

108TH CONGRESS
2^D SESSION

S. 2974

AN ACT

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.**

4 This Act may be cited as the “Family Smoking Pre-
5 vention and Tobacco Control Act”.

1 **SEC. 2. FINDINGS.**

2 The Congress finds the following:

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

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

11 (3) Nicotine is an addictive drug.

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

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

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

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

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

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

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

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

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

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

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

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

10 (14) Reducing the use of tobacco by minors by
11 50 percent would prevent well over 6,500,000 of to-
12 day's children from becoming regular, daily smokers,
13 saving over 2,000,000 of them from premature
14 death due to tobacco induced disease. Such a reduc-
15 tion in youth smoking would also result in approxi-
16 mately \$75,000,000,000 in savings attributable to
17 reduced health care costs.

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

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

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

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

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

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

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

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

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

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

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

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

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

24 (27) International experience shows that adver-
25 tising regulations that are stringent and comprehen-

1 sive have a greater impact on overall tobacco use
2 and young people's use than weaker or less com-
3 prehensive ones.

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

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

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

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

21 (32) The regulations described in paragraph
22 (30) impose no more extensive restrictions on com-
23 munication by tobacco manufacturers and sellers
24 than are necessary to reduce the number of children
25 and adolescents who use cigarettes and smokeless to-

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

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

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

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

21 (36) It is essential that the Food and Drug Ad-
22 ministration review products sold or distributed for
23 use to reduce risks or exposures associated with to-
24 bacco products and that it be empowered to review
25 any advertising and labeling for such products. It is

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

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

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

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

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

22 (41) As the Federal Trade Commission has
23 found, consumers have misinterpreted advertise-
24 ments in which one product is claimed to be less
25 harmful than a comparable product, even in the

1 presence of disclosures and advisories intended to
2 provide clarification.

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

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

16 **SEC. 3. PURPOSE.**

17 The purposes of this Act are—

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

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

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

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

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

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

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

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

7 (9) to promote cessation to reduce disease risk
8 and the social costs associated with tobacco related
9 diseases; and

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

12 **SEC. 4. SCOPE AND EFFECT.**

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

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

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

21 (b) AGRICULTURAL ACTIVITIES.—The provisions of
22 this Act (or an amendment made by this Act) which au-
23 thorize the Secretary to take certain actions with regard
24 to tobacco and tobacco products shall not be construed to
25 affect any authority of the Secretary of Agriculture under

1 existing law regarding the growing, cultivation, or curing
2 of raw tobacco.

3 **SEC. 5. SEVERABILITY.**

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

11 **TITLE I—AUTHORITY OF THE**
12 **FOOD AND DRUG ADMINIS-**
13 **TRATION**

14 **SEC. 101. AMENDMENT OF FEDERAL FOOD, DRUG, AND**
15 **COSMETIC ACT.**

16 (a) DEFINITION OF TOBACCO PRODUCTS.—Section
17 201 of the Federal Food, Drug, and Cosmetic Act (21
18 U.S.C. 321) is amended by adding at the end the fol-
19 lowing:

20 “(nn)(1) The term ‘tobacco product’ means any prod-
21 uct made or derived from tobacco that is intended for
22 human consumption, including any component, part, or
23 accessory of a tobacco product (except for raw materials
24 other than tobacco used in manufacturing a component,
25 part, or accessory of a tobacco product).

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

2 “(A) a product in the form of conventional food
3 (including water and chewing gum), a product rep-
4 resented for use as or for use in a conventional food,
5 or a product that is intended for ingestion in cap-
6 sule, tablet, softgel, or liquid form; or

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

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

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

17 (b) FDA AUTHORITY OVER TOBACCO PRODUCTS.—
18 The Federal Food, Drug, and Cosmetic Act (21 U.S.C.
19 301 et seq.) is amended—

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

21 (2) by redesignating sections 901 through 907
22 as sections 1001 through 1007; and

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

1 **“CHAPTER IX—TOBACCO**
2 **PRODUCTS**

3 **“SEC. 900. DEFINITIONS.**

4 “In this chapter:

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

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

22 “(3) CIGARETTE.—The term ‘cigarette’ has the
23 meaning given that term by section 3(1) of the Fed-
24 eral Cigarette Labeling and Advertising Act (15
25 U.S.C. 1332(1)), but also includes tobacco, in any

1 form, that is functional in the product, which, be-
2 cause of its appearance, the type of tobacco used in
3 the filler, or its packaging and labeling, is likely to
4 be offered to, or purchased by, consumers as a ciga-
5 rette or as roll-your-own tobacco.

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

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

16 “(6) COUNTERFEIT TOBACCO PRODUCT.—The
17 term ‘counterfeit tobacco product’ means a tobacco
18 product (or the container or labeling of such a prod-
19 uct) that, without authorization, bears the trade-
20 mark, trade name, or other identifying mark, im-
21 print or device, or any likeness thereof, of a tobacco
22 product listed in a registration under section
23 905(i)(1).

24 “(7) DISTRIBUTOR.—The term ‘distributor’ as
25 regards a tobacco product means any person who

1 furthers the distribution of a tobacco product,
2 whether domestic or imported, at any point from the
3 original place of manufacture to the person who sells
4 or distributes the product to individuals for personal
5 consumption. Common carriers are not considered
6 distributors for purposes of this chapter.

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

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

17 “(10) LITTLE CIGAR.—The term ‘little cigar’
18 has the meaning given that term by section 3(7) of
19 the Federal Cigarette Labeling and Advertising Act
20 (15 U.S.C. 1332(7)).

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

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

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

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

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

24 “(16) SMOKELESS TOBACCO.—The term
25 ‘smokeless tobacco’ means any tobacco product that

1 consists of cut, ground, powdered, or leaf tobacco
2 and that is intended to be placed in the oral or nasal
3 cavity.

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

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

15 “(A) manufactures, fabricates, assembles,
16 processes, or labels a tobacco product; or

17 “(B) imports a finished cigarette or
18 smokeless tobacco product for sale or distribu-
19 tion in the United States.

20 “(19) UNITED STATES.—The term ‘United
21 States’ means the 50 States of the United States of
22 America and the District of Columbia, the Common-
23 wealth of Puerto Rico, Guam, the Virgin Islands,
24 American Samoa, Wake Island, Midway Islands,
25 Kingman Reef, Johnston Atoll, the Northern Mar-

1 iana Islands, and any other trust territory or posses-
2 sion of the United States.

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

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

7 “(1) such products are intended for use in the
8 diagnosis, cure, mitigation, treatment, or prevention
9 of disease (within the meaning of section
10 201(g)(1)(B) or section 201(h)(2)); or

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

15 “(b) APPLICABILITY.—This chapter shall apply to all
16 tobacco products subject to the regulations referred to in
17 section 102 of the Family Smoking Prevention and To-
18 bacco Control Act, and to any other tobacco products that
19 the Secretary by regulation deems to be subject to this
20 chapter.

21 “(c) SCOPE.—

22 “(1) IN GENERAL.—Nothing in this chapter, or
23 any policy issued or regulation promulgated there-
24 under, or the Family Smoking Prevention and To-
25 bacco Control Act, shall be construed to affect the

1 Secretary's authority over, or the regulation of,
2 products under this Act that are not tobacco prod-
3 ucts under chapter V or any other chapter.

4 “(2) LIMITATION OF AUTHORITY.—

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

15 “(B) EXCEPTION.—Notwithstanding any
16 other provision of this subparagraph, if a pro-
17 ducer of tobacco leaf is also a tobacco product
18 manufacturer or controlled by a tobacco prod-
19 uct manufacturer, the producer shall be subject
20 to this chapter in the producer's capacity as a
21 manufacturer.

