and information and a statement of the reason or
3 basis for the recommendation. A copy of such report and
4 recommendation shall be made public by the Secretary.

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

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

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

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

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

1 Secretary shall consult with the persons who are to give
2 notice under the order.

3 “(b) NO EXEMPTION FROM OTHER LIABILITY.—

4 Compliance with an order issued under this section shall
5 not relieve any person from liability under Federal or
6 State law. In awarding damages for economic loss in an
7 action brought for the enforcement of any such liability,
8 the value to the plaintiff in such action of any remedy
9 provided under such order shall be taken into account.

10 “(c) RECALL AUTHORITY.—

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

1 a recall of such tobacco product. If, after providing
2 an opportunity for such a hearing, the Secretary de-
3 termines that inadequate grounds exist to support
4 the actions required by the order, the Secretary shall
5 vacate the order.

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

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

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

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

1 “(ii) shall provide for notice to per-
2 sons subject to the risks associated with
3 the use of such tobacco product.

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

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

13 **“SEC. 909. RECORDS AND REPORTS ON TOBACCO PROD-**
14 **UCTS.**

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

23 “(1) may require a tobacco product manufac-
24 turer or importer to report to the Secretary when-
25 ever the manufacturer or importer receives or other-

1 wise becomes aware of information that reasonably
2 suggests that one of its marketed tobacco products
3 may have caused or contributed to a serious unex-
4 pected adverse experience associated with the use of
5 the product or any significant increase in the fre-
6 quency of a serious, expected adverse product experi-
7 ence;

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

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

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

24 “(5) when requiring submission of a report or
25 information to the Secretary, shall state the reason

1 or purpose for the submission of such report or in-
2 formation and identify to the fullest extent prac-
3 ticable such report or information; and

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

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

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

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

1 manufacturer or importer if the removal or correc-
2 tion was undertaken—

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

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

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

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

18 **“SEC. 910. APPLICATION FOR REVIEW OF CERTAIN TO-**

19 **BACCO PRODUCTS.**

20 “(a) IN GENERAL.—

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

24 “(A) any tobacco product (including those
25 products in test markets) that was not commer-

1 cially marketed in the United States as of June
2 1, 2003; or

3 “(B) any modification (including a change
4 in design, any component, any part, or any con-
5 stituent, including a smoke constituent, or in
6 the content, delivery or form of nicotine, or any
7 other additive or ingredient) of a tobacco prod-
8 uct where the modified product was commer-
9 cially marketed in the United States after June
10 1, 2003.

11 “(2) PREMARKET APPROVAL REQUIRED.—

12 “(A) NEW PRODUCTS.—Approval under
13 this section of an application for premarket ap-
14 proval for any new tobacco product is required
15 unless—

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

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

20 “(I) is substantially equivalent to
21 a tobacco product commercially mar-
22 keted (other than for test marketing)
23 in the United States as of June 1,
24 2003; and

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

3 “(bb) is exempt from the require-
4 ments of section 905(j) pursuant to a
5 regulation issued under section
6 905(j)(3).

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

10 “(i) that was first introduced or deliv-
11 ered for introduction into interstate com-
12 merce for commercial distribution in the
13 United States after June 1, 2003, and
14 prior to the date that is 15 months after
15 the date of enactment of the Family Smok-
16 ing Prevention and Tobacco Control Act;
17 and

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

23 “(3) SUBSTANTIALLY EQUIVALENT DEFINED.—

24 “(A) IN GENERAL.—In this section and
25 section 905(j), the terms ‘substantially equiva-

1 lent’ or ‘substantial equivalence’ mean, with re-
2 spect to the tobacco product being compared to
3 the predicate tobacco product, that the Sec-
4 retary by order has found that the tobacco
5 product—

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

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

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

21 “(C) LIMITATION.—A tobacco product may
22 not be found to be substantially equivalent to a
23 predicate tobacco product that has been re-
24 moved from the market at the initiative of the

1 Secretary or that has been determined by a ju-
2 dicial order to be misbranded or adulterated.

3 “(4) HEALTH INFORMATION.—

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

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

21 “(b) APPLICATION.—

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

24 “(A) full reports of all information, pub-
25 lished or known to, or which should reasonably

1 be known to, the applicant, concerning inves-
2 tigations which have been made to show the
3 health risks of such tobacco product and wheth-
4 er such tobacco product presents less risk than
5 other tobacco products;

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

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

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

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

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

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

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

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

12 “(B) may, upon the request of an appli-
13 cant,

14 refer such application to the Tobacco Products Sci-
15 entific Advisory Committee for reference and for
16 submission (within such period as the Secretary may
17 establish) of a report and recommendation respect-
18 ing approval of the application, together with all un-
19 derlying data and the reasons or basis for the rec-
20 ommendation.

21 “(c) ACTION ON APPLICATION.—

22 “(1) DEADLINE.—

23 “(A) IN GENERAL.—As promptly as pos-
24 sible, but in no event later than 180 days after
25 the receipt of an application under subsection

1 (b), the Secretary, after considering the report
2 and recommendation submitted under para-
3 graph (2) of such subsection, shall—

4 “(i) issue an order approving the ap-
5 plication if the Secretary finds that none of
6 the grounds for denying approval specified
7 in paragraph (2) of this subsection applies;
8 or

9 “(ii) deny approval of the application
10 if the Secretary finds (and sets forth the
11 basis for such finding as part of or accom-
12 panying such denial) that 1 or more
13 grounds for denial specified in paragraph
14 (2) of this subsection apply.

15 “(B) RESTRICTIONS ON SALE AND DIS-
16 TRIBUTION.—An order approving an application
17 for a tobacco product may require as a condi-
18 tion to such approval that the sale and distribu-
19 tion of the tobacco product be restricted but
20 only to the extent that the sale and distribution
21 of a tobacco product may be restricted under a
22 regulation under section 906(d).

23 “(2) DENIAL OF APPROVAL.—The Secretary
24 shall deny approval of an application for a tobacco
25 product if, upon the basis of the information sub-

1 mitted to the Secretary as part of the application
2 and any other information before the Secretary with
3 respect to such tobacco product, the Secretary finds
4 that—

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

9 “(B) the methods used in, or the facilities
10 or controls used for, the manufacture, proc-
11 essing, or packing of such tobacco product do
12 not conform to the requirements of section
13 906(e);

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

17 “(D) such tobacco product is not shown to
18 conform in all respects to a tobacco product
19 standard in effect under section 907, compli-
20 ance with which is a condition to approval of
21 the application, and there is a lack of adequate
22 information to justify the deviation from such
23 standard.

24 “(3) DENIAL INFORMATION.—Any denial of an
25 application shall, insofar as the Secretary determines

1 to be practicable, be accompanied by a statement in-
2 forming the applicant of the measures required to
3 place such application in approvable form (which
4 measures may include further research by the appli-
5 cant in accordance with 1 or more protocols pre-
6 scribed by the Secretary).

