

108TH CONGRESS
2D SESSION

S. 2461

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

IN THE SENATE OF THE UNITED STATES

MAY 20, 2004

Mr. DEWINE (for himself and Mr. KENNEDY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

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

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

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

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

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

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

Sec. 5. Severability.

TITLE I—AUTHORITY OF THE FOOD AND DRUG
ADMINISTRATION

Sec. 101. Amendment of Federal food, drug, and cosmetic act.

Sec. 102. Construction of current regulations.

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, record keeping, records inspection.

Sec. 302. Study and report.

1 SEC. 2. FINDINGS.

2 The Congress finds the following:

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

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

11 (3) Nicotine is an addictive drug.

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

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

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

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

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

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

22 (10) The sale, distribution, marketing, adver-
23 tising, and use of tobacco products are activities in
24 and substantially affecting interstate commerce be-
25 cause they are sold, marketed, advertised, and dis-

1 tributed in interstate commerce on a nationwide
2 basis, and have a substantial effect on the Nation's
3 economy.

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

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

16 (13) Tobacco use is the foremost preventable
17 cause of premature death in America. It causes over
18 400,000 deaths in the United States each year and
19 approximately 8,600,000 Americans have chronic ill-
20 nesses related to smoking.

21 (14) Reducing the use of tobacco by minors by
22 50 percent would prevent well over 6,500,000 of to-
23 day's children from becoming regular, daily smokers,
24 saving over 2,000,000 of them from premature
25 death due to tobacco induced disease. Such a reduc-

1 tion in youth smoking would also result in approxi-
2 mately \$75,000,000,000 in savings attributable to
3 reduced health care costs.

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

11 (16) In 2001, the tobacco industry spent more
12 than \$11,000,000,000 to attract new users, retain
13 current users, increase current consumption, and
14 generate favorable long-term attitudes toward smok-
15 ing and tobacco use.

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

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

23 (19) Through advertisements during and spon-
24 sorship of sporting events, tobacco has become
25 strongly associated with sports and has become por-

1 trayed as an integral part of sports and the healthy
2 lifestyle associated with rigorous sporting activity.

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

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

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

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

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

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

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

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

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

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

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

1 sistent with the First Amendment to the United
2 States Constitution and with the standards set forth
3 in the amendments made by this Act for the regula-
4 tion of tobacco products by the Food and Drug Ad-
5 ministration and the restriction on the sale and dis-
6 tribution, including access to and the advertising
7 and promotion of, tobacco products contained in
8 such regulations are substantially related to accom-
9 plishing the public health goals of this Act.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 **SEC. 3. PURPOSE.**

2 The purposes of this Act are—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

11 **SEC. 5. SEVERABILITY.**

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

19 **TITLE I—AUTHORITY OF THE**
20 **FOOD AND DRUG ADMINIS-**
21 **TRATION**

22 **SEC. 101. AMENDMENT OF FEDERAL FOOD, DRUG, AND**
23 **COSMETIC ACT.**

24 (a) DEFINITION OF TOBACCO PRODUCTS.—Section
25 201 of the Federal Food, Drug, and Cosmetic Act (21

1 U.S.C. 321) is amended by adding at the end the fol-
2 lowing:

3 “(m)(1) The term ‘tobacco product’ means any prod-
4 uct made or derived from tobacco that is intended for
5 human consumption, including any component, part, or
6 accessory of a tobacco product (except for raw materials
7 other than tobacco used in manufacturing a component,
8 part, or accessory of a tobacco product).

9 “(2) The term ‘tobacco product’ does not mean—

10 “(A) a product in the form of conventional food
11 (including water and chewing gum), a product rep-
12 resented for use as or for use in a conventional food,
13 or a product that is intended for ingestion in cap-
14 sule, tablet, softgel, or liquid form; or

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

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

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

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

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

5 (2) by redesignating sections 901 through 907
 6 as sections 1001 through 1007; and

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

8 **“CHAPTER IX—TOBACCO**
 9 **PRODUCTS**

10 **“SEC. 900. DEFINITIONS.**

11 “In this chapter:

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

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

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

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

13 “(4) CIGARETTE TOBACCO.—The term ‘ciga-
14 rette tobacco’ means any product that consists of
15 loose tobacco that is intended for use by consumers
16 in a cigarette. Unless otherwise stated, the require-
17 ments for cigarettes shall also apply to cigarette to-
18 bacco.

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

23 “(6) COUNTERFEIT TOBACCO PRODUCT.—The
24 term ‘counterfeit tobacco product’ means a tobacco
25 product (or the container or labeling of such a prod-

1 uct) that, without authorization, bears the trade-
2 mark, trade name, or other identifying mark, im-
3 print or device, or any likeness thereof, of a tobacco
4 product listed in a registration under section
5 905(i)(1).

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

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

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

24 “(10) LITTLE CIGAR.—The term ‘little cigar’
25 has the meaning given that term by section 3(7) of

1 the Federal Cigarette Labeling and Advertising Act
2 (15 U.S.C. 1332(7)).

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

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

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

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

23 “(15) SMOKE CONSTITUENT.—The term ‘smoke
24 constituent’ means any chemical or chemical com-
25 pound in mainstream or sidestream tobacco smoke

1 that either transfers from any component of the cig-
2 arette to the smoke or that is formed by the combus-
3 tion or heating of tobacco, additives, or other compo-
4 nent of the tobacco product.

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

10 “(17) STATE.—The term ‘State’ means any
11 State of the United States and, for purposes of this
12 chapter, includes the District of Columbia, the Com-
13 monwealth of Puerto Rico, Guam, the Virgin Is-
14 lands, American Samoa, Wake Island, Midway Is-
15 lands, Kingman Reef, Johnston Atoll, the Northern
16 Mariana Islands, and any other trust territory or
17 possession of the United States.

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

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

23 “(B) imports a finished cigarette or
24 smokeless tobacco product for sale or distribu-
25 tion in the United States.

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

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

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

13 “(1) such products are intended for use in the
14 diagnosis, cure, mitigation, treatment, or prevention
15 of disease (within the meaning of section
16 201(g)(1)(B) or section 201(h)(2)); or

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

21 “(b) APPLICABILITY.—This chapter shall apply to all
22 tobacco products subject to the regulations referred to in
23 section 102 of the Family Smoking Prevention and To-
24 bacco Control Act, and to any other tobacco products that

1 the Secretary by regulation deems to be subject to this
2 chapter.

3 “(c) SCOPE.—

4 “(1) IN GENERAL.—Nothing in this chapter, or
5 any policy issued or regulation promulgated there-
6 under, or the Family Smoking Prevention and To-
7 bacco Control Act, shall be construed to affect the
8 Secretary’s authority over, or the regulation of,
9 products under this Act that are not tobacco prod-
10 ucts under chapter V or any other chapter.

11 “(2) LIMITATION OF AUTHORITY.—

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

22 “(B) EXCEPTION.—Notwithstanding any
23 other provision of this subparagraph, if a pro-
24 ducer of tobacco leaf is also a tobacco product
25 manufacturer or controlled by a tobacco prod-

1 uct manufacturer, the producer shall be subject
2 to this chapter in the producer’s capacity as a
3 manufacturer.