22 “(C) RULE OF CONSTRUCTION.—Nothing
23 in this chapter shall be construed to grant the
24 Secretary authority to promulgate regulations
25 on any matter that involves the production of

1 tobacco leaf or a producer thereof, other than
2 activities by a manufacturer affecting produc-
3 tion.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

5 “(D) the statement required under section
6 921(a),
7 except that under subparagraph (B) reasonable vari-
8 ations shall be permitted, and exemptions as to
9 small packages shall be established, by regulations
10 prescribed by the Secretary;

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

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

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

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

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

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

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

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

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

1 ter issued or caused to be issued by the manufac-
2 turer, packer, or distributor with respect to that to-
3 bacco product—

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

7 “(B) a brief statement of—

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

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

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

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

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

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

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

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

22 **“SEC. 904. SUBMISSION OF HEALTH INFORMATION TO THE**
23 **SECRETARY.**

24 “(a) REQUIREMENT.—Not later than 6 months after
25 the date of enactment of the Family Smoking Prevention

1 and Tobacco Control Act, each tobacco product manufac-
2 turer or importer, or agents thereof, shall submit to the
3 Secretary the following information:

4 “(1) A listing of all ingredients, including to-
5 bacco, substances, compounds, and additives that
6 are, as of such date, added by the manufacturer to
7 the tobacco, paper, filter, or other part of each to-
8 bacco product by brand and by quantity in each
9 brand and subbrand.

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

16 “(3) A listing of all constituents, including
17 smoke constituents as applicable, identified by the
18 Secretary as harmful or potentially harmful to
19 health in each tobacco product, and as applicable in
20 the smoke of each tobacco product, by brand and by
21 quantity in each brand and subbrand. Effective be-
22 ginning 2 years after the date of enactment of this
23 chapter, the manufacturer, importer, or agent shall
24 comply with regulations promulgated under section

1 915 in reporting information under this paragraph,
2 where applicable.

3 “(4) All documents developed after the date of
4 enactment of the Family Smoking Prevention and
5 Tobacco Control Act that relate to health, toxicological,
6 behavioral, or physiologic effects of current
7 or future tobacco products, their constituents (including
8 smoke constituents), ingredients, components,
9 and additives.

10 “(b) DATA SUBMISSION.—At the request of the Secretary,
11 each tobacco product manufacturer or importer of
12 tobacco products, or agents thereof, shall submit the following:
13

14 “(1) Any or all documents (including underlying
15 scientific information) relating to research activities,
16 and research findings, conducted, supported, or possessed
17 by the manufacturer (or agents thereof) on the health,
18 toxicological, behavioral, or physiologic effects of tobacco
19 products and their constituents (including smoke constituents),
20 ingredients, components, and additives.

22 “(2) Any or all documents (including underlying
23 scientific information) relating to research activities,
24 and research findings, conducted, supported, or possessed
25 by the manufacturer (or agents thereof)

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

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

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

14 “(c) TIME FOR SUBMISSION.—

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

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

1 manufacturer shall, except as provided in paragraph
2 (3), at least 90 days prior to such action so advise
3 the Secretary in writing.

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

13 “(d) DATA LIST.—

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

22 “(2) CONSUMER RESEARCH.—The Secretary
23 shall conduct periodic consumer research to ensure
24 that the list published under paragraph (1) is not
25 misleading to lay persons. Not later than 5 years

1 after the date of enactment of the Family Smoking
2 Prevention and Tobacco Control Act, the Secretary
3 shall submit to the appropriate committees of Con-
4 gress a report on the results of such research, to-
5 gether with recommendations on whether such publi-
6 cation should be continued or modified.

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

18 **“SEC. 905. ANNUAL REGISTRATION.**

19 “(a) DEFINITIONS.—In this section:

20 “(1) MANUFACTURE, PREPARATION,
21 COMPOUNDING, OR PROCESSING.—The term ‘manu-
22 facture, preparation, compounding, or processing’
23 shall include repackaging or otherwise changing the
24 container, wrapper, or labeling of any tobacco prod-
25 uct package in furtherance of the distribution of the

1 tobacco product from the original place of manufac-
2 ture to the person who makes final delivery or sale
3 to the ultimate consumer or user.

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

9 “(b) REGISTRATION BY OWNERS AND OPERATORS.—
10 On or before December 31 of each year every person who
11 owns or operates any establishment in any State engaged
12 in the manufacture, preparation, compounding, or proc-
13 essing of a tobacco product or tobacco products shall reg-
14 ister with the Secretary the name, places of business, and
15 all such establishments of that person.

16 “(c) REGISTRATION OF NEW OWNERS AND OPERA-
17 TORS.—Every person upon first engaging in the manufac-
18 ture, preparation, compounding, or processing of a tobacco
19 product or tobacco products in any establishment owned
20 or operated in any State by that person shall immediately
21 register with the Secretary that person’s name, place of
22 business, and such establishment.

23 “(d) REGISTRATION OF ADDED ESTABLISHMENTS.—
24 Every person required to register under subsection (b) or
25 (c) shall immediately register with the Secretary any addi-

1 tional establishment which that person owns or operates
2 in any State and in which that person begins the manufac-
3 ture, preparation, compounding, or processing of a tobacco
4 product or tobacco products.

5 “(e) UNIFORM PRODUCT IDENTIFICATION SYS-
6 TEM.—The Secretary may by regulation prescribe a uni-
7 form system for the identification of tobacco products and
8 may require that persons who are required to list such
9 tobacco products under subsection (i) shall list such to-
10 bacco products in accordance with such system.

11 “(f) PUBLIC ACCESS TO REGISTRATION INFORMA-
12 TION.—The Secretary shall make available for inspection,
13 to any person so requesting, any registration filed under
14 this section.

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

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

18 “(i) REGISTRATION INFORMATION.—

19 “(1) PRODUCT LIST.—Every person who reg-
20 isters with the Secretary under subsection (b), (c),
21 (d), or (h) shall, at the time of registration under
22 any such subsection, file with the Secretary a list of
23 all tobacco products which are being manufactured,
24 prepared, compounded, or processed by that person
25 for commercial distribution and which has not been

1 included in any list of tobacco products filed by that
2 person with the Secretary under this paragraph or
3 paragraph (2) before such time of registration. Such
4 list shall be prepared in such form and manner as
5 the Secretary may prescribe and shall be accom-
6 panied by—

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

14 “(B) in the case of any other tobacco prod-
15 uct contained in an applicable list, a copy of all
16 consumer information and other labeling for
17 such tobacco product, a representative sampling
18 of advertisements for such tobacco product,
19 and, upon request made by the Secretary for
20 good cause, a copy of all advertisements for a
21 particular tobacco product; and

22 “(C) if the registrant filing a list has de-
23 termined that a tobacco product contained in
24 such list is not subject to a tobacco product
25 standard established under section 907, a brief

1 statement of the basis upon which the reg-
2 istrant made such determination if the Sec-
3 retary requests such a statement with respect
4 to that particular tobacco product.

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

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

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

1 notice of such discontinuance, the date of such
2 discontinuance, and the identity of its estab-
3 lished name.

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

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

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

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

1 duction into interstate commerce for commercial dis-
2 tribution of a tobacco product intended for human
3 use that was not commercially marketed (other than
4 for test marketing) in the United States as of June
5 1, 2003, shall, at least 90 days prior to making such
6 introduction or delivery, report to the Secretary (in
7 such form and manner as the Secretary shall pre-
8 scribe)—

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

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

19 “(2) APPLICATION TO CERTAIN POST JUNE 1,
20 2003 PRODUCTS.—A report under this subsection for
21 a tobacco product that was first introduced or deliv-
22 ered for introduction into interstate commerce for
23 commercial distribution in the United States after
24 June 1, 2003, and prior to the date that is 15
25 months after the date of enactment of the Family

1 Smoking Prevention and Tobacco Control Act shall
2 be submitted to the Secretary not later than 15
3 months after such date of enactment.

4 “(3) EXEMPTIONS.—

5 “(A) IN GENERAL.—The Secretary may by
6 regulation, exempt from the requirements of
7 this subsection tobacco products that are modi-
8 fied by adding or deleting a tobacco additive, or
9 increasing or decreasing the quantity of an ex-
10 isting tobacco additive, if the Secretary deter-
11 mines that—

12 “(i) such modification would be a
13 minor modification of a tobacco product
14 authorized for sale under this Act;

15 “(ii) a report under this subsection is
16 not necessary to ensure that permitting the
17 tobacco product to be marketed would be
18 appropriate for protection of the public
19 health; and

20 “(iii) an exemption is otherwise appro-
21 priate.