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

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

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

20 “(5) BASIS FOR ACTION.—

21 “(A) INVESTIGATIONS.—For purposes of
22 paragraph (2)(A), whether permitting a tobacco
23 product to be marketed would be appropriate
24 for the protection of the public health shall,
25 when appropriate, be determined on the basis of

1 well-controlled investigations, which may in-
2 clude 1 or more clinical investigations by ex-
3 perts qualified by training and experience to
4 evaluate the tobacco product.

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

13 “(d) WITHDRAWAL AND TEMPORARY SUSPENSION.—

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

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

1 “(B) that the application contained or was
2 accompanied by an untrue statement of a mate-
3 rial fact;

4 “(C) that the applicant—

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

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

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

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

1 reasonable time after receipt of written notice
2 from the Secretary of nonconformity;

3 “(E) on the basis of new information be-
4 fore the Secretary, evaluated together with the
5 evidence before the Secretary when the applica-
6 tion was approved, that the labeling of such to-
7 bacco product, based on a fair evaluation of all
8 material facts, is false or misleading in any par-
9 ticular and was not corrected within a reason-
10 able time after receipt of written notice from
11 the Secretary of such fact; or

12 “(F) on the basis of new information be-
13 fore the Secretary, evaluated together with the
14 evidence before the Secretary when the applica-
15 tion was approved, that such tobacco product is
16 not shown to conform in all respects to a to-
17 bacco product standard which is in effect under
18 section 907, compliance with which was a con-
19 dition to approval of the application, and that
20 there is a lack of adequate information to jus-
21 tify the deviation from such standard.

22 “(2) APPEAL.—The holder of an application
23 subject to an order issued under paragraph (1) with-
24 drawing approval of the application may, by petition
25 filed on or before the 30th day after the date upon

1 which such holder receives notice of such with-
2 drawal, obtain review thereof in accordance with
3 subsection (e).

4 “(3) TEMPORARY SUSPENSION.—If, after pro-
5 viding an opportunity for an informal hearing, the
6 Secretary determines there is reasonable probability
7 that the continuation of distribution of a tobacco
8 product under an approved application would cause
9 serious, adverse health consequences or death, that
10 is greater than ordinarily caused by tobacco prod-
11 ucts on the market, the Secretary shall by order
12 temporarily suspend the approval of the application
13 approved under this section. If the Secretary issues
14 such an order, the Secretary shall proceed expedi-
15 tiously under paragraph (1) to withdraw such appli-
16 cation.

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

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

21 “(2) by mailing the order by registered mail or
22 certified mail addressed to the applicant at the ap-
23 plicant’s last known address in the records of the
24 Secretary.

25 “(f) RECORDS.—

1 “(1) ADDITIONAL INFORMATION.—In the case
2 of any tobacco product for which an approval of an
3 application filed under subsection (b) is in effect, the
4 applicant shall establish and maintain such records,
5 and make such reports to the Secretary, as the Sec-
6 retary may by regulation, or by order with respect
7 to such application, prescribe on the basis of a find-
8 ing that such records and reports are necessary in
9 order to enable the Secretary to determine, or facili-
10 tate a determination of, whether there is or may be
11 grounds for withdrawing or temporarily suspending
12 such approval.

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

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

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

2 “(a) IN GENERAL.—No person may introduce or de-
3 liver for introduction into interstate commerce any modi-
4 fied risk tobacco product unless approval of an application
5 filed pursuant to subsection (d) is effective with respect
6 to such product.

7 “(b) DEFINITIONS.—In this section:

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

14 “(2) SOLD OR DISTRIBUTED.—

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

21 “(i) the label, labeling, or advertising
22 of which represents explicitly or implicitly
23 that—

24 “(I) the tobacco product presents
25 a lower risk of tobacco-related disease
26 or is less harmful than one or more

1 other commercially marketed tobacco
2 products;

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

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

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

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

1 ucts, or presents a reduced exposure to, or
2 does not contain or is free of, a substance
3 or substances.

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

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

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

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

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

21 “(3) the formulation of the product;

22 “(4) sample product labels and labeling;

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

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

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

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

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

19 “(f) ADVISORY COMMITTEE.—

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

23 “(2) RECOMMENDATIONS.—Not later than 60
24 days after the date an application is referred to an
25 advisory committee under paragraph (1), the advi-

1 sory committee shall report its recommendations on
2 the application to the Secretary.

3 “(g) APPROVAL.—

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

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

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

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

19 “(A) IN GENERAL.—The Secretary may
20 approve an application for a tobacco product
21 that has not been approved as a modified risk
22 tobacco product pursuant to paragraph (1) if
23 the Secretary makes the findings required
24 under this paragraph and determines that the
25 applicant has demonstrated that—

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

4 “(ii) any aspect of the label, labeling,
5 and advertising for such product that
6 would cause the tobacco product to be a
7 modified risk tobacco product under sub-
8 section (b)(2) is limited to an explicit or
9 implicit representation that such tobacco
10 product or its smoke contains or is free of
11 a substance or contains a reduced level of
12 a substance, or presents a reduced expo-
13 sure to a substance in tobacco smoke;

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

20 “(iv) the scientific evidence that is
21 available without conducting long-term epi-
22 demiological studies demonstrates that a
23 measurable and substantial reduction in
24 morbidity or mortality among individual

1 tobacco users is anticipated in subsequent
2 studies.

3 “(B) ADDITIONAL FINDINGS REQUIRED.—

4 In order to approve an application under sub-
5 paragraph (A) the Secretary must also find
6 that the applicant has demonstrated that—

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

15 “(ii) the product as actually used by
16 consumers will not expose them to higher
17 levels of other harmful substances com-
18 pared to the similar types of tobacco prod-
19 ucts then on the market unless such in-
20 creases are minimal and the anticipated
21 overall impact of use of the product re-
22 mains a substantial and measurable reduc-
23 tion in overall morbidity and mortality
24 among individual tobacco users;

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

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

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

12 “(iv) approval of the application is ex-
13 pected to benefit the health of the popu-
14 lation as a whole taking into account both
15 users of tobacco products and persons who
16 do not currently use tobacco products.

17 “(C) CONDITIONS OF APPROVAL.—

18 “(i) IN GENERAL.—Applications ap-
19 proved under this paragraph shall be lim-
20 ited to a term of not more than 5 years,
21 but may be renewed upon a finding by the
22 Secretary that the requirements of this
23 paragraph continue to be satisfied based
24 on the filing of a new application.

1 “(ii) AGREEMENTS BY APPLICANT.—
2 Applications approved under this para-
3 graph shall be conditioned on the appli-
4 cant’s agreement to conduct post-market
5 surveillance and studies and to submit to
6 the Secretary the results of such surveil-
7 lance and studies to determine the impact
8 of the application approval on consumer
9 perception, behavior, and health and to en-
10 able the Secretary to review the accuracy
11 of the determinations upon which the ap-
12 proval was based in accordance with a pro-
13 tocol approved by the Secretary.