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

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

12 “A tobacco product shall be deemed to be adulterated
13 if—

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

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

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

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

6 “(5)(A) it is required by section 910(a) to have
7 premarket approval and does not have an approved
8 application in effect;

9 “(B) it is in violation of the order approving
10 such an application; or

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

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

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

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

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

23 “(2) if in package form unless it bears a label
24 containing—

1 “(A) the name and place of business of the
2 tobacco product manufacturer, packer, or dis-
3 tributor;

4 “(B) an accurate statement of the quantity
5 of the contents in terms of weight, measure, or
6 numerical count;

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

11 “(D) the statement required under section
12 921(a),

13 except that under subparagraph (B) reasonable vari-
14 ations shall be permitted, and exemptions as to
15 small packages shall be established, by regulations
16 prescribed by the Secretary;

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

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

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

12 “(6) if it was manufactured, prepared, propa-
13 gated, compounded, or processed in any State in an
14 establishment not duly registered under section
15 905(b), 905(c), 905(d), or 905(h), if it was not in-
16 cluded in a list required by section 905(i), if a notice
17 or other information respecting it was not provided
18 as required by such section or section 905(j), or if
19 it does not bear such symbols from the uniform sys-
20 tem for identification of tobacco products prescribed
21 under section 905(e) as the Secretary by regulation
22 requires;

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

1 “(A) its advertising is false or misleading
2 in any particular; or

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

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

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

15 “(B) a brief statement of—

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

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

1 ingredient of such tobacco product to the
2 extent required in regulations which shall
3 be issued by the Secretary after an oppor-
4 tunity for a hearing;

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

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

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

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

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

15 The Secretary may, by regulation, require prior approval
16 of statements made on the label of a tobacco product. No
17 regulation issued under this subsection may require prior
18 approval by the Secretary of the content of any advertise-
19 ment, except for modified risk tobacco products as pro-
20 vided in section 911. No advertisement of a tobacco prod-
21 uct published after the date of enactment of the Family
22 Smoking Prevention and Tobacco Control Act shall, with
23 respect to the language of label statements as prescribed
24 under section 4 of the Cigarette Labeling and Advertising
25 Act and section 3 of the Comprehensive Smokeless To-

1 bacco Health Education Act of 1986 or the regulations
2 issued under such sections, be subject to the provisions
3 of sections 12 through 15 of the Federal Trade Commis-
4 sion Act (15 U.S.C. 52 through 55).

5 **“SEC. 904. SUBMISSION OF HEALTH INFORMATION TO THE**
6 **SECRETARY.**

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

12 “(1) A listing of all ingredients, including to-
13 bacco, substances, compounds, and additives that
14 are, as of such date, added by the manufacturer to
15 the tobacco, paper, filter, or other part of each to-
16 bacco product by brand and by quantity in each
17 brand and subbrand.

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

24 “(3) A listing of all constituents, including
25 smoke constituents as applicable, identified by the

1 Secretary as harmful or potentially harmful to
2 health in each tobacco product, and as applicable in
3 the smoke of each tobacco product, by brand and by
4 quantity in each brand and subbrand. Effective be-
5 ginning 2 years after the date of enactment of this
6 chapter, the manufacturer, importer, or agent shall
7 comply with regulations promulgated under section
8 915 in reporting information under this paragraph,
9 where applicable.

10 “(4) All documents developed after the date of
11 enactment of the Family Smoking Prevention and
12 Tobacco Control Act that relate to health, toxi-
13 cological, behavioral, or physiologic effects of current
14 or future tobacco products, their constituents (in-
15 cluding smoke constituents), ingredients, compo-
16 nents, and additives.

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

21 “(1) Any or all documents (including under-
22 lying scientific information) relating to research ac-
23 tivities, and research findings, conducted, supported,
24 or possessed by the manufacturer (or agents thereof)
25 on the health, toxicological, behavioral, or physio-

1 logic effects of tobacco products and their constitu-
2 ents (including smoke constituents), ingredients,
3 components, and additives.

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

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

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

21 “(c) TIME FOR SUBMISSION.—

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

1 tion and Tobacco Control Act, the manufacturer of
2 such product shall provide the information required
3 under subsection (a).

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

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

20 “(d) DATA LIST.—

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

1 person, and place on public display (in a manner de-
2 termined by the Secretary) the list established under
3 subsection (e).

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

14 “(e) DATA COLLECTION.—Not later than 12 months
15 after the date of enactment of the Family Smoking Pre-
16 vention and Tobacco Control Act, the Secretary shall es-
17 tablish a list of harmful and potentially harmful constitu-
18 ents, including smoke constituents, to health in each to-
19 bacco product by brand and by quantity in each brand
20 and subbrand. The Secretary shall publish a public notice
21 requesting the submission by interested persons of sci-
22 entific and other information concerning the harmful and
23 potentially harmful constituents in tobacco products and
24 tobacco smoke.

1 **“SEC. 905. ANNUAL REGISTRATION.**

2 “(a) DEFINITIONS.—In this section:

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

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

17 “(b) REGISTRATION BY OWNERS AND OPERATORS.—
18 On or before December 31 of each year every person who
19 owns or operates any establishment in any State engaged
20 in the manufacture, preparation, compounding, or proc-
21 essing of a tobacco product or tobacco products shall reg-
22 ister with the Secretary the name, places of business, and
23 all such establishments of that person.

24 “(c) REGISTRATION OF NEW OWNERS AND OPERA-
25 TORS.—Every person upon first engaging in the manufac-
26 ture, preparation, compounding, or processing of a tobacco

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

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

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

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

22 “(g) BIENNIAL INSPECTION OF REGISTERED ESTAB-
23 LISHMENTS.—Every establishment in any State registered
24 with the Secretary under this section shall be subject to
25 inspection under section 704, and every such establish-

1 ment engaged in the manufacture, compounding, or proc-
2 essing of a tobacco product or tobacco products shall be
3 so inspected by 1 or more officers or employees duly des-
4 ignated by the Secretary at least once in the 2-year period
5 beginning with the date of registration of such establish-
6 ment under this section and at least once in every succes-
7 sive 2-year period thereafter.

8 “(h) FOREIGN ESTABLISHMENTS SHALL REG-
9 ISTER.—Any establishment within any foreign country en-
10 gaged in the manufacture, preparation, compounding, or
11 processing of a tobacco product or tobacco products, shall
12 register under this section under regulations promulgated
13 by the Secretary. Such regulations shall require such es-
14 tablishment to provide the information required by sub-
15 section (i) of this section and shall include provisions for
16 registration of any such establishment upon condition that
17 adequate and effective means are available, by arrange-
18 ment with the government of such foreign country or oth-
19 erwise, to enable the Secretary to determine from time to
20 time whether tobacco products manufactured, prepared,
21 compounded, or processed in such establishment, if im-
22 ported or offered for import into the United States, shall
23 be refused admission on any of the grounds set forth in
24 section 801(a).

25 “(i) REGISTRATION INFORMATION.—

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

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

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

1 and, upon request made by the Secretary for
2 good cause, a copy of all advertisements for a
3 particular tobacco product; and

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

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

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

1 shall be accompanied by the other information
2 required by paragraph (1).

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

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

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

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

7 “(1) IN GENERAL.—Each person who is re-
8 quired to register under this section and who pro-
9 poses to begin the introduction or delivery for intro-
10 duction into interstate commerce for commercial dis-
11 tribution of a tobacco product intended for human
12 use that was not commercially marketed (other than
13 for test marketing) in the United States as of June
14 1, 2003, shall, at least 90 days prior to making such
15 introduction or delivery, report to the Secretary (in
16 such form and manner as the Secretary shall pre-
17 scribe)—

18 “(A) the basis for such person’s determina-
19 tion that the tobacco product is substantially
20 equivalent, within the meaning of section 910,
21 to a tobacco product commercially marketed
22 (other than for test marketing) in the United
23 States as of June 1, 2003, that is in compliance
24 with the requirements of this Act; and

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

4 “(2) APPLICATION TO CERTAIN POST JUNE 1,
5 2003 PRODUCTS.—A report under this subsection for
6 a tobacco product that was first introduced or deliv-
7 ered for introduction into interstate commerce for
8 commercial distribution in the United States after
9 June 1, 2003, and prior to the date that is 15
10 months after the date of enactment of the Family
11 Smoking Prevention and Tobacco Control Act shall
12 be submitted to the Secretary not later than 15
13 months after such date of enactment.