22 “(B) REGULATIONS.—Not later than 9
23 months after the date of enactment of the Fam-
24 ily Smoking Prevention and Tobacco Control

1 Act, the Secretary shall issue regulations to im-
2 plement this paragraph.

3 **“SEC. 906. GENERAL PROVISIONS RESPECTING CONTROL**
4 **OF TOBACCO PRODUCTS.**

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

16 “(b) INFORMATION ON PUBLIC ACCESS AND COM-
17 MENT.—Each notice of proposed rulemaking under section
18 907, 908, 909, 910, or 911 or under this section, any
19 other notice which is published in the Federal Register
20 with respect to any other action taken under any such sec-
21 tion and which states the reasons for such action, and
22 each publication of findings required to be made in con-
23 nection with rulemaking under any such section shall set
24 forth—

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

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

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

23 “(d) RESTRICTIONS.—

24 “(1) IN GENERAL.—The Secretary may by reg-
25 ulation require restrictions on the sale and distribu-

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

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

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

21 No such regulation may require that the sale or dis-
22 tribution of a tobacco product be limited to the writ-
23 ten or oral authorization of a practitioner licensed
24 by law to prescribe medical products.

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

6 “(3) LIMITATIONS.—

7 “(A) IN GENERAL.—No restrictions under
8 paragraph (1) may—

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

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

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

1 retary may determine by regulation that match-
2 books shall not be considered adult written pub-
3 lications.

4 “(e) GOOD MANUFACTURING PRACTICE REQUIRE-
5 MENTS.—

6 “(1) METHODS, FACILITIES, AND CONTROLS TO
7 CONFORM.—

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

1 “(B) REQUIREMENTS.—The Secretary
2 shall—

3 “(i) before promulgating any regula-
4 tion under subparagraph (A), afford the
5 Tobacco Products Scientific Advisory Com-
6 mittee an opportunity to submit rec-
7 ommendations with respect to the regula-
8 tion proposed to be promulgated;

9 “(ii) before promulgating any regula-
10 tion under subparagraph (A), afford oppor-
11 tunity for an oral hearing;

12 “(iii) provide the advisory committee a
13 reasonable time to make its recommenda-
14 tion with respect to proposed regulations
15 under subparagraph (A); and

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

1 such manufacturers to conform to good
2 manufacturing practices.

3 “(2) EXEMPTIONS; VARIANCES.—

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

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

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

1 “(iii) contain such other information
2 as the Secretary shall prescribe.

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

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

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

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

21 “(C) APPROVAL.—The Secretary may
22 approve—

23 “(i) a petition for an exemption for a
24 tobacco product from a requirement if the
25 Secretary determines that compliance with

1 such requirement is not required to assure
2 that the tobacco product will be in compli-
3 ance with this chapter; and

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

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

23 “(E) HEARING.—After the issuance of an
24 order under subparagraph (B) respecting a pe-

1 tition, the petitioner shall have an opportunity
2 for an informal hearing on such order.

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

8 “(f) RESEARCH AND DEVELOPMENT.—The Secretary
9 may enter into contracts for research, testing, and dem-
10 onstrations respecting tobacco products and may obtain
11 tobacco products for research, testing, and demonstration
12 purposes without regard to section 3324(a) and (b) of title
13 31, United States Code, and section 5 of title 41, United
14 States Code.

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

16 “(a) IN GENERAL.—

17 “(1) SPECIAL RULE FOR CIGARETTES.—A ciga-
18 rette or any of its component parts (including the
19 tobacco, filter, or paper) shall not contain, as a con-
20 stituent (including a smoke constituent) or additive,
21 an artificial or natural flavor (other than tobacco or
22 menthol) or an herb or spice, including strawberry,
23 grape, orange, clove, cinnamon, pineapple, vanilla,
24 coconut, licorice, cocoa, chocolate, cherry, or coffee,
25 that is a characterizing flavor of the tobacco product

1 or tobacco smoke. Nothing in this subparagraph
2 shall be construed to limit the Secretary's authority
3 to take action under this section or other sections of
4 this Act applicable to menthol or any artificial or
5 natural flavor, herb, or spice not specified in this
6 paragraph.

7 “(2) REVISION OF TOBACCO PRODUCT STAND-
8 ARDS.—The Secretary may revise the tobacco prod-
9 uct standards in paragraph (1) in accordance with
10 subsection (b).

11 “(3) TOBACCO PRODUCT STANDARDS.—The
12 Secretary may adopt tobacco product standards in
13 addition to those in paragraph (1) if the Secretary
14 finds that a tobacco product standard is appropriate
15 for the protection of the public health. This finding
16 shall be determined with respect to the risks and
17 benefits to the population as a whole, including
18 users and non-users of the tobacco product, and tak-
19 ing into account—

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

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

1 “(4) CONTENT OF TOBACCO PRODUCT STAND-
2 ARDS.—A tobacco product standard established
3 under this section for a tobacco product—

4 “(A) shall include provisions that are ap-
5 propriate for the protection of the public health,
6 including provisions, where appropriate—

7 “(i) for the reduction of nicotine
8 yields of the product;

9 “(ii) for the reduction or elimination
10 of other constituents, including smoke con-
11 stituents, or harmful components of the
12 product; or

13 “(iii) relating to any other require-
14 ment under (B);

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

17 “(i) provisions respecting the con-
18 struction, components, ingredients, addi-
19 tives, constituents, including smoke con-
20 stituents, and properties of the tobacco
21 product;

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

1 “(iii) provisions for the measurement
2 of the tobacco product characteristics of
3 the tobacco product;

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

11 “(v) a provision requiring that the
12 sale and distribution of the tobacco prod-
13 uct be restricted but only to the extent
14 that the sale and distribution of a tobacco
15 product may be restricted under a regula-
16 tion under section 906(d); and

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

20 “(5) PERIODIC RE-EVALUATION OF TOBACCO
21 PRODUCT STANDARDS.—The Secretary shall provide
22 for periodic evaluation of tobacco product standards
23 established under this section to determine whether
24 such standards should be changed to reflect new
25 medical, scientific, or other technological data. The

1 Secretary may provide for testing under paragraph
2 (4)(B) by any person.

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

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

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

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

20 “(b) ESTABLISHMENT OF STANDARDS.—

21 “(1) NOTICE.—

22 “(A) IN GENERAL.—The Secretary shall
23 publish in the Federal Register a notice of pro-
24 posed rulemaking for the establishment, amend-

1 ment, or revocation of any tobacco product
2 standard.

3 “(B) REQUIREMENTS OF NOTICE.—A no-
4 tice of proposed rulemaking for the establish-
5 ment or amendment of a tobacco product stand-
6 ard for a tobacco product shall—

7 “(i) set forth a finding with sup-
8 porting justification that the tobacco prod-
9 uct standard is appropriate for the protec-
10 tion of the public health;

11 “(ii) set forth proposed findings with
12 respect to the risk of illness or injury that
13 the tobacco product standard is intended
14 to reduce or eliminate; and

15 “(iii) invite interested persons to sub-
16 mit an existing tobacco product standard
17 for the tobacco product, including a draft
18 or proposed tobacco product standard, for
19 consideration by the Secretary.

20 “(C) STANDARD.—Upon a determination
21 by the Secretary that an additive, constituent
22 (including smoke constituent), or other compo-
23 nent of the product that is the subject of the
24 proposed tobacco product standard is harmful,
25 it shall be the burden of any party challenging

1 the proposed standard to prove that the pro-
2 posed standard will not reduce or eliminate the
3 risk of illness or injury.

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

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

1 “(F) COMMENT.—The Secretary shall pro-
2 vide for a comment period of not less than 60
3 days.

4 “(2) PROMULGATION.—

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

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

17 “(ii) publish a notice terminating the
18 proceeding for the development of the
19 standard together with the reasons for
20 such termination.