14 “(iii) ANNUAL SUBMISSION.—The re-
15 sults of such post-market surveillance and
16 studies described in clause (ii) shall be
17 submitted annually.

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

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

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

24 “(4) BENEFIT TO HEALTH OF INDIVIDUALS
25 AND OF POPULATION AS A WHOLE.—In making the

1 determinations under paragraphs (1) and (2), the
2 Secretary shall take into account—

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

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

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

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

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

23 “(h) ADDITIONAL CONDITIONS FOR APPROVAL.—

24 “(1) MODIFIED RISK PRODUCTS.—The Sec-
25 retary shall require for the approval of an applica-

1 tion under this section that any advertising or label-
2 ing concerning modified risk products enable the
3 public to comprehend the information concerning
4 modified risk and to understand the relative signifi-
5 cance of such information in the context of total
6 health and in relation to all of the diseases and
7 health-related conditions associated with the use of
8 tobacco products.

9 “(2) COMPARATIVE CLAIMS.—

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

20 “(B) QUANTITATIVE COMPARISONS.—The
21 Secretary may also require, for purposes of sub-
22 paragraph (A), that the percent (or fraction) of
23 change and identity of the reference tobacco
24 product and a quantitative comparison of the
25 amount of the substance claimed to be reduced

1 shall be stated in immediate proximity to the
2 most prominent claim.

3 “(3) LABEL DISCLOSURE.—

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

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

18 “(4) TIME.—The Secretary shall limit an ap-
19 proval under subsection (g)(1) for a specified period
20 of time.

21 “(5) ADVERTISING.—The Secretary may re-
22 quire that an applicant, whose application has been
23 approved under this subsection, comply with require-
24 ments relating to advertising and promotion of the
25 tobacco product.

1 “(i) POSTMARKET SURVEILLANCE AND STUDIES.—

2 “(1) IN GENERAL.—The Secretary shall require
3 that an applicant under subsection (g)(1) conduct
4 post market surveillance and studies for a tobacco
5 product for which an application has been approved
6 to determine the impact of the application approval
7 on consumer perception, behavior, and health, to en-
8 able the Secretary to review the accuracy of the de-
9 terminations upon which the approval was based,
10 and to provide information that the Secretary deter-
11 mines is otherwise necessary regarding the use or
12 health risks involving the tobacco product. The re-
13 sults of post-market surveillance and studies shall be
14 submitted to the Secretary on an annual basis.

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

1 result in collection of the data or other information
2 designated by the Secretary as necessary to protect
3 the public health.

4 “(j) WITHDRAWAL OF APPROVAL.—The Secretary,
5 after an opportunity for an informal hearing, shall with-
6 draw the approval of an application under this section if
7 the Secretary determines that—

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

13 “(2) the application failed to include material
14 information or included any untrue statement of ma-
15 terial fact;

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

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

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

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

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

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

10 “(k) CHAPTER IV OR V.—A product approved in ac-
11 cordance with this section shall not be subject to chapter
12 IV or V.

13 “(l) IMPLEMENTING REGULATIONS OR GUIDANCE.—

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

22 “(A) establish minimum standards for sci-
23 entific studies needed prior to approval to show
24 that a substantial reduction in morbidity or

1 mortality among individual tobacco users is
2 likely;

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

6 “(C) establish minimum standards for post
7 market studies, that shall include regular and
8 long-term assessments of health outcomes and
9 mortality, intermediate clinical endpoints, con-
10 sumer 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 for which the applicant
12 seeks approval as a modified risk tobacco product
13 under this section.

14 “(m) DISTRIBUTORS.—No distributor may take any
15 action, after the date of enactment of the Family Smoking
16 Prevention and Tobacco Control Act, with respect to a to-
17 bacco product that would reasonably be expected to result
18 in consumers believing that the tobacco product or its
19 smoke may present a lower risk of disease or is less harm-
20 ful than one or more commercially marketed tobacco prod-
21 ucts, or presents a reduced exposure to, or does not con-
22 tain or is free of, a substance 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 for ap-
7 proval under section 910(c),
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 (15 U.S.C. 45(a))
16 and shall be considered a violation of a rule promul-
17 gated under section 18 of that Act (15 U.S.C. 57a).

18 “(b) COORDINATION.—With respect to the require-
19 ments of section 4 of the Federal Cigarette Labeling and
20 Advertising Act (15 U.S.C. 1333) and section 3 of the
21 Comprehensive Smokeless Tobacco Health Education Act
22 of 1986 (15 U.S.C. 4402)—

23 “(1) the Chairman of the Federal Trade Com-
24 mission shall coordinate with the Secretary con-
25 cerning the enforcement of such Act as such enforce-
26 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 regula-
11 tions referred to in section 102 of the Family Smoking
12 Prevention and Tobacco Control Act.

13 **“SEC. 916. REGULATION REQUIREMENT.**

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

21 “(b) CONTENTS OF RULES.—The regulations pro-
22 mulgated under subsection (a) shall require testing and
23 reporting of tobacco product constituents, ingredients, and
24 additives, including smoke constituents, by brand and sub-
25 brand that the Secretary determines should be tested to

1 protect the public health. The regulations may require
2 that tobacco product manufacturers, packagers, or import-
3 ers make disclosures relating to the results of the testing
4 of tar and nicotine through labels or advertising or other
5 appropriate means, and make disclosures regarding the re-
6 sults of the testing of other constituents, including smoke
7 constituents, ingredients, or additives, that the Secretary
8 determines should be disclosed to the public to protect the
9 public health and will not mislead consumers about the
10 risk of tobacco related disease.

11 “(c) **AUTHORITY.**—The Food and Drug Administra-
12 tion shall have the authority under this chapter to conduct
13 or to require the testing, reporting, or disclosure of to-
14 bacco product constituents, including smoke constituents.

15 **“SEC. 917. PRESERVATION OF STATE AND LOCAL AUTHOR-**
16 **ITY.**

17 “(a) **IN GENERAL.**—

18 “(1) **PRESERVATION.**—Nothing in this chapter,
19 or rules promulgated under this chapter, shall be
20 construed to limit the authority of a Federal agency
21 (including the Armed Forces), a State or political
22 subdivision of a State, or the government of an In-
23 dian tribe to enact, adopt, promulgate, and enforce
24 any law, rule, regulation, or other measure with re-
25 spect to tobacco products that is in addition to, or

1 more stringent than, requirements established under
2 this chapter, including a law, rule, regulation, or
3 other measure relating to or prohibiting the sale,
4 distribution, possession, exposure to, access to, ad-
5 vertising and promotion of, or use of tobacco prod-
6 ucts by individuals of any age, information reporting
7 to the State, or measures relating to fire safety
8 standards for tobacco products. No provision of this
9 chapter shall limit or otherwise affect any State,
10 Tribal, or local taxation of tobacco products.