14 “(3) EXEMPTIONS.—

15 “(A) IN GENERAL.—The Secretary may by
16 regulation, exempt from the requirements of
17 this subsection tobacco products that are modi-
18 fied by adding or deleting a tobacco additive, or
19 increasing or decreasing the quantity of an ex-
20 isting tobacco additive, if the Secretary deter-
21 mines that—

22 “(i) such modification would be a
23 minor modification of a tobacco product
24 authorized for sale under this Act;

1 “(ii) a report under this subsection is
2 not necessary to ensure that permitting the
3 tobacco product to be marketed would be
4 appropriate for protection of the public
5 health; and

6 “(iii) an exemption is otherwise appro-
7 priate.

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

13 **“SEC. 906. GENERAL PROVISIONS RESPECTING CONTROL**
14 **OF TOBACCO PRODUCTS.**

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

1 “(b) INFORMATION ON PUBLIC ACCESS AND COM-
2 MENT.—Each notice of proposed rulemaking under section
3 907, 908, 909, 910, or 911 or under this section, any
4 other notice which is published in the Federal Register
5 with respect to any other action taken under any such sec-
6 tion and which states the reasons for such action, and
7 each publication of findings required to be made in con-
8 nection with rulemaking under any such section shall set
9 forth—

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

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

20 “(c) LIMITED CONFIDENTIALITY OF INFORMA-
21 TION.—Any information reported to or otherwise obtained
22 by the Secretary or the Secretary’s representative under
23 section 903, 904, 907, 908, 909, 910, 911, or 704, or
24 under subsection (e) or (f) of this section, which is exempt
25 from disclosure under subsection (a) of section 552 of title

1 5, United States Code, by reason of subsection (b)(4) of
2 that section shall be considered confidential and shall not
3 be disclosed, except that the information may be disclosed
4 to other officers or employees concerned with carrying out
5 this chapter, or when relevant in any proceeding under
6 this chapter.

7 “(d) RESTRICTIONS.—

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

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

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

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

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

16 “(3) LIMITATIONS.—

17 “(A) IN GENERAL.—No restrictions under
18 paragraph (1) may—

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

22 “(ii) establish a minimum age of sale
23 of tobacco products to any person older
24 than 18 years of age.

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

15 “(e) GOOD MANUFACTURING PRACTICE REQUIRE-
16 MENTS.—

17 “(1) METHODS, FACILITIES, AND CONTROLS TO
18 CONFORM.—

19 “(A) IN GENERAL.—The Secretary may, in
20 accordance with subparagraph (B), prescribe
21 regulations (which may differ based on the type
22 of tobacco product involved) requiring that the
23 methods used in, and the facilities and controls
24 used for, the manufacture, pre-production de-
25 sign validation (including a process to assess

1 the performance of a tobacco product), packing
2 and storage of a tobacco product, conform to
3 current good manufacturing practice, as pre-
4 scribed in such regulations, to assure that the
5 public health is protected and that the tobacco
6 product is in compliance with this chapter.
7 Good manufacturing practices may include the
8 testing of raw tobacco for pesticide chemical
9 residues regardless of whether a tolerance for
10 such chemical residues has been established.

11 “(B) REQUIREMENTS.—The Secretary
12 shall—

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

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

22 “(iii) provide the advisory committee a
23 reasonable time to make its recommenda-
24 tion with respect to proposed regulations
25 under subparagraph (A); and

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

13 “(2) EXEMPTIONS; VARIANCES.—

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

21 “(i) in the case of a petition for an ex-
22 emption from a requirement, set forth the
23 basis for the petitioner’s determination
24 that compliance with the requirement is
25 not required to assure that the tobacco

1 product will be in compliance with this
2 chapter;

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

11 “(iii) contain such other information
12 as the Secretary shall prescribe.

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

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

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

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

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

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

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

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

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

12 “(3) COMPLIANCE.—Compliance with require-
13 ments under this subsection shall not be required be-
14 fore the period ending 3 years after the date of en-
15 actment of the Family Smoking Prevention and To-
16 bacco Control Act.

17 “(f) RESEARCH AND DEVELOPMENT.—The Secretary
18 may enter into contracts for research, testing, and dem-
19 onstrations respecting tobacco products and may obtain
20 tobacco products for research, testing, and demonstration
21 purposes without regard to section 3324(a) and (b) of title
22 31, United States Code, and section 5 of title 41, United
23 States Code.

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

25 “(a) IN GENERAL.—

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

16 “(2) REVISION OF TOBACCO PRODUCT STAND-
17 ARDS.—The Secretary may revise the tobacco prod-
18 uct standards in paragraph (1) in accordance with
19 subsection (b).

20 “(3) TOBACCO PRODUCT STANDARDS.—The
21 Secretary may adopt tobacco product standards in
22 addition to those in paragraph (1) if the Secretary
23 finds that a tobacco product standard is appropriate
24 for the protection of the public health. This finding
25 shall be determined with respect to the risks and

1 benefits to the population as a whole, including
2 users and non-users of the tobacco product, and tak-
3 ing into account—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4 “(b) ESTABLISHMENT OF STANDARDS.—

5 “(1) NOTICE.—

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

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

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

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

23 “(iii) invite interested persons to sub-
24 mit an existing tobacco product standard
25 for the tobacco product, including a draft

1 or proposed tobacco product standard, for
2 consideration by the Secretary.

3 “(C) STANDARD.—Upon a determination
4 by the Secretary that an additive, constituent
5 (including smoke constituent), or other compo-
6 nent of the product that is the subject of the
7 proposed tobacco product standard is harmful,
8 it shall be the burden of any party challenging
9 the proposed standard to prove that the pro-
10 posed standard will not reduce or eliminate the
11 risk of illness or injury.

12 “(D) FINDING.—A notice of proposed rule-
13 making for the revocation of a tobacco product
14 standard shall set forth a finding with sup-
15 porting justification that the tobacco product
16 standard is no longer appropriate for the pro-
17 tection of the public health.

18 “(E) CONSIDERATION BY SECRETARY.—
19 The Secretary shall consider all information
20 submitted in connection with a proposed stand-
21 ard, including information concerning the coun-
22 tervailing effects of the tobacco product stand-
23 ard on the health of adolescent tobacco users,
24 adult tobacco users, or non-tobacco users, such
25 as the creation of a significant demand for con-

1 traband or other tobacco products that do not
2 meet the requirements of this chapter and the
3 significance of such demand, and shall issue the
4 standard if the Secretary determines that the
5 standard would be appropriate for the protec-
6 tion of the public health.

7 “(F) COMMENT.—The Secretary shall pro-
8 vide for a comment period of not less than 60
9 days.

10 “(2) PROMULGATION.—

11 “(A) IN GENERAL.—After the expiration of
12 the period for comment on a notice of proposed
13 rulemaking published under paragraph (1) re-
14 specting a tobacco product standard and after
15 consideration of such comments and any report
16 from the Tobacco Products Scientific Advisory
17 Committee, the Secretary shall—

18 “(i) promulgate a regulation estab-
19 lishing a tobacco product standard and
20 publish in the Federal Register findings on
21 the matters referred to in paragraph (1);
22 or

23 “(ii) publish a notice terminating the
24 proceeding for the development of the

1 standard together with the reasons for
2 such termination.

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

15 “(3) POWER RESERVED TO CONGRESS.—Be-
16 cause of the importance of a decision of the Sec-
17 retary to issue a regulation establishing a tobacco
18 product standard—

19 “(A) banning all cigarettes, all smokeless
20 tobacco products, all little cigars, all cigars
21 other than little cigars, all pipe tobacco, or all
22 roll your own tobacco products; or

23 “(B) requiring the reduction of nicotine
24 yields of a tobacco product to zero,

25 Congress expressly reserves to itself such power.

1 “(4) AMENDMENT; REVOCATION.—

2 “(A) AUTHORITY.—The Secretary, upon
3 the Secretary’s own initiative or upon petition
4 of an interested person may by a regulation,
5 promulgated in accordance with the require-
6 ments of paragraphs (1) and (2)(B), amend or
7 revoke a tobacco product standard.