21 “(B) EFFECTIVE DATE.—A regulation es-
22 tablishing a tobacco product standard shall set
23 forth the date or dates upon which the standard
24 shall take effect, but no such regulation may
25 take effect before 1 year after the date of its

1 publication unless the Secretary determines
2 that an earlier effective date is necessary for
3 the protection of the public health. Such date or
4 dates shall be established so as to minimize,
5 consistent with the public health, economic loss
6 to, and disruption or dislocation of, domestic
7 and international trade.

8 “(3) POWER RESERVED TO CONGRESS.—Be-
9 cause of the importance of a decision of the Sec-
10 retary to issue a regulation establishing a tobacco
11 product standard—

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

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

18 Congress expressly reserves to itself such power.

19 “(4) AMENDMENT; REVOCATION.—

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

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

9 “(5) REFERENCE TO ADVISORY COMMITTEE.—
10 The Secretary may—

11 “(A) on the Secretary’s own initiative,
12 refer a proposed regulation for the establish-
13 ment, amendment, or revocation of a tobacco
14 product standard; or

15 “(B) upon the request of an interested per-
16 son which demonstrates good cause for referral
17 and which is made before the expiration of the
18 period for submission of comments on such pro-
19 posed regulation,

20 refer such proposed regulation to the Tobacco Products
21 Scientific Advisory Committee, for a report and rec-
22 ommendation with respect to any matter involved in the
23 proposed regulation which requires the exercise of sci-
24 entific judgment. If a proposed regulation is referred
25 under this paragraph to the Tobacco Products Scientific

1 Advisory Committee, the Secretary shall provide the advi-
2 sory committee with the data and information on which
3 such proposed regulation is based. The Tobacco Products
4 Scientific Advisory Committee shall, within 60 days after
5 the referral of a proposed regulation and after inde-
6 pendent study of the data and information furnished to
7 it by the Secretary and other data and information before
8 it, submit to the Secretary a report and recommendation
9 respecting such regulation, together with all underlying
10 data and information and a statement of the reason or
11 basis for the recommendation. A copy of such report and
12 recommendation shall be made public by the Secretary.

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

14 “(a) NOTIFICATION.—If the Secretary determines
15 that—

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

20 “(2) notification under this subsection is nec-
21 essary to eliminate the unreasonable risk of such
22 harm and no more practicable means is available
23 under the provisions of this chapter (other than this
24 section) to eliminate such risk,

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

11 “(b) NO EXEMPTION FROM OTHER LIABILITY.—
12 Compliance with an order issued under this section shall
13 not relieve any person from liability under Federal or
14 State law. In awarding damages for economic loss in an
15 action brought for the enforcement of any such liability,
16 the value to the plaintiff in such action of any remedy
17 provided under such order shall be taken into account.

18 “(c) RECALL AUTHORITY.—

19 “(1) IN GENERAL.—If the Secretary finds that
20 there is a reasonable probability that a tobacco prod-
21 uct contains a manufacturing or other defect not or-
22 dinarily contained in tobacco products on the market
23 that would cause serious, adverse health con-
24 sequences or death, the Secretary shall issue an
25 order requiring the appropriate person (including

1 the manufacturers, importers, distributors, or retail-
2 ers of the tobacco product) to immediately cease dis-
3 tribution of such tobacco product. The order shall
4 provide the person subject to the order with an op-
5 portunity for an informal hearing, to be held not
6 later than 10 days after the date of the issuance of
7 the order, on the actions required by the order and
8 on whether the order should be amended to require
9 a recall of such tobacco product. If, after providing
10 an opportunity for such a hearing, the Secretary de-
11 termines that inadequate grounds exist to support
12 the actions required by the order, the Secretary shall
13 vacate the order.

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

16 “(A) IN GENERAL.—If, after providing an
17 opportunity for an informal hearing under
18 paragraph (1), the Secretary determines that
19 the order should be amended to include a recall
20 of the tobacco product with respect to which the
21 order was issued, the Secretary shall, except as
22 provided in subparagraph (B), amend the order
23 to require a recall. The Secretary shall specify
24 a timetable in which the tobacco product recall
25 will occur and shall require periodic reports to

1 the Secretary describing the progress of the re-
2 call.

3 “(B) NOTICE.—An amended order under
4 subparagraph (A)—

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

7 “(ii) shall provide for notice to per-
8 sons subject to the risks associated with
9 the use of such tobacco product.

10 In providing the notice required by clause (ii),
11 the Secretary may use the assistance of retail-
12 ers and other persons who distributed such to-
13 bacco product. If a significant number of such
14 persons cannot be identified, the Secretary shall
15 notify such persons under section 705(b).

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

19 **“SEC. 909. RECORDS AND REPORTS ON TOBACCO PROD-**
20 **UCTS.**

21 “(a) IN GENERAL.—Every person who is a tobacco
22 product manufacturer or importer of a tobacco product
23 shall establish and maintain such records, make such re-
24 ports, and provide such information, as the Secretary may
25 by regulation reasonably require to assure that such to-

1 bacco product is not adulterated or misbranded and to
2 otherwise protect public health. Regulations prescribed
3 under the preceding sentence—

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

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

17 “(3) shall not impose requirements unduly bur-
18 densome to a tobacco product manufacturer or im-
19 porter, taking into account the cost of complying
20 with such requirements and the need for the protec-
21 tion of the public health and the implementation of
22 this chapter;

23 “(4) when prescribing the procedure for making
24 requests for reports or information, shall require
25 that each request made under such regulations for

1 submission of a report or information to the Sec-
2 retary state the reason or purpose for such request
3 and identify to the fullest extent practicable such re-
4 port or information;

5 “(5) when requiring submission of a report or
6 information to the Secretary, shall state the reason
7 or purpose for the submission of such report or in-
8 formation and identify to the fullest extent prac-
9 ticable such report or information; and

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

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

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

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

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

11 “(B) to remedy a violation of this chapter
12 caused by the tobacco product which may
13 present a risk to health.

14 A tobacco product manufacturer or importer of a to-
15 bacco product who undertakes a corrective action or
16 removal from the market of a tobacco product which
17 is not required to be reported under this subsection
18 shall keep a record of such correction or removal.

19 “(2) EXCEPTION.—No report of the corrective
20 action or removal of a tobacco product may be re-
21 quired under paragraph (1) if a report of the correc-
22 tive action or removal is required and has been sub-
23 mitted under subsection (a).

1 **“SEC. 910. APPLICATION FOR REVIEW OF CERTAIN TO-**
2 **BACCO PRODUCTS.**

3 “(a) IN GENERAL.—

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

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

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

19 “(2) PREMARKET APPROVAL REQUIRED.—

20 “(A) NEW PRODUCTS.—Approval under
21 this section of an application for premarket ap-
22 proval for any new tobacco product is required
23 unless—

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

1 “(ii) the Secretary has issued an order
2 that the tobacco product—

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

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

10 “(bb) is exempt from the require-
11 ments of section 905(j) pursuant to a
12 regulation issued under section
13 905(j)(3).

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

17 “(i) that was first introduced or deliv-
18 ered for introduction into interstate com-
19 merce for commercial distribution in the
20 United States after June 1, 2003, and
21 prior to the date that is 15 months after
22 the date of enactment of the Family Smok-
23 ing Prevention and Tobacco Control Act;
24 and

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

6 “(3) SUBSTANTIALLY EQUIVALENT DEFINED.—

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

14 “(i) has the same characteristics as
15 the predicate tobacco product; or

16 “(ii) has different characteristics and
17 the information submitted contains infor-
18 mation, including clinical data if deemed
19 necessary by the Secretary, that dem-
20 onstrates that it is not appropriate to reg-
21 ulate the product under this section be-
22 cause the product does not raise different
23 questions of public health.

24 “(B) CHARACTERISTICS.—In subpara-
25 graph (A), the term ‘characteristics’ means the

1 materials, ingredients, design, composition,
2 heating source, or other features of a tobacco
3 product.

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

10 “(4) HEALTH INFORMATION.—

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

19 “(B) REQUIRED INFORMATION.—Any sum-
20 mary under subparagraph (A) respecting a to-
21 bacco product shall contain detailed information
22 regarding data concerning adverse health ef-
23 fects and shall be made available to the public
24 by the Secretary within 30 days of the issuance
25 of a determination that such tobacco product is

1 substantially equivalent to another tobacco
2 product.