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

13 “(A) IN GENERAL.—Except as provided in
14 paragraph (1) and subparagraph (B), no State
15 or political subdivision of a State may establish
16 or continue in effect with respect to a tobacco
17 product any requirement which is different
18 from, or in addition to, any requirement under
19 the provisions of this chapter relating to to-
20 bacco product standards, premarket approval,
21 adulteration, misbranding, labeling, registra-
22 tion, good manufacturing standards, or modi-
23 fied risk tobacco products.

24 “(B) EXCEPTION.—Subparagraph (A)
25 does not apply to requirements relating to the

1 sale, distribution, possession, information re-
2 porting to the State, exposure to, access to, the
3 advertising and promotion of, or use of, tobacco
4 products by individuals of any age, or relating
5 to fire safety standards for tobacco products.
6 Information disclosed to a State under subpara-
7 graph (A) that is exempt from disclosure under
8 section 554(b)(4) of title 5, United States Code,
9 shall be treated as trade secret and confidential
10 information by the State.

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

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

18 “(a) **ESTABLISHMENT.**—Not later than 1 year after
19 the date of enactment of the Family Smoking Prevention
20 and Tobacco Control Act, the Secretary shall establish a
21 11-member advisory committee, to be known as the ‘To-
22 bacco Products Scientific Advisory Committee’.

23 “(b) **MEMBERSHIP.**—

24 “(1) **IN GENERAL.**—

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

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

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

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

21 “(iv) 1 individual as a representative
22 of the interests in the tobacco manufac-
23 turing industry; and

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

1 “(B) NONVOTING MEMBERS.—The mem-
2 bers of the committee appointed under clauses
3 (iv) and (v) of subparagraph (A) shall serve as
4 consultants to those described in clauses (i)
5 through (iii) of subparagraph (A) and shall be
6 nonvoting representatives.

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

13 “(3) CHAIRPERSON.—The Secretary shall des-
14 ignate 1 of the members of the Advisory Committee
15 to serve as chairperson.

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 for level 4 of the Senior Executive
13 Schedule under section 5382 of title 5, United
14 States Code, for each day (including travel time)
15 they are so engaged; and while so serving away from
16 their homes or regular places of business each mem-
17 ber may be allowed travel expenses, including per
18 diem in lieu of subsistence, as authorized by section
19 5703 of title 5, United States Code, for persons in
20 the Government service employed intermittently.

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

1 **“SEC. 920. USER FEE.**

2 “(a) ESTABLISHMENT OF QUARTERLY USER FEE.—

3 The Secretary shall assess a quarterly user fee with re-
4 spect to every quarter of each fiscal year commencing fis-
5 cal year 2005, calculated in accordance with this section,
6 upon each manufacturer and importer of tobacco products
7 subject to this chapter.

8 “(b) FUNDING OF FDA REGULATION OF TOBACCO

9 PRODUCTS.—The Secretary shall make user fees collected
10 pursuant to this section available to pay, in each fiscal
11 year, for the costs of the activities of the Food and Drug
12 Administration related to the regulation of tobacco prod-
13 ucts under this chapter.

14 “(c) ASSESSMENT OF USER FEE.—

15 “(1) AMOUNT OF ASSESSMENT.—Except as
16 provided in paragraph (4), the total user fees as-
17 sessed each year pursuant to this section shall be
18 sufficient, and shall not exceed what is necessary, to
19 pay for the costs of the activities described in sub-
20 section (b) for each fiscal year.

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

23 “(A) IN GENERAL.—Subject to paragraph
24 (3), the total user fees assessed each fiscal year
25 with respect to each class of importers and
26 manufacturers shall be equal to an amount that

1 is the applicable percentage of the total costs of
2 activities of the Food and Drug Administration
3 described in subsection (b).

4 “(B) APPLICABLE PERCENTAGE.—For
5 purposes of subparagraph (A) the applicable
6 percentage for a fiscal year shall be the fol-
7 lowing:

8 “(i) 92.07 percent shall be assessed
9 on manufacturers and importers of ciga-
10 rettes;

11 “(ii) 0.05 percent shall be assessed on
12 manufacturers and importers of little ci-
13 gars;

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

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

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

22 “(vi) 0.06 percent shall be assessed on
23 manufacturers and importers of pipe to-
24 bacco; and

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

4 “(3) DISTRIBUTION OF FEE SHARES OF MANU-
5 FACTURERS AND IMPORTERS EXEMPT FROM USER
6 FEE.—Where a class of tobacco products is not sub-
7 ject to a user fee under this section, the portion of
8 the user fee assigned to such class under subsection
9 (d)(2) shall be allocated by the Secretary on a pro
10 rata basis among the classes of tobacco products
11 that are subject to a user fee under this section.
12 Such pro rata allocation for each class of tobacco
13 products that are subject to a user fee under this
14 section shall be the quotient of—

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

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

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

22 “(A) for fiscal year 2005 shall be
23 \$85,000,000;

24 “(B) for fiscal year 2006 shall be
25 \$175,000,000;

1 “(C) for fiscal year 2007 shall be
2 \$300,000,000; and

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

8 “(i) the total percentage change that
9 occurred in the Consumer Price Index for
10 all urban consumers (all items; United
11 States city average) for the 12-month pe-
12 riod ending on June 30 of the preceding
13 fiscal year for which fees are being estab-
14 lished; or

15 “(ii) the total percentage change for
16 the previous fiscal year in basic pay under
17 the General Schedule in accordance with
18 section 5332 of title 5, United States
19 Code, as adjusted by any locality-based
20 comparability payment pursuant to section
21 5304 of such title for Federal employees
22 stationed in the District of Columbia.

23 “(5) TIMING OF USER FEE ASSESSMENT.—The
24 Secretary shall notify each manufacturer and im-
25 porter of tobacco products subject to this section of

1 the amount of the quarterly assessment imposed on
2 such manufacturer or importer under subsection (f)
3 during each quarter of each fiscal year. Such notifi-
4 cations shall occur not earlier than 3 months prior
5 to the end of the quarter for which such assessment
6 is made, and payments of all assessments shall be
7 made not later than 60 days after each such notifi-
8 cation.

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

11 “(1) IN GENERAL.—The user fee to be paid by
12 each manufacturer or importer of a given class of to-
13 bacco products shall be determined in each quarter
14 by multiplying—

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

18 “(B) the portion of the user fee amount
19 for the current quarter to be assessed on manu-
20 facturers and importers of such class of tobacco
21 products as determined under subsection (e).