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

16 “(5) REFERENCE TO ADVISORY COMMITTEE.—
17 The Secretary may—

18 “(A) on the Secretary’s own initiative,
19 refer a proposed regulation for the establish-
20 ment, amendment, or revocation of a tobacco
21 product standard; or

22 “(B) upon the request of an interested per-
23 son which demonstrates good cause for referral
24 and which is made before the expiration of the

1 period for submission of comments on such pro-
2 posed regulation,
3 refer such proposed regulation to the Tobacco Products
4 Scientific Advisory Committee, for a report and rec-
5 ommendation with respect to any matter involved in the
6 proposed regulation which requires the exercise of sci-
7 entific judgment. If a proposed regulation is referred
8 under this paragraph to the Tobacco Products Scientific
9 Advisory Committee, the Secretary shall provide the advi-
10 sory committee with the data and information on which
11 such proposed regulation is based. The Tobacco Products
12 Scientific Advisory Committee shall, within 60 days after
13 the referral of a proposed regulation and after inde-
14 pendent study of the data and information furnished to
15 it by the Secretary and other data and information before
16 it, submit to the Secretary a report and recommendation
17 respecting such regulation, together with all underlying
18 data and information and a statement of the reason or
19 basis for the recommendation. A copy of such report and
20 recommendation shall be made public by the Secretary.

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

22 “(a) NOTIFICATION.—If the Secretary determines
23 that—

24 “(1) a tobacco product which is introduced or
25 delivered for introduction into interstate commerce

1 for commercial distribution presents an unreasonable
2 risk of substantial harm to the public health; and

3 “(2) notification under this subsection is nec-
4 essary to eliminate the unreasonable risk of such
5 harm and no more practicable means is available
6 under the provisions of this chapter (other than this
7 section) to eliminate such risk,

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

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

25 “(c) RECALL AUTHORITY.—

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

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

23 “(A) IN GENERAL.—If, after providing an
24 opportunity for an informal hearing under
25 paragraph (1), the Secretary determines that

1 the order should be amended to include a recall
2 of the tobacco product with respect to which the
3 order was issued, the Secretary shall, except as
4 provided in subparagraph (B), amend the order
5 to require a recall. The Secretary shall specify
6 a timetable in which the tobacco product recall
7 will occur and shall require periodic reports to
8 the Secretary describing the progress of the re-
9 call.

10 “(B) NOTICE.—An amended order under
11 subparagraph (A)—

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

14 “(ii) shall provide for notice to per-
15 sons subject to the risks associated with
16 the use of such tobacco product.

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

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

1 **“SEC. 909. RECORDS AND REPORTS ON TOBACCO PROD-**
2 **UCTS.**

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

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

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

24 “(3) shall not impose requirements unduly bur-
25 densome to a tobacco product manufacturer or im-
26 porter, taking into account the cost of complying

1 with such requirements and the need for the protec-
2 tion of the public health and the implementation of
3 this chapter;

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

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

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

23 In prescribing regulations under this subsection, the Sec-
24 retary shall have due regard for the professional ethics of
25 the medical profession and the interests of patients. The

1 prohibitions of paragraph (6) continue to apply to records,
2 reports, and information concerning any individual who
3 has been a patient, irrespective of whether or when he
4 ceases to be a patient.

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

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

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

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

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

24 “(2) EXCEPTION.—No report of the corrective
25 action or removal of a tobacco product may be re-

1 required under paragraph (1) if a report of the correc-
2 tive action or removal is required and has been sub-
3 mitted under subsection (a).

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

6 “(a) IN GENERAL.—

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

10 “(A) any tobacco product (including those
11 products in test markets) that was not commer-
12 cially marketed in the United States as of June
13 1, 2003; or

14 “(B) any modification (including a change
15 in design, any component, any part, or any con-
16 stituent, including a smoke constituent, or in
17 the content, delivery or form of nicotine, or any
18 other additive or ingredient) of a tobacco prod-
19 uct where the modified product was commer-
20 cially marketed in the United States after June
21 1, 2003.

22 “(2) PREMARKET APPROVAL REQUIRED.—

23 “(A) NEW PRODUCTS.—Approval under
24 this section of an application for premarket ap-

1 proval for any new tobacco product is required
2 unless—

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

5 “(ii) the Secretary has issued an order
6 that the tobacco product—

7 “(I) is substantially equivalent to
8 a tobacco product commercially mar-
9 keted (other than for test marketing)
10 in the United States as of June 1,
11 2003; and

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

14 “(bb) is exempt from the require-
15 ments of section 905(j) pursuant to a
16 regulation issued under section
17 905(j)(3).

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

21 “(i) that was first introduced or deliv-
22 ered for introduction into interstate com-
23 merce for commercial distribution in the
24 United States after June 1, 2003, and
25 prior to the date that is 15 months after

1 the date of enactment of the Family Smok-
2 ing Prevention and Tobacco Control Act;
3 and

4 “(ii) for which a report was submitted
5 under section 905(j) within such 15-month
6 period, until the Secretary issues an order
7 that the tobacco product is not substan-
8 tially equivalent.

9 “(3) SUBSTANTIALLY EQUIVALENT DEFINED.—

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

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

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

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

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

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

14 “(4) HEALTH INFORMATION.—

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

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

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

7 “(b) APPLICATION.—

8 “(1) CONTENTS.—An application for premarket
9 approval shall contain—

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

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

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

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

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

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

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

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

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

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

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

8 “(c) ACTION ON APPLICATION.—

9 “(1) DEADLINE.—

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

16 “(i) issue an order approving the ap-
17 plication if the Secretary finds that none of
18 the grounds for denying approval specified
19 in paragraph (2) of this subsection applies;
20 or

21 “(ii) deny approval of the application
22 if the Secretary finds (and sets forth the
23 basis for such finding as part of or accom-
24 panying such denial) that 1 or more

1 grounds for denial specified in paragraph
2 (2) of this subsection apply.

3 “(B) RESTRICTIONS ON SALE AND DIS-
4 TRIBUTION.—An order approving an application
5 for a tobacco product may require as a condi-
6 tion to such approval that the sale and distribu-
7 tion of the tobacco product be restricted but
8 only to the extent that the sale and distribution
9 of a tobacco product may be restricted under a
10 regulation under section 906(d).

11 “(2) DENIAL OF APPROVAL.—The Secretary
12 shall deny approval of an application for a tobacco
13 product if, upon the basis of the information sub-
14 mitted to the Secretary as part of the application
15 and any other information before the Secretary with
16 respect to such tobacco product, the Secretary finds
17 that—

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

22 “(B) the methods used in, or the facilities
23 or controls used for, the manufacture, proc-
24 essing, or packing of such tobacco product do

1 not conform to the requirements of section
2 906(e);

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

6 “(D) such tobacco product is not shown to
7 conform in all respects to a tobacco product
8 standard in effect under section 907, compli-
9 ance with which is a condition to approval of
10 the application, and there is a lack of adequate
11 information to justify the deviation from such
12 standard.

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

21 “(4) BASIS FOR FINDING.—For purposes of
22 this section, the finding as to whether approval of a
23 tobacco product is appropriate for the protection of
24 the public health shall be determined with respect to
25 the risks and benefits to the population as a whole,

1 including users and nonusers of the tobacco product,
2 and taking into account—

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

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

9 “(5) BASIS FOR ACTION.—

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

19 “(B) OTHER EVIDENCE.—If the Secretary
20 determines that there exists valid scientific evi-
21 dence (other than evidence derived from inves-
22 tigations described in subparagraph (A)) which
23 is sufficient to evaluate the tobacco product the
24 Secretary may authorize that the determination

1 for purposes of paragraph (2)(A) be made on
2 the basis of such evidence.