3 “(b) APPLICATION.—

4 “(1) CONTENTS.—An application for premarket
5 approval shall contain—

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

13 “(B) a full statement of the components,
14 ingredients, additives, and properties, and of
15 the principle or principles of operation, of such
16 tobacco product;

17 “(C) a full description of the methods used
18 in, and the facilities and controls used for, the
19 manufacture, processing, and, when relevant,
20 packing and installation of, such tobacco prod-
21 uct;

22 “(D) an identifying reference to any to-
23 bacco product standard under section 907
24 which would be applicable to any aspect of such
25 tobacco product, and either adequate informa-

1 tion to show that such aspect of such tobacco
2 product fully meets such tobacco product stand-
3 ard or adequate information to justify any devi-
4 ation from such standard;

5 “(E) such samples of such tobacco product
6 and of components thereof as the Secretary
7 may reasonably require;

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

10 “(G) such other information relevant to
11 the subject matter of the application as the Sec-
12 retary may require.

13 “(2) REFERENCE TO TOBACCO PRODUCTS SCI-
14 ENTIFIC ADVISORY COMMITTEE.—Upon receipt of an
15 application meeting the requirements set forth in
16 paragraph (1), the Secretary—

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

19 “(B) may, upon the request of an appli-
20 cant,

21 refer such application to the Tobacco Products Sci-
22 entific Advisory Committee for reference and for
23 submission (within such period as the Secretary may
24 establish) of a report and recommendation respect-
25 ing approval of the application, together with all un-

1 derlying data and the reasons or basis for the rec-
2 ommendation.

3 “(c) ACTION ON APPLICATION.—

4 “(1) DEADLINE.—

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

11 “(i) issue an order approving the ap-
12 plication if the Secretary finds that none of
13 the grounds for denying approval specified
14 in paragraph (2) of this subsection applies;
15 or

16 “(ii) deny approval of the application
17 if the Secretary finds (and sets forth the
18 basis for such finding as part of or accom-
19 panying such denial) that 1 or more
20 grounds for denial specified in paragraph
21 (2) of this subsection apply.

22 “(B) RESTRICTIONS ON SALE AND DIS-
23 TRIBUTION.—An order approving an application
24 for a tobacco product may require as a condi-
25 tion to such approval that the sale and distribu-

1 tion of the tobacco product be restricted but
2 only to the extent that the sale and distribution
3 of a tobacco product may be restricted under a
4 regulation under section 906(d).

5 “(2) DENIAL OF APPROVAL.—The Secretary
6 shall deny approval of an application for a tobacco
7 product if, upon the basis of the information sub-
8 mitted to the Secretary as part of the application
9 and any other information before the Secretary with
10 respect to such tobacco product, the Secretary finds
11 that—

12 “(A) there is a lack of a showing that per-
13 mitting such tobacco product to be marketed
14 would be appropriate for the protection of the
15 public health;

16 “(B) the methods used in, or the facilities
17 or controls used for, the manufacture, proc-
18 essing, or packing of such tobacco product do
19 not conform to the requirements of section
20 906(e);

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

24 “(D) such tobacco product is not shown to
25 conform in all respects to a tobacco product

1 standard in effect under section 907, compli-
2 ance with which is a condition to approval of
3 the application, and there is a lack of adequate
4 information to justify the deviation from such
5 standard.

6 “(3) DENIAL INFORMATION.—Any denial of an
7 application shall, insofar as the Secretary determines
8 to be practicable, be accompanied by a statement in-
9 forming the applicant of the measures required to
10 place such application in approvable form (which
11 measures may include further research by the appli-
12 cant in accordance with 1 or more protocols pre-
13 scribed by the Secretary).

14 “(4) BASIS FOR FINDING.—For purposes of
15 this section, the finding as to whether approval of a
16 tobacco product is appropriate for the protection of
17 the public health shall be determined with respect to
18 the risks and benefits to the population as a whole,
19 including users and nonusers of the tobacco product,
20 and taking into account—

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

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

4 “(5) BASIS FOR ACTION.—

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

14 “(B) OTHER EVIDENCE.—If the Secretary
15 determines that there exists valid scientific evi-
16 dence (other than evidence derived from inves-
17 tigations described in subparagraph (A)) which
18 is sufficient to evaluate the tobacco product the
19 Secretary may authorize that the determination
20 for purposes of paragraph (2)(A) be made on
21 the basis of such evidence.

22 “(d) WITHDRAWAL AND TEMPORARY SUSPENSION.—

23 “(1) IN GENERAL.—The Secretary shall, upon
24 obtaining, where appropriate, advice on scientific
25 matters from an advisory committee, and after due

1 notice and opportunity for informal hearing to the
2 holder of an approved application for a tobacco
3 product, issue an order withdrawing approval of the
4 application if the Secretary finds—

5 “(A) that the continued marketing of such
6 tobacco product no longer is appropriate for the
7 protection of the public health;

8 “(B) that the application contained or was
9 accompanied by an untrue statement of a mate-
10 rial fact;

11 “(C) that the applicant—

12 “(i) has failed to establish a system
13 for maintaining records, or has repeatedly
14 or deliberately failed to maintain records
15 or to make reports, required by an applica-
16 ble regulation under section 909;

17 “(ii) has refused to permit access to,
18 or copying or verification of, such records
19 as required by section 704; or

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

22 “(D) on the basis of new information be-
23 fore the Secretary with respect to such tobacco
24 product, evaluated together with the evidence
25 before the Secretary when the application was

1 approved, that the methods used in, or the fa-
2 cilities and controls used for, the manufacture,
3 processing, packing, or installation of such to-
4 bacco product do not conform with the require-
5 ments of section 906(e) and were not brought
6 into conformity with such requirements within a
7 reasonable time after receipt of written notice
8 from the Secretary of nonconformity;

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

18 “(F) on the basis of new information be-
19 fore the Secretary, evaluated together with the
20 evidence before the Secretary when the applica-
21 tion was approved, that such tobacco product is
22 not shown to conform in all respects to a to-
23 bacco product standard which is in effect under
24 section 907, compliance with which was a con-
25 dition to approval of the application, and that

1 there is a lack of adequate information to jus-
2 tify the deviation from such standard.

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

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

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

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

3 “(2) by mailing the order by registered mail or
4 certified mail addressed to the applicant at the ap-
5 plicant’s last known address in the records of the
6 Secretary.

7 “(f) RECORDS.—

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

20 “(2) ACCESS TO RECORDS.—Each person re-
21 quired under this section to maintain records, and
22 each person in charge or custody thereof, shall, upon
23 request of an officer or employee designated by the
24 Secretary, permit such officer or employee at all rea-

1 sonable times to have access to and copy and verify
2 such records.

3 “(g) INVESTIGATIONAL TOBACCO PRODUCT EXEMP-
4 TION FOR INVESTIGATIONAL USE.—The Secretary may
5 exempt tobacco products intended for investigational use
6 from the provisions of this chapter under such conditions
7 as the Secretary may by regulation prescribe.

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

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

14 “(b) DEFINITIONS.—In this section:

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

21 “(2) SOLD OR DISTRIBUTED.—

22 “(A) IN GENERAL.—With respect to a to-
23 bacco product, the term ‘sold or distributed for
24 use to reduce harm or the risk of tobacco-re-
25 lated disease associated with commercially mar-

1 marketed tobacco products’ means a tobacco
2 product—

3 “(A) the label, labeling, or advertising
4 of which represents explicitly or implicitly
5 that—

6 “(I) the tobacco product presents
7 a lower risk of tobacco-related disease
8 or is less harmful than one or more
9 other commercially marketed tobacco
10 products;

11 “(II) the tobacco product or its
12 smoke contains a reduced level of a
13 substance or presents a reduced expo-
14 sure to a substance; or

15 “(III) the tobacco product or its
16 smoke does not contain or is free of a
17 substance;

18 “(ii) the label, labeling, or advertising
19 of which uses the descriptors ‘light’, ‘mild’,
20 or ‘low’ or similar descriptors; or

21 “(iii) the tobacco product manufac-
22 turer of which has taken any action di-
23 rected to consumers through the media or
24 otherwise, other than by means of the to-
25 bacco product’s label, labeling or adver-

1 tising, after the date of enactment of the
2 Family Smoking Prevention and Tobacco
3 Control Act, respecting the product that
4 would be reasonably expected to result in
5 consumers believing that the tobacco prod-
6 uct or its smoke may present a lower risk
7 of disease or is less harmful than one or
8 more commercially marketed tobacco prod-
9 ucts, or presents a reduced exposure to, or
10 does not contain or is free of, a substance
11 or substances.