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

1 “(e) DETERMINATION OF VOLUME OF DOMESTIC
2 SALES.—

3 “(1) IN GENERAL.—The calculation of gross
4 domestic volume of a class of tobacco product by a
5 manufacturer or importer, and by all manufacturers
6 and importers as a group, shall be made by the Sec-
7 retary using information provided by manufacturers
8 and importers pursuant to subsection (f), as well as
9 any other relevant information provided to or ob-
10 tained by the Secretary.

11 “(2) MEASUREMENT.—For purposes of the cal-
12 culations under this subsection and the information
13 provided under subsection (f) by the Secretary, gross
14 domestic volume shall be measured by—

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

17 “(B) in the case of little cigars, the num-
18 ber of little cigars sold;

19 “(C) in the case of large cigars, the num-
20 ber of cigars weighing more than 3 pounds per
21 thousand sold; and

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

1 “(f) MEASUREMENT OF GROSS DOMESTIC VOL-
2 UME.—

3 “(1) IN GENERAL.—Each manufacturer and
4 importer of tobacco products shall submit to the
5 Secretary a certified copy of each of the returns or
6 forms described by this paragraph that are required
7 to be filed with a Government agency on the same
8 date that those returns or forms are filed, or re-
9 quired to be filed, with such agency. The returns
10 and forms described by this paragraph are those re-
11 turns and forms related to the release of tobacco
12 products into domestic commerce, as defined by sec-
13 tion 5702(k) of the Internal Revenue Code of 1986,
14 and the repayment of the taxes imposed under chap-
15 ter 52 of such Code (ATF Form 500.24 and United
16 States Customs Form 7501 under currently applica-
17 ble regulations).

18 “(2) PENALTIES.—Any person that knowingly
19 fails to provide information required under this sub-
20 section or that provides false information under this
21 subsection shall be subject to the penalties described
22 in section 1003 of title 18, United States Code. In
23 addition, such person may be subject to a civil pen-
24 alty in an amount not to exceed 2 percent of the
25 value of the kind of tobacco products manufactured

1 or imported by such person during the applicable
2 quarter, as determined by the Secretary.

3 “(h) EFFECTIVE DATE.—The user fees prescribed by
4 this section shall be assessed in fiscal year 2005, based
5 on domestic sales of tobacco products during fiscal year
6 2004 and shall be assessed in each fiscal year thereafter.”.

7 **SEC. 102. INTERIM FINAL RULE.**

8 (a) CIGARETTES AND SMOKELESS TOBACCO.—

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

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

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

1 (B) strike Subpart C—Labeling and sec-
2 tion 897.32(e); and

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

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

10 (4) RULE OF CONSTRUCTION.—Except as pro-
11 vided in paragraph (3), nothing in this section shall
12 be construed to limit the authority of the Secretary
13 to amend, in accordance with the Administrative
14 Procedures Act, the regulation promulgated pursu-
15 ant to this section.

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

24 (1) The preamble to the proposed rule in the
25 document entitled “Regulations Restricting the Sale

1 and Distribution of Cigarettes and Smokeless To-
2 bacco Products to Protect Children and Adoles-
3 cents” (60 Fed. Reg. 41314–41372 (August 11,
4 1995)).

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

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

15 (4) The document entitled “Nicotine in Ciga-
16 rettes and Smokeless Tobacco is a Drug and These
17 Products are Nicotine Delivery Devices Under the
18 Federal Food, Drug, and Cosmetic Act; Jurisdic-
19 tional Determination” (61 Fed. Reg. 44619–45318
20 (August 28, 1996)).

21 **SEC. 103. CONFORMING AND OTHER AMENDMENTS TO GEN-**
22 **ERAL PROVISIONS.**

23 (a) AMENDMENT OF FEDERAL FOOD, DRUG, AND
24 COSMETIC ACT.—Except as otherwise expressly provided,
25 whenever in this section an amendment is expressed in

1 terms of an amendment to, or repeal of, a section or other
2 provision, the reference is to a section or other provision
3 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
4 301 et seq.).

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

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

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

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

13 (4) in subsection (e), by striking “515(f), or
14 519” and inserting “515(f), 519, or 909”;

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

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

19 (7) in subsection (j), by striking “708, or 721”
20 and inserting “708, 721, 904, 905, 906, 907, 908,
21 909, or section 921(b)”;

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

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

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

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

8 “(q)(1) The failure or refusal—

9 “(A) to comply with any requirement prescribed
10 under section 518, 520(g), 903(b)(8), or 908, or
11 condition prescribed under section
12 903(b)(6)(B)(ii)(II);

13 “(B) to furnish any notification or other mate-
14 rial or information required by or under section 519,
15 520(g), 904, 909, or section 921; or

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

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

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

22 and

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

1 “(aa) The sale of tobacco products in violation
2 of a no-tobacco-sale order issued under section
3 303(f).

4 “(bb) The introduction or delivery for introduc-
5 tion into interstate commerce of a tobacco product
6 in violation of section 911.

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

14 “(2) Making, selling, disposing of, or keeping in
15 possession, control, or custody, or concealing any
16 punch, die, plate, stone, or other item that is de-
17 signed to print, imprint, or reproduce the trade-
18 mark, trade name, or other identifying mark, im-
19 print, or device of another or any likeness of any of
20 the foregoing upon any tobacco product or container
21 or labeling thereof so as to render such tobacco
22 product a counterfeit tobacco product.

23 “(3) The doing of any act that causes a tobacco
24 product to be a counterfeit tobacco product, or the

1 sale or dispensing, or the holding for sale or dis-
2 pensing, of a counterfeit tobacco product.

3 “(dd) The charitable distribution of tobacco
4 products.

5 “(ee) The failure of a manufacturer or dis-
6 tributor to notify the Attorney General of their
7 knowledge of tobacco products used in illicit trade.”.

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

10 (1) by striking the subsection heading and in-
11 serting the following:

12 “(f) CIVIL PENALTIES; NO-TOBACCO-SALE OR-
13 DERS.—”;

14 (2) in paragraph (1)(A), by inserting “or to-
15 bacco products” after “devices”;

16 (3) in paragraph (2)(C), by striking “paragraph
17 (3)(A)” and inserting “paragraph (4)(A)”;

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

21 “(3) If the Secretary finds that a person has
22 committed repeated violations of restrictions promul-
23 gated under section 906(d) at a particular retail out-
24 let then the Secretary may impose a no-tobacco-sale
25 order on that person prohibiting the sale of tobacco

1 products in that outlet. A no-tobacco-sale order may
2 be imposed with a civil penalty under paragraph
3 (1).”;

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

5 (A) in subparagraph (A)—

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

10 (ii) by striking “penalty” and insert-
11 ing “penalty, or upon whom a no-tobacco-
12 order is to be imposed,”;

13 (B) in subparagraph (B)—

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

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

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

1 “(D) The Secretary may compromise, mod-
2 ify, or terminate, with or without conditions,
3 any no-tobacco-sale order.”;

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

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

7 (B) by inserting “or the imposition of a
8 no-tobacco-sale order” after “penalty” the first
9 2 places it appears; and

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

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

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

18 (1) in subsection (a)(2)—

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

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

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

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

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

6 (e) SECTION 702.—Section 702(a) (21 U.S.C.
7 372(a)) is amended—

8 (1) by inserting “(1)” after “(a)”; and

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

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

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

17 (1) by inserting “tobacco product,” after “de-
18 vice,” each place it appears; and

19 (2) by inserting “tobacco products,” after “de-
20 vices,” each place it appears.