3 “(d) WITHDRAWAL AND TEMPORARY SUSPENSION.—

4 “(1) IN GENERAL.—The Secretary shall, upon
5 obtaining, where appropriate, advice on scientific
6 matters from an advisory committee, and after due
7 notice and opportunity for informal hearing to the
8 holder of an approved application for a tobacco
9 product, issue an order withdrawing approval of the
10 application if the Secretary finds—

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

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

17 “(C) that the applicant—

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

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

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

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

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

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

1 evidence before the Secretary when the applica-
2 tion was approved, that such tobacco product is
3 not shown to conform in all respects to a to-
4 bacco product standard which is in effect under
5 section 907, compliance with which was a con-
6 dition to approval of the application, and that
7 there is a lack of adequate information to jus-
8 tify the deviation from such standard.

9 “(2) APPEAL.—The holder of an application
10 subject to an order issued under paragraph (1) with-
11 drawing approval of the application may, by petition
12 filed on or before the 30th day after the date upon
13 which such holder receives notice of such with-
14 drawal, obtain review thereof in accordance with
15 subsection (e).

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

1 such an order, the Secretary shall proceed expedi-
2 tiously under paragraph (1) to withdraw such appli-
3 cation.

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

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

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

12 “(f) RECORDS.—

13 “(1) ADDITIONAL INFORMATION.—In the case
14 of any tobacco product for which an approval of an
15 application filed under subsection (b) is in effect, the
16 applicant shall establish and maintain such records,
17 and make such reports to the Secretary, as the Sec-
18 retary may by regulation, or by order with respect
19 to such application, prescribe on the basis of a find-
20 ing that such records and reports are necessary in
21 order to enable the Secretary to determine, or facili-
22 tate a determination of, whether there is or may be
23 grounds for withdrawing or temporarily suspending
24 such approval.

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

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

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

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

19 “(b) DEFINITIONS.—In this section:

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

1 “(2) SOLD OR DISTRIBUTED.—

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

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

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

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

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

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

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

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

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

1 risk tobacco product under this section and is subject to
2 the requirements of chapter V.

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

5 Such application shall include—

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

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

9 “(3) the formulation of the product;

10 “(4) sample product labels and labeling;

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

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

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

24 “(e) PUBLIC AVAILABILITY.—The Secretary shall
25 make the application described in subsection (d) publicly

1 available (except matters in the application which are
2 trade secrets or otherwise confidential, commercial infor-
3 mation) and shall request comments by interested persons
4 on the information contained in the application and on the
5 label, labeling, and advertising accompanying such appli-
6 cation.

7 “(f) ADVISORY COMMITTEE.—

8 “(1) IN GENERAL.—The Secretary shall refer to
9 an advisory committee any application submitted
10 under this subsection.

11 “(2) RECOMMENDATIONS.—Not later than 60
12 days after the date an application is referred to an
13 advisory committee under paragraph (1), the advi-
14 sory committee shall report its recommendations on
15 the application to the Secretary.

16 “(g) APPROVAL.—

17 “(1) MODIFIED RISK PRODUCTS.—Except as
18 provided in paragraph (2), the Secretary shall ap-
19 prove an application for a modified risk tobacco
20 product filed under this section only if the Secretary
21 determines that the applicant has demonstrated that
22 such product, as it is actually used by consumers,
23 will—

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

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

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

9 “(A) IN GENERAL.—The Secretary may
10 approve an application for a tobacco product
11 that has not been approved as a modified risk
12 tobacco product pursuant to paragraph (1) if
13 the Secretary makes the findings required
14 under this paragraph and determines that the
15 applicant has demonstrated that—

16 “(i) the approval of the application
17 would be appropriate to promote the public
18 health;

19 “(ii) any aspect of the label, labeling,
20 and advertising for such product that
21 would cause the tobacco product to be a
22 modified risk tobacco product under sub-
23 section (b)(2) is limited to an explicit or
24 implicit representation that such tobacco
25 product or its smoke contains or is free of

1 a substance or contains a reduced level of
2 a substance, or presents a reduced expo-
3 sure to a substance in tobacco smoke.

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

10 “(iv) the scientific evidence that is
11 available without conducting long-term epi-
12 demiological studies demonstrates that a
13 measurable and substantial reduction in
14 morbidity or mortality among individual
15 tobacco users is anticipated in subsequent
16 studies.

17 “(B) ADDITIONAL FINDINGS REQUIRED.—

18 In order to approve an application under sub-
19 paragraph (A) the Secretary must also find
20 that the applicant has demonstrated that—

21 “(i) the magnitude of the overall re-
22 ductions in exposure to the substance or
23 substances which are the subject of the ap-
24 plication is substantial, such substance or
25 substances are harmful, and the product as

1 actually used exposes consumers to the
2 specified reduced level of the substance or
3 substances;

4 “(ii) the product as actually used by
5 consumers will not expose them to higher
6 levels of other harmful substances com-
7 pared to the similar types of tobacco prod-
8 ucts then on the market unless such in-
9 creases are minimal and the anticipated
10 overall impact of use of the product re-
11 mains a substantial and measurable reduc-
12 tion in overall morbidity and mortality
13 among individual tobacco users;

14 “(iii) testing of actual consumer per-
15 ception shows that, as the applicant pro-
16 poses to label and market the product, con-
17 sumers will not be misled into believing
18 that the product—

19 “(I) is or has been demonstrated
20 to be less harmful; or

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

1 “(iv) approval of the application is ex-
2 pected to benefit the health of the popu-
3 lation as a whole taking into account both
4 users of tobacco products and persons who
5 do not currently use tobacco products.

6 “(C) CONDITIONS OF APPROVAL.—

7 “(i) IN GENERAL.—Applications ap-
8 proved under this paragraph shall be lim-
9 ited to a term of not more than 5 years,
10 but may be renewed upon a finding by the
11 Secretary that the requirements of this
12 paragraph continue to be satisfied based
13 on the filing of a new application.

14 “(ii) AGREEMENTS BY APPLICANT.—
15 Applications approved under this para-
16 graph shall be conditioned on the appli-
17 cant’s agreement to conduct post-market
18 surveillance and studies and to submit to
19 the Secretary the results of such surveil-
20 lance and studies to determine the impact
21 of the application approval on consumer
22 perception, behavior, and health and to en-
23 able the Secretary to review the accuracy
24 of the determinations upon which the ap-

1 proval was based in accordance with a pro-
2 tocol approved by the Secretary.

3 “(iii) ANNUAL SUBMISSION.—The re-
4 sults of such post-market surveillance and
5 studies described in clause (ii) shall be
6 submitted annually.

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

9 “(A) the scientific evidence submitted by
10 the applicant; and

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

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

17 “(A) the relative health risks to individuals
18 of the tobacco product that is the subject of the
19 application;

20 “(B) the increased or decreased likelihood
21 that existing users of tobacco products who
22 would otherwise stop using such products will
23 switch to the tobacco product that is the subject
24 of the application;

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

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

11 “(E) comments, data, and information
12 submitted by interested persons.

13 “(h) ADDITIONAL CONDITIONS FOR APPROVAL.—

14 “(1) MODIFIED RISK PRODUCTS.—The Sec-
15 retary shall require for the approval of an applica-
16 tion under this section that any advertising or label-
17 ing concerning modified risk products enable the
18 public to comprehend the information concerning
19 modified risk and to understand the relative signifi-
20 cance of such information in the context of total
21 health and in relation to all of the diseases and
22 health-related conditions associated with the use of
23 tobacco products.