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

18 “(c) TOBACCO DEPENDENCE PRODUCTS.—A product
19 that is intended to be used for the treatment of tobacco
20 dependence, including smoking cessation, is not a modified
21 risk tobacco product under this section and is subject to
22 the requirements of chapter V.

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

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

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

4 “(3) the formulation of the product;

5 “(4) sample product labels and labeling;

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

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

17 “(7) such other information as the Secretary
18 may require.

19 “(e) PUBLIC AVAILABILITY.—The Secretary shall
20 make the application described in subsection (d) publicly
21 available (except matters in the application which are
22 trade secrets or otherwise confidential, commercial infor-
23 mation) and shall request comments by interested persons
24 on the information contained in the application and on the

1 label, labeling, and advertising accompanying such appli-
2 cation.

3 “(f) ADVISORY COMMITTEE.—

4 “(1) IN GENERAL.—The Secretary shall refer to
5 an advisory committee any application submitted
6 under this subsection.

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

12 “(g) APPROVAL.—

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

20 “(A) significantly reduce harm and the
21 risk of tobacco-related disease to individual to-
22 bacco users; and

23 “(B) benefit the health of the population
24 as a whole taking into account both users of to-

1 bacco products and persons who do not cur-
2 rently use tobacco products.

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

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

11 “(i) the approval of the application
12 would be appropriate to promote the public
13 health;

14 “(ii) any aspect of the label, labeling,
15 and advertising for such product that
16 would cause the tobacco product to be a
17 modified risk tobacco product under sub-
18 section (b)(2) is limited to an explicit or
19 implicit representation that such tobacco
20 product or its smoke contains or is free of
21 a substance or contains a reduced level of
22 a substance, or presents a reduced expo-
23 sure to a substance in tobacco smoke.

24 “(iii) scientific evidence is not avail-
25 able and, using the best available scientific

1 methods, cannot be made available without
2 conducting long-term epidemiological stud-
3 ies for an application to meet the stand-
4 ards set forth in paragraph (1); and

5 “(iv) the scientific evidence that is
6 available without conducting long-term epi-
7 demiological studies demonstrates that a
8 measurable and substantial reduction in
9 morbidity or mortality among individual
10 tobacco users is anticipated in subsequent
11 studies.

12 “(B) ADDITIONAL FINDINGS REQUIRED.—

13 In order to approve an application under sub-
14 paragraph (A) the Secretary must also find
15 that the applicant has demonstrated that—

16 “(i) the magnitude of the overall re-
17 ductions in exposure to the substance or
18 substances which are the subject of the ap-
19 plication is substantial, such substance or
20 substances are harmful, and the product as
21 actually used exposes consumers to the
22 specified reduced level of the substance or
23 substances;

24 “(ii) the product as actually used by
25 consumers will not expose them to higher

1 levels of other harmful substances com-
2 pared to the similar types of tobacco prod-
3 ucts then on the market unless such in-
4 creases are minimal and the anticipated
5 overall impact of use of the product re-
6 mains a substantial and measurable reduc-
7 tion in overall morbidity and mortality
8 among individual tobacco users;

9 “(iii) testing of actual consumer per-
10 ception shows that, as the applicant pro-
11 poses to label and market the product, con-
12 sumers will not be misled into believing
13 that the product—

14 “(I) is or has been demonstrated
15 to be less harmful; or

16 “(II) presents or has been dem-
17 onstrated to present less of a risk of
18 disease than 1 or more other commer-
19 cially marketed tobacco products; and

20 “(iv) approval of the application is ex-
21 pected to benefit the health of the popu-
22 lation as a whole taking into account both
23 users of tobacco products and persons who
24 do not currently use tobacco products.

25 “(C) CONDITIONS OF APPROVAL.—

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

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

21 “(iii) ANNUAL SUBMISSION.—The re-
22 sults of such post-market surveillance and
23 studies described in clause (ii) shall be
24 submitted annually.

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

3 “(A) the scientific evidence submitted by
4 the applicant; and

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

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

11 “(A) the relative health risks to individuals
12 of the tobacco product that is the subject of the
13 application;

14 “(B) the increased or decreased likelihood
15 that existing users of tobacco products who
16 would otherwise stop using such products will
17 switch to the tobacco product that is the subject
18 of the application;

19 “(C) the increased or decreased likelihood
20 that persons who do not use tobacco products
21 will start using the tobacco product that is the
22 subject of the application;

23 “(D) the risks and benefits to persons
24 from the use of the tobacco product that is the
25 subject of the application as compared to the

1 use of products for smoking cessation approved
2 under chapter V to treat nicotine dependence;
3 and

4 “(E) comments, data, and information
5 submitted by interested persons.

6 “(h) ADDITIONAL CONDITIONS FOR APPROVAL.—

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

17 “(2) COMPARATIVE CLAIMS.—

18 “(A) IN GENERAL.—The Secretary may re-
19 quire for the approval of an application under
20 this subsection that a claim comparing a to-
21 bacco product to 1 or more other commercially
22 marketed tobacco products shall compare the
23 tobacco product to a commercially marketed to-
24 bacco product that is representative of that type
25 of tobacco product on the market (for example

1 the average value of the top 3 brands of an es-
2 tablished regular tobacco product).

3 “(B) QUANTITATIVE COMPARISONS.—The
4 Secretary may also require, for purposes of sub-
5 paragraph (A), that the percent (or fraction) of
6 change and identity of the reference tobacco
7 product and a quantitative comparison of the
8 amount of the substance claimed to be reduced
9 shall be stated in immediate proximity to the
10 most prominent claim.

11 “(3) LABEL DISCLOSURE.—

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

21 “(B) CONDITIONS OF USE.—If the condi-
22 tions of use of the tobacco product may affect
23 the risk of the product to human health, the
24 Secretary may require the labeling of conditions
25 of use.

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

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

9 “(i) POSTMARKET SURVEILLANCE AND STUDIES.—

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

23 “(2) SURVEILLANCE PROTOCOL.—Each appli-
24 cant required to conduct a surveillance of a tobacco
25 product under paragraph (1) shall, within 30 days

1 after receiving notice that the applicant is required
2 to conduct such surveillance, submit, for the ap-
3 proval of the Secretary, a protocol for the required
4 surveillance. The Secretary, within 60 days of the
5 receipt of such protocol, shall determine if the prin-
6 cipal investigator proposed to be used in the surveil-
7 lance has sufficient qualifications and experience to
8 conduct such surveillance and if such protocol will
9 result in collection of the data or other information
10 designated by the Secretary as necessary to protect
11 the public health.