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

23 (1) in subsection (a)(1)(A), by inserting “to-
24 bacco products,” after “devices,” each place it ap-
25 pears;

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

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

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

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

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

13 (1) in subsection (a)—

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

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

18 (C) by striking “drugs or devices” each
19 time it appears and inserting “drugs, devices,
20 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 2 years after the date of enact-
25 ment of the Family Smoking Prevention and Tobacco

1 Control Act, and annually thereafter, the Secretary shall
2 submit to the Committee on Health, Education, Labor,
3 and Pensions of the Senate and the Committee on Energy
4 and Commerce of the House of Representatives, a report
5 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 (k) SECTION 1003.—Section 1003(d)(2)(C) (as re-
21 designated by section 101(a)) is amended—

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

23 (2) inserting a comma and “and tobacco prod-
24 ucts” after “devices”.

25 (l) GUIDANCE AND EFFECTIVE DATES.—

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

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

10 (B) providing for timely and effective no-
11 tice to the retailer of each alleged violation at
12 a particular retail outlet;

13 (C) providing for an expedited procedure
14 for the administrative appeal of an alleged vio-
15 lation;

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

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

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

8 (i) adopting and enforcing a written
9 policy against sales to minors;

10 (ii) informing its employees of all ap-
11 plicable laws;

12 (iii) establishing disciplinary sanctions
13 for employee noncompliance; and

14 (iv) requiring its employees to verify
15 age by way of photographic identification
16 or electronic scanning device.

17 (2) GENERAL EFFECTIVE DATE.—The amend-
18 ments made by subsection (c), other than the
19 amendment made by paragraph (2) of such sub-
20 section, shall take effect upon the issuance of guid-
21 ance described in paragraph (1).

22 (3) SPECIAL EFFECTIVE DATE.—The amend-
23 ments made by paragraph (2) of subsection (c) shall
24 take effect on 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 Section 4 of the Federal Cigarette Labeling and Ad-
7 vertising Act (15 U.S.C. 1333) is amended to read as fol-
8 lows:

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 your chil-
19 dren’.

20 ‘WARNING: Cigarettes cause fatal lung disease’.

21 ‘WARNING: Cigarettes cause cancer’.

22 ‘WARNING: Cigarettes cause strokes and heart dis-
23 ease’.

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

1 'WARNING: Smoking can kill you'.

2 'WARNING: Tobacco smoke causes fatal lung dis-
3 ease in non-smokers'.

4 'WARNING: Quitting smoking now greatly reduces
5 serious risks to your health'.

6 "(2) PLACEMENT; TYPOGRAPHY; ETC.—

7 "(A) IN GENERAL.—Each label statement
8 required by paragraph (1) shall be located in
9 the upper portion of the front and rear panels
10 of the package, directly on the package under-
11 neath the cellophane or other clear wrapping.
12 Except as provided in subparagraph (B), each
13 label statement shall comprise at least the top
14 30 percent of the front and rear panels of the
15 package. The word 'WARNING' shall appear in
16 capital letters and all text shall be in con-
17 spicuous and legible 17-point type, unless the
18 text of the label statement would occupy more
19 than 70 percent of such area, in which case the
20 text may be in a smaller conspicuous and leg-
21 ible type size, provided that at least 60 percent
22 of such area is occupied by required text. The
23 text shall be black on a white background, or
24 white on a black background, in a manner that
25 contrasts, by typography, layout, or color, with

1 all other printed material on the package, in an
2 alternating fashion under the plan submitted
3 under subsection (b)(4).

4 “(B) HINGED LID BOXES.—For any ciga-
5 rette brand package manufactured or distrib-
6 uted before January 1, 2000, which employs a
7 hinged lid style (if such packaging was used for
8 that brand in commerce prior to June 21,
9 1997), the label statement required by para-
10 graph (1) shall be located on the hinged lid
11 area of the package, even if such area is less
12 than 25 percent of the area of the front panel.
13 Except as provided in this paragraph, the provi-
14 sions of this subsection shall apply to such
15 packages.

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

22 “(4) APPLICABILITY TO RETAILERS.—A retailer
23 of cigarettes shall not be in violation of this sub-
24 section for packaging that is supplied to the retailer
25 by a tobacco product manufacturer, importer, or dis-

1 tributor and is not altered by the retailer in a way
2 that is material to the requirements of this sub-
3 section except that this paragraph shall not relieve
4 a retailer of liability if the retailer sells or distributes
5 tobacco products that are not labeled in accordance
6 with this subsection.

7 “(b) ADVERTISING REQUIREMENTS.—

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

15 “(2) TYPOGRAPHY, ETC.—Each label statement
16 required by subsection (a) of this section in cigarette
17 advertising shall comply with the standards set forth
18 in this paragraph. For press and poster advertise-
19 ments, each such statement and (where applicable)
20 any required statement relating to tar, nicotine, or
21 other constituent (including a smoke constituent)
22 yield shall comprise at least 20 percent of the area
23 of the advertisement and shall appear in a con-
24 spicuous and prominent format and location at the
25 top of each advertisement within the trim area. The

1 Secretary may revise the required type sizes in such
2 area in such manner as the Secretary determines ap-
3 propriate. The word 'WARNING' shall appear in
4 capital letters, and each label statement shall appear
5 in conspicuous and legible type. The text of the label
6 statement shall be black if the background is white
7 and white if the background is black, under the plan
8 submitted under paragraph (4) of this subsection.
9 The label statements shall be enclosed by a rectan-
10 gular border that is the same color as the letters of
11 the statements and that is the width of the first
12 downstroke of the capital 'W' of the word 'WARN-
13 ING' in the label statements. The text of such label
14 statements shall be in a typeface pro rata to the fol-
15 lowing requirements: 45-point type for a whole-page
16 broadsheet newspaper advertisement; 39-point type
17 for a half-page broadsheet newspaper advertisement;
18 39-point type for a whole-page tabloid newspaper ad-
19 vertisement; 27-point type for a half-page tabloid
20 newspaper advertisement; 31.5-point type for a dou-
21 ble page spread magazine or whole-page magazine
22 advertisement; 22.5-point type for a 28 centimeter
23 by 3 column advertisement; and 15-point type for a
24 20 centimeter by 2 column advertisement. The label

1 statements shall be in English, except that in the
2 case of—

3 “(A) an advertisement that appears in a
4 newspaper, magazine, periodical, or other publi-
5 cation that is not in English, the statements
6 shall appear in the predominant language of the
7 publication; and

8 “(B) in the case of any other advertise-
9 ment that is not in English, the statements
10 shall appear in the same language as that prin-
11 cipally used in the advertisement.