24 “(2) COMPARATIVE CLAIMS.—

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

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

19 “(3) LABEL DISCLOSURE.—

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

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

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

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

12 “(5) ADVERTISING.—The Secretary may re-
13 quire that an applicant, whose application has been
14 approved under this subsection, comply with require-
15 ments relating to advertising and promotion of the
16 tobacco product.

17 “(i) POSTMARKET SURVEILLANCE AND STUDIES.—

18 “(1) IN GENERAL.—The Secretary shall require
19 that an applicant under subsection (g)(1) conduct
20 post market surveillance and studies for a tobacco
21 product for which an application has been approved
22 to determine the impact of the application approval
23 on consumer perception, behavior, and health, to en-
24 able the Secretary to review the accuracy of the de-
25 terminations upon which the approval was based,

1 and to provide information that the Secretary deter-
2 mines is otherwise necessary regarding the use or
3 health risks involving the tobacco product. The re-
4 sults of post-market surveillance and studies shall be
5 submitted to the Secretary on an annual basis.

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

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

24 “(1) the applicant, based on new information,
25 can no longer make the demonstrations required

1 under subsection (g), or the Secretary can no longer
2 make the determinations required under subsection
3 (g);

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

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

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

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

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

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

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

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

4 “(l) IMPLEMENTING REGULATIONS OR GUIDANCE.—

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

13 “(A) establish minimum standards for sci-
14 entific studies needed prior to approval to show
15 that a substantial reduction in morbidity or
16 mortality among individual tobacco users is
17 likely;

18 “(B) include validated biomarkers, inter-
19 mediate clinical endpoints, and other feasible
20 outcome measures, as appropriate;

21 “(C) establish minimum standards for post
22 market studies, that shall include regular and
23 long-term assessments of health outcomes and
24 mortality, intermediate clinical endpoints, con-
25 sumer perception of harm reduction, and the

1 impact on quitting behavior and new use of to-
2 bacco products, as appropriate;

3 “(D) establish minimum standards for re-
4 quired postmarket surveillance, including ongo-
5 ing assessments of consumer perception; and

6 “(E) require that data from the required
7 studies and surveillance be made available to
8 the Secretary prior to the decision on renewal
9 of a modified risk tobacco product.

10 “(2) CONSULTATION.—The regulations or guid-
11 ance issued under paragraph (1) shall be developed
12 in consultation with the Institute of Medicine, and
13 with the input of other appropriate scientific and
14 medical experts, on the design and conduct of such
15 studies and surveillance.

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

20 “(4) NEW TOBACCO PRODUCTS.—Not later
21 than 2 years after the date of enactment of the
22 Family Smoking Prevention and Tobacco Control
23 Act, the Secretary shall issue a regulation or guid-
24 ance that permits the filing of a single application
25 for any tobacco product that is a new tobacco prod-

1 uct under section 910 and for which the applicant
2 seeks approval as a modified risk tobacco product
3 under this section.

4 “(m) DISTRIBUTORS.—No distributor may take any
5 action, after the date of enactment of the Family Smoking
6 Prevention and Tobacco Control Act, with respect to a to-
7 bacco product that would reasonably be expected to result
8 in consumers believing that the tobacco product or its
9 smoke may present a lower risk of disease or is less harm-
10 ful than one or more commercially marketed tobacco prod-
11 ucts, or presents a reduced exposure to, or does not con-
12 tain or is free of, a substance or substances.

13 **“SEC. 912. JUDICIAL REVIEW.**

14 “(a) RIGHT TO REVIEW.—

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

17 “(A) the promulgation of a regulation
18 under section 907 establishing, amending, or
19 revoking a tobacco product standard; or

20 “(B) a denial of an application for ap-
21 proval under section 910(c),

22 any person adversely affected by such regulation or
23 denial may file a petition for judicial review of such
24 regulation or denial with the United States Court of
25 Appeals for the District of Columbia or for the cir-

1 cuit in which such person resides or has their prin-
2 cipal place of business.

3 “(2) REQUIREMENTS.—

4 “(A) COPY OF PETITION.—A copy of the
5 petition filed under paragraph (1) shall be
6 transmitted by the clerk of the court involved to
7 the Secretary.

8 “(B) RECORD OF PROCEEDINGS.—On re-
9 ceipt of a petition under subparagraph (A), the
10 Secretary shall file in the court in which such
11 petition was filed—

12 “(i) the record of the proceedings on
13 which the regulation or order was based;
14 and

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

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

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

22 “(ii) all information submitted to the
23 Secretary with respect to such regulation
24 or order;

1 “(iii) proceedings of any panel or ad-
2 visory committee with respect to such reg-
3 ulation or order;

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

6 “(v) any other information identified
7 by the Secretary, in the administrative pro-
8 ceeding held with respect to such regula-
9 tion or order, as being relevant to such
10 regulation or order.

11 “(b) STANDARD OF REVIEW.—Upon the filing of the
12 petition under subsection (a) for judicial review of a regu-
13 lation or order, the court shall have jurisdiction to review
14 the regulation or order in accordance with chapter 7 of
15 title 5, United States Code, and to grant appropriate re-
16 lief, including interim relief, as provided for in such chap-
17 ter. A regulation or denial described in subsection (a) shall
18 be reviewed in accordance with section 706(2)(A) of title
19 5, United States Code.

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

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

4 “(e) REGULATIONS AND ORDERS MUST RECITE
5 BASIS IN RECORD.—To facilitate judicial review, a regula-
6 tion or order issued under section 906, 907, 908, 909,
7 910, or 916 shall contain a statement of the reasons for
8 the issuance of such regulation or order in the record of
9 the proceedings held in connection with its issuance.

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

11 “The Secretary shall issue regulations to require that
12 retail establishments for which the predominant business
13 is the sale of tobacco products comply with any advertising
14 restrictions applicable to retail establishments accessible
15 to individuals under the age of 18.

16 **“SEC. 914. JURISDICTION OF AND COORDINATION WITH**
17 **THE FEDERAL TRADE COMMISSION.**

18 “(a) JURISDICTION.—

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

1 “(2) ENFORCEMENT.—Any advertising that vio-
2 lates this chapter or a provision of the regulations
3 referred to in section 102 of the Family Smoking
4 Prevention and Tobacco Control Act, is an unfair or
5 deceptive act or practice under section 5(a) of the
6 Federal Trade Commission Act (15 U.S.C. 45(a))
7 and shall be considered a violation of a rule promul-
8 gated under section 18 of that Act (15 U.S.C. 57a).

9 “(b) COORDINATION.—With respect to the require-
10 ments of section 4 of the Federal Cigarette Labeling and
11 Advertising Act (15 U.S.C. 1333) and section 3 of the
12 Comprehensive Smokeless Tobacco Health Education Act
13 of 1986 (15 U.S.C. 4402)—

14 “(1) the Chairman of the Federal Trade Com-
15 mission shall coordinate with the Secretary con-
16 cerning the enforcement of such Act as such enforce-
17 ment relates to unfair or deceptive acts or practices
18 in the advertising of cigarettes or smokeless tobacco;
19 and

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

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

24 “‘In accordance with section 801 of title 5, United
25 States Code, Congress shall review, and may disapprove,

1 any rule under this chapter that is subject to section 801.
2 This section and section 801 do not apply to the regula-
3 tions referred to in section 102 of the Family Smoking
4 Prevention and Tobacco Control Act.

5 **“SEC. 916. REGULATION REQUIREMENT.**

6 “(a) TESTING, REPORTING, AND DISCLOSURE.—Not
7 later than 24 months after the date of enactment of the
8 Family Smoking Prevention and Tobacco Control Act, the
9 Secretary, acting through the Commissioner of the Food
10 and Drug Administration, shall promulgate regulations
11 under this Act that meet the requirements of subsection
12 (b).