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

16 “(1) the applicant, based on new information,
17 can no longer make the demonstrations required
18 under subsection (g), or the Secretary can no longer
19 make the determinations required under subsection
20 (g);

21 “(2) the application failed to include material
22 information or included any untrue statement of ma-
23 terial fact;

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

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

6 “(B) an action is taken that affects the
7 risks presented by other commercially marketed
8 tobacco products that were compared to the
9 product that is the subject of the application; or

10 “(C) any postmarket surveillance or stud-
11 ies reveal that the approval of the application is
12 no longer consistent with the protection of the
13 public health;

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

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

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

22 “(l) IMPLEMENTING REGULATIONS OR GUIDANCE.—

23 “(1) SCIENTIFIC EVIDENCE.—Not later than 2
24 years after the date of enactment of the Family
25 Smoking Prevention and Tobacco Control Act, the

1 Secretary shall issue regulations or guidance (or any
2 combination thereof) on the scientific evidence re-
3 quired for assessment and ongoing review of modi-
4 fied risk tobacco products. Such regulations or guid-
5 ance shall—

6 “(A) establish minimum standards for sci-
7 entific studies needed prior to approval to show
8 that a substantial reduction in morbidity or
9 mortality among individual tobacco users is
10 likely;

11 “(B) include validated biomarkers, inter-
12 mediate clinical endpoints, and other feasible
13 outcome measures, as appropriate;

14 “(C) establish minimum standards for post
15 market studies, that shall include regular and
16 long-term assessments of health outcomes and
17 mortality, intermediate clinical endpoints, con-
18 sumer perception of harm reduction, and the
19 impact on quitting behavior and new use of to-
20 bacco products, as appropriate;

21 “(D) establish minimum standards for re-
22 quired postmarket surveillance, including ongo-
23 ing assessments of consumer perception; and

24 “(E) require that data from the required
25 studies and surveillance be made available to

1 the Secretary prior to the decision on renewal
2 of a modified risk tobacco product.

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

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

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

22 “(m) DISTRIBUTORS.—No distributor may take any
23 action, after the date of enactment of the Family Smoking
24 Prevention and Tobacco Control Act, with respect to a to-
25 bacco product that would reasonably be expected to result

1 in consumers believing that the tobacco product or its
2 smoke may present a lower risk of disease or is less harm-
3 ful than one or more commercially marketed tobacco prod-
4 ucts, or presents a reduced exposure to, or does not con-
5 tain or is free of, a substance or substances.

6 **“SEC. 912. JUDICIAL REVIEW.**

7 “(a) RIGHT TO REVIEW.—

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

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

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

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

21 “(2) REQUIREMENTS.—

22 “(A) COPY OF PETITION.—A copy of the
23 petition filed under paragraph (1) shall be
24 transmitted by the clerk of the court involved to
25 the Secretary.

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

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

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

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

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

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

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

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

23 “(v) any other information identified
24 by the Secretary, in the administrative pro-
25 ceeding held with respect to such regula-

1 tion or order, as being relevant to such
2 regulation or order.

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

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

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

21 “(e) REGULATIONS AND ORDERS MUST RECITE
22 BASIS IN RECORD.—To facilitate judicial review, a regula-
23 tion or order issued under section 906, 907, 908, 909,
24 910, or 916 shall contain a statement of the reasons for

1 the issuance of such regulation or order in the record of
2 the proceedings held in connection with its issuance.

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

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

9 **“SEC. 914. JURISDICTION OF AND COORDINATION WITH**
10 **THE FEDERAL TRADE COMMISSION.**

11 “(a) JURISDICTION.—

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

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

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

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

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

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

16 “‘In accordance with section 801 of title 5, United
17 States Code, Congress shall review, and may disapprove,
18 any rule under this chapter that is subject to section 801.
19 This section and section 801 do not apply to the regula-
20 tions referred to in section 102 of the Family Smoking
21 Prevention and Tobacco Control Act.

22 **“SEC. 916. REGULATION REQUIREMENT.**

23 “(a) TESTING, REPORTING, AND DISCLOSURE.—Not
24 later than 24 months after the date of enactment of the
25 Family Smoking Prevention and Tobacco Control Act, the

1 Secretary, acting through the Commissioner of the Food
2 and Drug Administration, shall promulgate regulations
3 under this Act that meet the requirements of subsection
4 (b).

5 “(b) CONTENTS OF RULES.—The regulations pro-
6 mulgated under subsection (a) shall require testing and
7 reporting of tobacco product constituents, ingredients, and
8 additives, including smoke constituents, by brand and sub-
9 brand that the Secretary determines should be tested to
10 protect the public health. The regulations may require
11 that tobacco product manufacturers, packagers, or import-
12 ers make disclosures relating to the results of the testing
13 of tar and nicotine through labels or advertising or other
14 appropriate means, and make disclosures regarding the re-
15 sults of the testing of other constituents, including smoke
16 constituents, ingredients, or additives, that the Secretary
17 determines should be disclosed to the public to protect the
18 public health and will not mislead consumers about the
19 risk of tobacco related disease.

20 “(c) AUTHORITY.—The Food and Drug Administra-
21 tion shall have the authority under this chapter to conduct
22 or to require the testing, reporting, or disclosure of to-
23 bacco product constituents, including smoke constituents.

1 **“SEC. 917. PRESERVATION OF STATE AND LOCAL AUTHOR-**
2 **ITY.**

3 “(a) IN GENERAL.—

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

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

24 “(A) IN GENERAL.—Except as provided in
25 paragraph (1) and subparagraph (B), no State
26 or political subdivision of a State may establish

1 or continue in effect with respect to a tobacco
2 product any requirement which is different
3 from, or in addition to, any requirement under
4 the provisions of this chapter relating to to-
5 bacco product standards, premarket approval,
6 adulteration, misbranding, labeling, registra-
7 tion, good manufacturing standards, or reduced
8 risk products.

9 “(B) EXCEPTION.—Subparagraph (A)
10 does not apply to requirements relating to the
11 sale, distribution, possession, information re-
12 porting to the State, exposure to, access to, the
13 advertising and promotion of, or use of, tobacco
14 products by individuals of any age, or relating
15 to fire safety standards for tobacco products.
16 Information disclosed to a State under subpara-
17 graph (A) that is exempt from disclosure under
18 section 554(b)(4) of title 5, United States Code,
19 shall be treated as trade secret and confidential
20 information by the State.

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

1 **“SEC. 918. TOBACCO PRODUCTS SCIENTIFIC ADVISORY**
2 **COMMITTEE.**

3 “(a) ESTABLISHMENT.—Not later than 1 year after
4 the date of enactment of the Family Smoking Prevention
5 and Tobacco Control Act, the Secretary shall establish a
6 11-member advisory committee, to be known as the ‘To-
7 bacco Products Scientific Advisory Committee’.

8 “(b) MEMBERSHIP.—

9 “(1) IN GENERAL.—

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

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

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

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

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

9 “(v) 1 individual as a representative
10 of the interests of the tobacco growers.

11 “(B) NONVOTING MEMBERS.—The mem-
12 bers of the committee appointed under clauses
13 (iv) and (v) of subparagraph (A) shall serve as
14 consultants to those described in clauses (i)
15 through (iii) of subparagraph (A) and shall be
16 nonvoting representatives.

17 “(2) LIMITATION.—The Secretary may not ap-
18 point to the Advisory Committee any individual who
19 is in the regular full-time employ of the Food and
20 Drug Administration or any agency responsible for
21 the enforcement of this Act. The Secretary may ap-
22 point Federal officials as ex officio members.

23 “(3) CHAIRPERSON.—The Secretary shall des-
24 ignate 1 of the members of the Advisory Committee
25 to serve as chairperson.

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

4 “(1) as provided in this chapter;

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

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

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

13 “(d) COMPENSATION; SUPPORT; FACA.—

14 “(1) COMPENSATION AND TRAVEL.—Members
15 of the Advisory Committee who are not officers or
16 employees of the United States, while attending con-
17 ferences or meetings of the committee or otherwise
18 engaged in its business, shall be entitled to receive
19 compensation at rates to be fixed by the Secretary,
20 which may not exceed the daily equivalent of the
21 rate in effect for level 4 of the Senior Executive
22 Schedule under section 5382 of title 5, United
23 States Code, for each day (including travel time)
24 they are so engaged; and while so serving away from
25 their homes or regular places of business each mem-

1 ber may be allowed travel expenses, including per
2 diem in lieu of subsistence, as authorized by section
3 5703 of title 5, United States Code, for persons in
4 the Government service employed intermittently.

5 “(2) ADMINISTRATIVE SUPPORT.—The Sec-
6 retary shall furnish the Advisory Committee clerical
7 and other assistance.

8 “(3) NONAPPLICATION OF FACa.—Section 14 of
9 the Federal Advisory Committee Act (5 U.S.C.
10 App.) does not apply to the Advisory Committee.