12 “(3) MATCHBOOKS.—Notwithstanding para-
13 graph (2), for matchbooks (defined as containing not
14 more than 20 matches) customarily given away with
15 the purchase of tobacco products, each label state-
16 ment required by subsection (a) may be printed on
17 the inside cover of the matchbook.

18 “(4) ADJUSTMENT BY SECRETARY.—The Sec-
19 retary may, through a rulemaking under section 553
20 of title 5, United States Code, adjust the format and
21 type sizes for the label statements required by this
22 section or the text, format, and type sizes of any re-
23 quired tar, nicotine yield, or other constituent (in-
24 cluding smoke constituent) disclosures, or to estab-
25 lish the text, format, and type sizes for any other

1 disclosures required under the Federal Food, Drug,
2 and Cosmetic Act (21 U.S.C. 301 et. seq.). The text
3 of any such label statements or disclosures shall be
4 required to appear only within the 20 percent area
5 of cigarette advertisements provided by paragraph
6 (2) of this subsection. The Secretary shall promul-
7 gate regulations which provide for adjustments in
8 the format and type sizes of any text required to ap-
9 pear in such area to ensure that the total text re-
10 quired to appear by law will fit within such area.

11 “(c) MARKETING REQUIREMENTS.—

12 “(1) RANDOM DISPLAY.—The label statements
13 specified in subsection (a)(1) shall be randomly dis-
14 played in each 12-month period, in as equal a num-
15 ber of times as is possible on each brand of the
16 product and be randomly distributed in all areas of
17 the United States in which the product is marketed
18 in accordance with a plan submitted by the tobacco
19 product manufacturer, importer, distributor, or re-
20 tailer and approved by the Secretary.

21 “(2) ROTATION.—The label statements speci-
22 fied in subsection (a)(1) shall be rotated quarterly in
23 alternating sequence in advertisements for each
24 brand of cigarettes in accordance with a plan sub-
25 mitted by the tobacco product manufacturer, im-

1 porter, distributor, or retailer to, and approved by,
2 the Secretary.

3 “(3) REVIEW.—The Secretary shall review each
4 plan submitted under paragraph (2) and approve it
5 if the plan—

6 “(A) will provide for the equal distribution
7 and display on packaging and the rotation re-
8 quired in advertising under this subsection; and

9 “(B) assures that all of the labels required
10 under this section will be displayed by the to-
11 bacco product manufacturer, importer, dis-
12 tributor, or retailer at the same time.

13 “(4) APPLICABILITY TO RETAILERS.—This sub-
14 section and subsection (b) apply to a retailer only if
15 that retailer is responsible for or directs the label
16 statements required under this section except that
17 this paragraph shall not relieve a retailer of liability
18 if the retailer displays, in a location open to the pub-
19 lic, an advertisement that is not labeled in accord-
20 ance with the requirements of this subsection and
21 subsection (b).”.

22 **SEC. 202. AUTHORITY TO REVISE CIGARETTE WARNING**
23 **LABEL STATEMENTS.**

24 Section 4 of the Federal Cigarette Labeling and Ad-
25 vertising Act (15 U.S.C. 1333), as amended by section

1 201, is further amended by adding at the end the fol-
2 lowing:

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

15 **SEC. 203. STATE REGULATION OF CIGARETTE ADVER-**
16 **TISING AND PROMOTION.**

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

20 “(c) EXCEPTION.—Notwithstanding subsection (b), a
21 State or locality may enact statutes and promulgate regu-
22 lations, based on smoking and health, that take effect
23 after the effective date of the Family Smoking Prevention
24 and Tobacco Control Act, imposing specific bans or re-

1 strictions on the time, place, and manner, but not content,
2 of the advertising or promotion of any cigarettes.”.

3 **SEC. 204. SMOKELESS TOBACCO LABELS AND ADVERTISING**
4 **WARNINGS.**

5 Section 3 of the Comprehensive Smokeless Tobacco
6 Health Education Act of 1986 (15 U.S.C. 4402) is amend-
7 ed to read as follows:

8 **“SEC. 3. SMOKELESS TOBACCO WARNING.**

9 “(a) GENERAL RULE.—

10 “(1) It shall be unlawful for any person to man-
11 ufacture, package, sell, offer to sell, distribute, or
12 import for sale or distribution within the United
13 States any smokeless tobacco product unless the
14 product package bears, in accordance with the re-
15 quirements of this Act, one of the following labels:
16 ‘WARNING: This product can cause mouth cancer’.
17 ‘WARNING: This product can cause gum disease
18 and tooth loss’.
19 ‘WARNING: This product is not a safe alternative
20 to cigarettes’.
21 ‘WARNING: Smokeless tobacco is addictive’.

22 “(2) Each label statement required by para-
23 graph (1) shall be—

24 “(A) located on the 2 principal display
25 panels of the package, and each label statement

1 shall comprise at least 30 percent of each such
2 display panel; and

3 “(B) in 17-point conspicuous and legible
4 type and in black text on a white background,
5 or white text on a black background, in a man-
6 ner that contrasts by typography, layout, or
7 color, with all other printed material on the
8 package, in an alternating fashion under the
9 plan submitted under subsection (b)(3), except
10 that if the text of a label statement would oc-
11 cupy more than 70 percent of the area specified
12 by subparagraph (A), such text may appear in
13 a smaller type size, so long as at least 60 per-
14 cent of such warning area is occupied by the
15 label statement.

16 “(3) The label statements required by para-
17 graph (1) shall be introduced by each tobacco prod-
18 uct manufacturer, packager, importer, distributor, or
19 retailer of smokeless tobacco products concurrently
20 into the distribution chain of such products.

21 “(4) The provisions of this subsection do not
22 apply to a tobacco product manufacturer or dis-
23 tributor of any smokeless tobacco product that does
24 not manufacture, package, or import smokeless to-

1 bacco products for sale or distribution within the
2 United States.

3 “(5) A retailer of smokeless tobacco products
4 shall not be in violation of this subsection for pack-
5 aging that is supplied to the retailer by a tobacco
6 products manufacturer, importer, or distributor and
7 that is not altered by the retailer unless the retailer
8 offers for sale, sells, or distributes a smokeless to-
9 bacco product that is not labeled in accordance with
10 this subsection.