13 “(b) CONTENTS OF RULES.—The regulations pro-
14 mulgated under subsection (a) shall require testing and
15 reporting of tobacco product constituents, ingredients, and
16 additives, including smoke constituents, by brand and sub-
17 brand that the Secretary determines should be tested to
18 protect the public health. The regulations may require
19 that tobacco product manufacturers, packagers, or import-
20 ers make disclosures relating to the results of the testing
21 of tar and nicotine through labels or advertising or other
22 appropriate means, and make disclosures regarding the re-
23 sults of the testing of other constituents, including smoke
24 constituents, ingredients, or additives, that the Secretary
25 determines should be disclosed to the public to protect the

1 public health and will not mislead consumers about the
2 risk of tobacco related disease.

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

7 **“SEC. 917. PRESERVATION OF STATE AND LOCAL AUTHOR-**
8 **ITY.**

9 “(a) **IN GENERAL.**—

10 “(1) **PRESERVATION.**—Nothing in this chapter,
11 or rules promulgated under this chapter, shall be
12 construed to limit the authority of a Federal agency
13 (including the Armed Forces), a State or political
14 subdivision of a State, or the government of an In-
15 dian tribe to enact, adopt, promulgate, and enforce
16 any law, rule, regulation, or other measure with re-
17 spect to tobacco products that is in addition to, or
18 more stringent than, requirements established under
19 this chapter, including a law, rule, regulation, or
20 other measure relating to or prohibiting the sale,
21 distribution, possession, exposure to, access to, ad-
22 vertising and promotion of, or use of tobacco prod-
23 ucts by individuals of any age, information reporting
24 to the State, or measures relating to fire safety
25 standards for tobacco products. No provision of this

1 chapter shall limit or otherwise affect any State,
2 Tribal, or local taxation of tobacco products.

3 “(2) PREEMPTION OF CERTAIN STATE AND
4 LOCAL REQUIREMENTS.—

5 “(A) IN GENERAL.—Except as provided in
6 paragraph (1) and subparagraph (B), no State
7 or political subdivision of a State may establish
8 or continue in effect with respect to a tobacco
9 product any requirement which is different
10 from, or in addition to, any requirement under
11 the provisions of this chapter relating to to-
12 bacco product standards, premarket approval,
13 adulteration, misbranding, labeling, registra-
14 tion, good manufacturing standards, or reduced
15 risk products.

16 “(B) EXCEPTION.—Subparagraph (A)
17 does not apply to requirements relating to the
18 sale, distribution, possession, information re-
19 porting to the State, exposure to, access to, the
20 advertising and promotion of, or use of, tobacco
21 products by individuals of any age, or relating
22 to fire safety standards for tobacco products.
23 Information disclosed to a State under subpara-
24 graph (A) that is exempt from disclosure under
25 section 554(b)(4) of title 5, United States Code,

1 shall be treated as trade secret and confidential
2 information by the State.

3 “(b) **RULE OF CONSTRUCTION REGARDING PRODUCT**
4 **LIABILITY.**—No provision of this chapter relating to a to-
5 bacco product shall be construed to modify or otherwise
6 affect any action or the liability of any person under the
7 product liability law of any State.

8 **“SEC. 918. TOBACCO PRODUCTS SCIENTIFIC ADVISORY**
9 **COMMITTEE.**

10 “(a) **ESTABLISHMENT.**—Not later than 1 year after
11 the date of enactment of the Family Smoking Prevention
12 and Tobacco Control Act, the Secretary shall establish a
13 11-member advisory committee, to be known as the ‘To-
14 bacco Products Scientific Advisory Committee’.

15 “(b) **MEMBERSHIP.**—

16 “(1) **IN GENERAL.**—

17 “(A) **MEMBERS.**—The Secretary shall ap-
18 point as members of the Tobacco Products Sci-
19 entific Advisory Committee individuals who are
20 technically qualified by training and experience
21 in the medicine, medical ethics, science, or tech-
22 nology involving the manufacture, evaluation, or
23 use of tobacco products, who are of appro-
24 priately diversified professional backgrounds.

25 The committee shall be composed of—

1 “(i) 7 individuals who are physicians,
2 dentists, scientists, or health care profes-
3 sionals practicing in the area of oncology,
4 pulmonology, cardiology, toxicology, phar-
5 macology, addiction, or any other relevant
6 specialty;

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

10 “(iii) 1 individual as a representative
11 of the general public;

12 “(iv) 1 individual as a representative
13 of the interests in the tobacco manufac-
14 turing industry; and

15 “(v) 1 individual as a representative
16 of the interests of the tobacco growers.

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

23 “(2) LIMITATION.—The Secretary may not ap-
24 point to the Advisory Committee any individual who
25 is in the regular full-time employ of the Food and

1 Drug Administration or any agency responsible for
2 the enforcement of this Act. The Secretary may ap-
3 point Federal officials as ex officio members.

4 “(3) CHAIRPERSON.—The Secretary shall des-
5 ignate 1 of the members of the Advisory Committee
6 to serve as chairperson.

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

10 “(1) as provided in this chapter;

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

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

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

19 “(d) COMPENSATION; SUPPORT; FACA.—

20 “(1) COMPENSATION AND TRAVEL.—Members
21 of the Advisory Committee who are not officers or
22 employees of the United States, while attending con-
23 ferences or meetings of the committee or otherwise
24 engaged in its business, shall be entitled to receive
25 compensation at rates to be fixed by the Secretary,

1 which may not exceed the daily equivalent of the
2 rate in effect for level 4 of the Senior Executive
3 Schedule under section 5382 of title 5, United
4 States Code, for each day (including travel time)
5 they are so engaged; and while so serving away from
6 their homes or regular places of business each mem-
7 ber may be allowed travel expenses, including per
8 diem in lieu of subsistence, as authorized by section
9 5703 of title 5, United States Code, for persons in
10 the Government service employed intermittently.

11 “(2) ADMINISTRATIVE SUPPORT.—The Sec-
12 retary shall furnish the Advisory Committee clerical
13 and other assistance.

14 “(3) NONAPPLICATION OF FACIA.—Section 14 of
15 the Federal Advisory Committee Act (5 U.S.C.
16 App.) does not apply to the Advisory Committee.

17 “(e) PROCEEDINGS OF ADVISORY PANELS AND COM-
18 MITTEES.—The Advisory Committee shall make and
19 maintain a transcript of any proceeding of the panel or
20 committee. Each such panel and committee shall delete
21 from any transcript made under this subsection informa-
22 tion which is exempt from disclosure under section 552(b)
23 of title 5, United States Code.

1 **“SEC. 919. DRUG PRODUCTS USED TO TREAT TOBACCO DE-**
2 **PENDENCE.**

3 The Secretary shall consider—

4 “(1) at the request of the applicant, designating
5 nicotine replacement products as fast track research
6 and approval products within the meaning of section
7 506;

8 “(2) direct the Commissioner to consider ap-
9 proving the extended use of nicotine replacement
10 products (such as nicotine patches, nicotine gum,
11 and nicotine lozenges) for the treatment of tobacco
12 dependence;

13 “(3) review and consider the evidence for addi-
14 tional indications for nicotine replacement products,
15 such as for craving relief or relapse prevention; and

16 “(4) consider—

17 “(A) relieving companies of premarket bur-
18 dens under section 505 if the requirement is re-
19 dundant considering other nicotine replacement
20 therapies already on the market; and

21 “(B) time and extent applications for nico-
22 tine replacement therapies that have been ap-
23 proved by a regulatory body in a foreign coun-
24 try and have marketing experience in such
25 country.

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 2004, 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 2004 shall be
23 \$85,000,000;

24 “(B) for fiscal year 2005 shall be
25 \$175,000,000;

1 “(C) for fiscal year 2006 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 2004, based
5 on domestic sales of tobacco products during fiscal year
6 2003 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) by redesignating paragraphs (3), (4), and
17 (5) as paragraphs (4), (5), and (6), and inserting
18 after paragraph (2) the following:

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

1 be imposed with a civil penalty under paragraph
2 (1).”;

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

4 (A) in subparagraph (A)—

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

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

12 (B) in subparagraph (B)—

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

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

24 (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 (5) 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 (6) 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 in connection with the enforcement of this Act.”.

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

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

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

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

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

1 (1) EFFECTIVE DATE FOR NO-TOBACCO-SALE
2 ORDER AMENDMENTS.—The amendments made by sub-
3 section (c), other than the amendment made by paragraph
4 (2) of such subsection, shall take effect upon the issuance
5 of guidance by the Secretary of Health and Human Serv-
6 ices—

7 (1) defining the term “repeated violation”, as
8 used in section 303(f) of the Federal Food, Drug,
9 and Cosmetic Act (21 U.S.C. 333(f)) as amended by
10 subsection (c), by identifying the number of viola-
11 tions of particular requirements over a specified pe-
12 riod of time at a particular retail outlet that con-
13 stitute a repeated violation;

14 (2) providing for timely and effective notice to
15 the retailer of each alleged violation at a particular
16 retail outlet and an expedited procedure for the ad-
17 ministrative appeal of an alleged violation;

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

22 (4) establishing a period of time during which,
23 if there are no violations by a particular retail out-
24 let, that outlet will not be considered to have been

1 the site of repeated violations when the next viola-
2 tion occurs; and

3 (5) providing that good faith reliance on the
4 presentation of a false government issued photo-
5 graphic identification that contains the bearer's date
6 of birth does not constitute a violation of any min-
7 imum age requirement for the sale of tobacco prod-
8 ucts if the retailer has taken effective steps to pre-
9 vent such violations, including—

10 (A) adopting and enforcing a written policy
11 against sales to minors;

12 (B) informing its employees of all applica-
13 ble laws;

14 (C) establishing disciplinary sanctions for
15 employee noncompliance; and

16 (D) requiring its employees to verify age
17 by way of photographic identification or elec-
18 tronic scanning device.

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) FLIP-TOP BOXES.—For any cigarette
5 brand package manufactured or distributed be-
6 fore January 1, 2000, which employs a flip-top
7 style (if such packaging was used for that
8 brand in commerce prior to June 21, 1997), the
9 label statement required by paragraph (1) shall
10 be located on the flip-top area of the package,
11 even if such area is less than 25 percent of the
12 area of the front panel. Except as provided in
13 this paragraph, the provisions of this subsection
14 shall apply to such packages.

15 “(3) DOES NOT APPLY TO FOREIGN DISTRIBU-
16 TION.—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.

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

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

6 “(b) ADVERTISING REQUIREMENTS.—

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

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

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

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

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

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

16 “(4) ADJUSTMENT BY SECRETARY.—The Sec-
17 retary may, through a rulemaking under section 553
18 of title 5, United States Code, adjust the format and
19 type sizes for the label statements required by this
20 section or the text, format, and type sizes of any re-
21 quired tar, nicotine yield, or other constituent (in-
22 cluding smoke constituent) disclosures, or to estab-
23 lish the text, format, and type sizes for any other
24 disclosures required under the Federal Food, Drug,
25 and Cosmetic Act (21 U.S.C. 301 et. seq.). The text

1 of any such label statements or disclosures shall be
2 required to appear only within the 20 percent area
3 of cigarette advertisements provided by paragraph
4 (2) of this subsection. The Secretary shall promul-
5 gate regulations which provide for adjustments in
6 the format and type sizes of any text required to ap-
7 pear in such area to ensure that the total text re-
8 quired to appear by law will fit within such area.

9 “(5) MARKETING REQUIREMENTS.—

10 “(A) The label statements specified in sub-
11 section (a)(1) shall be randomly displayed in
12 each 12-month period, in as equal a number of
13 times as is possible on each brand of the prod-
14 uct and be randomly distributed in all areas of
15 the United States in which the product is mar-
16 keted in accordance with a plan submitted by
17 the tobacco product manufacturer, importer,
18 distributor, or retailer and approved by the Sec-
19 retary.

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

1 importer, distributor, or retailer to, and ap-
2 proved by, the Secretary.

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

6 “(i) will provide for the equal distribu-
7 tion and display on packaging and the ro-
8 tation required in advertising under this
9 subsection; and

10 “(ii) assures that all of the labels re-
11 quired under this section will be displayed
12 by the tobacco product manufacturer, im-
13 porter, distributor, or retailer at the same
14 time.

15 “(6) APPLICABILITY TO RETAILERS.—This sub-
16 section applies to a retailer only if that retailer is re-
17 sponsible for or directs the label statements required
18 under this section except that this paragraph shall
19 not relieve a retailer of liability if the retailer dis-
20 plays, in a location open to the public, an advertise-
21 ment that is not labeled in accordance with the re-
22 quirements of this subsection.”.

1 **SEC. 202. AUTHORITY TO REVISE CIGARETTE WARNING**
2 **LABEL STATEMENTS.**

3 Section 4 of the Federal Cigarette Labeling and Ad-
4 vertising Act (15 U.S.C. 1333), as amended by section
5 201, is further amended by adding at the end the fol-
6 lowing:

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

19 **SEC. 203. STATE REGULATION OF CIGARETTE ADVER-**
20 **TISING AND PROMOTION.**

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

24 “(c) EXCEPTION.—Notwithstanding subsection (b), a
25 State or locality may enact statutes and promulgate regu-
26 lations, based on smoking and health, that take effect

1 after the effective date of the Family Smoking Prevention
 2 and Tobacco Control Act, imposing specific bans or re-
 3 strictions on the time, place, and manner, but not content,
 4 of the advertising or promotion of any cigarettes.”.

5 **SEC. 204. SMOKELESS TOBACCO LABELS AND ADVERTISING**
 6 **WARNINGS.**

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

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

11 “(a) GENERAL RULE.—

12 “(1) It shall be unlawful for any person to man-
 13 ufacture, package, sell, offer to sell, distribute, or
 14 import for sale or distribution within the United
 15 States any smokeless tobacco product unless the
 16 product package bears, in accordance with the re-
 17 quirements of this Act, one of the following labels:

18 ‘WARNING: This product can cause mouth cancer’.

19 ‘WARNING: This product can cause gum disease
 20 and tooth loss’.

21 ‘WARNING: This product is not a safe alternative
 22 to cigarettes’.

23 ‘WARNING: Smokeless tobacco is addictive’.

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

1 “(A) located on the 2 principal display
2 panels of the package, and each label statement
3 shall comprise at least 30 percent of each such
4 display panel; and

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

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

23 “(4) The provisions of this subsection do not
24 apply to a tobacco product manufacturer or dis-
25 tributor of any smokeless tobacco product that does

1 not manufacture, package, or import smokeless to-
2 bacco products for sale or distribution within the
3 United States.

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

12 “(b) REQUIRED LABELS.—

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

20 “(2) Each label statement required by sub-
21 section (a) in smokeless tobacco advertising shall
22 comply with the standards set forth in this para-
23 graph. For press and poster advertisements, each
24 such statement and (where applicable) any required

1 statement relating to tar, nicotine, or other con-
2 stituent yield shall—

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

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

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

23 “(B) The label statements specified in sub-
24 section (a)(1) shall be rotated quarterly in alter-
25 nating sequence in advertisements for each brand of

1 smokeless tobacco product in accordance with a plan
2 submitted by the tobacco product manufacturer, im-
3 porter, distributor, or retailer to, and approved by,
4 the Secretary.

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

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

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

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

21 “(e) TELEVISION AND RADIO ADVERTISING.—It is
22 unlawful to advertise smokeless tobacco on any medium
23 of electronic communications subject to the jurisdiction of
24 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 shall
14 bear the statement ‘sale only allowed in the United
15 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).

○