11 “(b) REQUIRED LABELS.—

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

19 “(2) Each label statement required by sub-
20 section (a) in smokeless tobacco advertising shall
21 comply with the standards set forth in this para-
22 graph. For press and poster advertisements, each
23 such statement and (where applicable) any required
24 statement relating to tar, nicotine, or other con-
25 stituent yield shall—

1 “(A) comprise at least 20 percent of the
2 area of the advertisement, and the warning area
3 shall be delineated by a dividing line of con-
4 trasting color from the advertisement; and

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

12 “(3)(A) The label statements specified in sub-
13 section (a)(1) shall be randomly displayed in each
14 12-month period, in as equal a number of times as
15 is possible on each brand of the product and be ran-
16 domly distributed in all areas of the United States
17 in which the product is marketed in accordance with
18 a plan submitted by the tobacco product manufac-
19 turer, importer, distributor, or retailer and approved
20 by the Secretary.

21 “(B) The label statements specified in sub-
22 section (a)(1) shall be rotated quarterly in alter-
23 nating sequence in advertisements for each brand of
24 smokeless tobacco product in accordance with a plan
25 submitted by the tobacco product manufacturer, im-

1 porter, distributor, or retailer to, and approved by,
2 the Secretary.

3 “(C) The Secretary shall review each plan sub-
4 mitted under subparagraph (B) and approve it if the
5 plan—

6 “(i) will provide for the equal distribution
7 and display on packaging and the rotation re-
8 quired in advertising under this subsection; and

9 “(ii) assures that all of the labels required
10 under this section will be displayed by the to-
11 bacco product manufacturer, importer, dis-
12 tributor, or retailer at the same time.

13 “(D) This paragraph applies to a retailer only
14 if that retailer is responsible for or directs the label
15 statements under this section, unless the retailer dis-
16 plays in a location open to the public, an advertise-
17 ment that is not labeled in accordance with the re-
18 quirements of this subsection.

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

1 **SEC. 205. AUTHORITY TO REVISE SMOKELESS TOBACCO**
2 **PRODUCT WARNING LABEL STATEMENTS.**

3 Section 3 of the Comprehensive Smokeless Tobacco
4 Health Education Act of 1986 (15 U.S.C. 4402), as
5 amended by section 203, is further amended by adding
6 at the end the following:

7 “(d) **AUTHORITY TO REVISE WARNING LABEL**
8 **STATEMENTS.**—The Secretary may, by a rulemaking con-
9 ducted under section 553 of title 5, United States Code,
10 adjust the format, type size, and text of any of the label
11 requirements, require color graphics to accompany the
12 text, increase the required label area from 30 percent up
13 to 50 percent of the front and rear panels of the package,
14 or establish the format, type size, and text of any other
15 disclosures required under the Federal Food, Drug, and
16 Cosmetic Act (21 U.S.C. 301 et seq.), if the Secretary
17 finds that such a change would promote greater public un-
18 derstanding of the risks associated with the use of smoke-
19 less tobacco products.”.

20 **SEC. 206. TAR, NICOTINE, AND OTHER SMOKE CON-**
21 **STITUENT DISCLOSURE TO THE PUBLIC.**

22 Section 4(a) of the Federal Cigarette Labeling and
23 Advertising Act (15 U.S.C. 1333 (a)), as amended by sec-
24 tion 201, is further amended by adding at the end the
25 following:

1 “(4)(A) The Secretary shall, by a rulemaking
2 conducted under section 553 of title 5, United
3 States Code, determine (in the Secretary’s sole dis-
4 cretion) whether cigarette and other tobacco product
5 manufacturers shall be required to include in the
6 area of each cigarette advertisement specified by
7 subsection (b) of this section, or on the package
8 label, or both, the tar and nicotine yields of the ad-
9 vertised or packaged brand. Any such disclosure
10 shall be in accordance with the methodology estab-
11 lished under such regulations, shall conform to the
12 type size requirements of subsection (b) of this sec-
13 tion, and shall appear within the area specified in
14 subsection (b) of this section.

15 “(B) Any differences between the requirements
16 established by the Secretary under subparagraph (A)
17 and tar and nicotine yield reporting requirements es-
18 tablished by the Federal Trade Commission shall be
19 resolved by a memorandum of understanding be-
20 tween the Secretary and the Federal Trade Commis-
21 sion.

22 “(C) In addition to the disclosures required by
23 subparagraph (A) of this paragraph, the Secretary
24 may, under a rulemaking conducted under section
25 553 of title 5, United States Code, prescribe disclo-

1 sure requirements regarding the level of any ciga-
2 rette or other tobacco product constituent including
3 any smoke constituent. Any such disclosure may be
4 required if the Secretary determines that disclosure
5 would be of benefit to the public health, or otherwise
6 would increase consumer awareness of the health
7 consequences of the use of tobacco products, except
8 that no such prescribed disclosure shall be required
9 on the face of any cigarette package or advertise-
10 ment. Nothing in this section shall prohibit the Sec-
11 retary from requiring such prescribed disclosure
12 through a cigarette or other tobacco product pack-
13 age or advertisement insert, or by any other means
14 under the Federal Food, Drug, and Cosmetic Act
15 (21 U.S.C. 301 et seq.).

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

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.—The label, packaging, and
12 shipping containers of tobacco products for introduction
13 or delivery for introduction into interstate commerce in the
14 United States shall bear the statement ‘sale only allowed
15 in the United States.’

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

18 “(1) IN GENERAL.—Not later than 9 months
19 after the date of enactment of the Family Smoking
20 Prevention and Tobacco Control Act, the Secretary
21 shall promulgate regulations regarding the establish-
22 ment and maintenance of records by any person who
23 manufactures, processes, transports, distributes, re-
24 ceives, packages, holds, exports, or imports tobacco
25 products.

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.—If
10 the manufacturer or distributor of a tobacco product has
11 knowledge which reasonably supports the conclusion that
12 a tobacco product manufactured or distributed by such
13 manufacturer or distributor that has left the control of
14 such person may be or has been—

15 “(A) imported, exported, distributed or of-
16 ferred for sale in interstate commerce by a per-
17 son without paying duties or taxes required by
18 law; or

19 “(B) imported, exported, distributed or di-
20 verted for possible illicit marketing,

21 the manufacturer or distributor shall promptly notify the
22 Attorney General of such knowledge.

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

1 “(A) the actual knowledge that the manu-
2 facturer or distributor had; or

3 “(B) the knowledge which a reasonable
4 person would have had under like circumstances
5 or which would have been obtained upon the ex-
6 ercise of due care.”.

7 **SEC. 302. STUDY AND REPORT.**

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

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

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

22 (b) **REPORT.**—Not later than 18 months after the
23 date of enactment of this Act, the Comptroller General
24 of the United States shall submit to the Committee on
25 Health, Education, Labor, and Pensions of the Senate and

1 the Committee on Energy and Commerce of the House
2 of Representatives a report on the study described in sub-
3 section (a).

○