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

18 **“SEC. 919. DRUG PRODUCTS USED TO TREAT TOBACCO DE-**

19 **PENDENCE.**

20 The Secretary shall consider—

21 “(1) at the request of the applicant, designating
22 nicotine replacement products as fast track research
23 and approval products within the meaning of section
24 506;

1 “(2) direct the Commissioner to consider ap-
2 proving the extended use of nicotine replacement
3 products (such as nicotine patches, nicotine gum,
4 and nicotine lozenges) for the treatment of tobacco
5 dependence;

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

9 “(4) consider—

10 “(A) relieving companies of premarket bur-
11 dens under section 505 if the requirement is re-
12 dundant considering other nicotine replacement
13 therapies already on the market; and

14 “(B) time and extent applications for nico-
15 tine replacement therapies that have been ap-
16 proved by a regulatory body in a foreign coun-
17 try and have marketing experience in such
18 country.

19 **“SEC. 920. USER FEE.**

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

21 The Secretary shall assess a quarterly user fee with re-
22 spect to every quarter of each fiscal year commencing fis-
23 cal year 2004, calculated in accordance with this section,
24 upon each manufacturer and importer of tobacco products
25 subject to this chapter.

1 “(b) FUNDING OF FDA REGULATION OF TOBACCO
2 PRODUCTS.—The Secretary shall make user fees collected
3 pursuant to this section available to pay, in each fiscal
4 year, for the costs of the activities of the Food and Drug
5 Administration related to the regulation of tobacco prod-
6 ucts under this chapter.

7 “(c) ASSESSMENT OF USER FEE.—

8 “(1) AMOUNT OF ASSESSMENT.—Except as
9 provided in paragraph (4), the total user fees as-
10 sessed each year pursuant to this section shall be
11 sufficient, and shall not exceed what is necessary, to
12 pay for the costs of the activities described in sub-
13 section (b) for each fiscal year.

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

16 “(A) IN GENERAL.—Subject to paragraph
17 (3), the total user fees assessed each fiscal year
18 with respect to each class of importers and
19 manufacturers shall be equal to an amount that
20 is the applicable percentage of the total costs of
21 activities of the Food and Drug Administration
22 described in subsection (b).

23 “(B) APPLICABLE PERCENTAGE.—For
24 purposes of subparagraph (A) the applicable

1 percentage for a fiscal year shall be the fol-
2 lowing:

3 “(i) 92.07 percent shall be assessed
4 on manufacturers and importers of ciga-
5 rettes;

6 “(ii) 0.05 percent shall be assessed on
7 manufacturers and importers of little ci-
8 gars;

9 “(iii) 7.15 percent shall be assessed
10 on manufacturers and importers of cigars
11 other than little cigars;

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

14 “(v) 0.10 percent shall be assessed on
15 manufacturers and importers of chewing
16 tobacco;

17 “(vi) 0.06 percent shall be assessed on
18 manufacturers and importers of pipe to-
19 bacco; and

20 “(vii) 0.14 percent shall be assessed
21 on manufacturers and importers of roll-
22 your-own tobacco.

23 “(3) DISTRIBUTION OF FEE SHARES OF MANU-
24 FACTURERS AND IMPORTERS EXEMPT FROM USER
25 FEE.—Where a class of tobacco products is not sub-

1 ject to a user fee under this section, the portion of
2 the user fee assigned to such class under subsection
3 (d)(2) shall be allocated by the Secretary on a pro
4 rata basis among the classes of tobacco products
5 that are subject to a user fee under this section.
6 Such pro rata allocation for each class of tobacco
7 products that are subject to a user fee under this
8 section shall be the quotient of—

9 “(A) the sum of the percentages assigned
10 to all classes of tobacco products subject to this
11 section; divided by

12 “(B) the percentage assigned to such class
13 under paragraph (2).

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

16 “(A) for fiscal year 2004 shall be
17 \$85,000,000;

18 “(B) for fiscal year 2005 shall be
19 \$175,000,000;

20 “(C) for fiscal year 2006 shall be
21 \$300,000,000; and

22 “(D) for each subsequent fiscal year, shall
23 not exceed the limit on the assessment imposed
24 during the previous fiscal year, as adjusted by

1 the Secretary (after notice, published in the
2 Federal Register) to reflect the greater of—

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

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

18 “(5) TIMING OF USER FEE ASSESSMENT.—The
19 Secretary shall notify each manufacturer and im-
20 porter of tobacco products subject to this section of
21 the amount of the quarterly assessment imposed on
22 such manufacturer or importer under subsection (f)
23 during each quarter of each fiscal year. Such notifi-
24 cations shall occur not earlier than 3 months prior
25 to the end of the quarter for which such assessment

1 is made, and payments of all assessments shall be
2 made not later than 60 days after each such notifi-
3 cation.

4 “(d) DETERMINATION OF USER FEE BY COMPANY
5 MARKET SHARE.—

6 “(1) IN GENERAL.—The user fee to be paid by
7 each manufacturer or importer of a given class of to-
8 bacco products shall be determined in each quarter
9 by multiplying—

10 “(A) such manufacturer’s or importer’s
11 market share of such class of tobacco products;
12 by

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

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

21 “(e) DETERMINATION OF VOLUME OF DOMESTIC
22 SALES.—

23 “(1) IN GENERAL.—The calculation of gross
24 domestic volume of a class of tobacco product by a
25 manufacturer or importer, and by all manufacturers

1 and importers as a group, shall be made by the Sec-
2 retary using information provided by manufacturers
3 and importers pursuant to subsection (f), as well as
4 any other relevant information provided to or ob-
5 tained by the Secretary.

6 “(2) MEASUREMENT.—For purposes of the cal-
7 culations under this subsection and the information
8 provided under subsection (f) by the Secretary, gross
9 domestic volume shall be measured by—

10 “(A) in the case of cigarettes, the number
11 of cigarettes sold;

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

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

17 “(D) in the case of other classes of tobacco
18 products, in terms of number of pounds, or
19 fraction thereof, of these products sold.

20 “(f) MEASUREMENT OF GROSS DOMESTIC VOL-
21 UME.—

22 “(1) IN GENERAL.—Each manufacturer and
23 importer of tobacco products shall submit to the
24 Secretary a certified copy of each of the returns or
25 forms described by this paragraph that are required

1 to be filed with a Government agency on the same
2 date that those returns or forms are filed, or re-
3 quired to be filed, with such agency. The returns
4 and forms described by this paragraph are those re-
5 turns and forms related to the release of tobacco
6 products into domestic commerce, as defined by sec-
7 tion 5702(k) of the Internal Revenue Code of 1986,
8 and the repayment of the taxes imposed under chap-
9 ter 52 of such Code (ATF Form 500.24 and United
10 States Customs Form 7501 under currently applica-
11 ble regulations).

12 “(2) PENALTIES.—Any person that knowingly
13 fails to provide information required under this sub-
14 section or that provides false information under this
15 subsection shall be subject to the penalties described
16 in section 1003 of title 18, United States Code. In
17 addition, such person may be subject to a civil pen-
18 alty in an amount not to exceed 2 percent of the
19 value of the kind of tobacco products manufactured
20 or imported by such person during the applicable
21 quarter, as determined by the Secretary.

22 “(h) EFFECTIVE DATE.—The user fees prescribed by
23 this section shall be assessed in fiscal year 2004, based
24 on domestic sales of tobacco products during fiscal year
25 2003 and shall be assessed in each fiscal year thereafter.”.

1 **SEC. 102. INTERIM FINAL RULE.**

2 (a) CIGARETTES AND SMOKELESS TOBACCO.—

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

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

17 (A) provide for the designation of jurisdic-
18 tional authority that is in accordance with this
19 subsection;

20 (B) strike Subpart C—Labeling and sec-
21 tion 897.32(e); and

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

24 (3) AMENDMENTS TO RULE.—Prior to making
25 amendments to the rule published under paragraph
26 (1), the Secretary shall promulgate a proposed rule

1 in accordance with the Administrative Procedures
2 Act.

3 (4) RULE OF CONSTRUCTION.—Except as pro-
4 vided in paragraph (3), nothing in this section shall
5 be construed to limit the authority of the Secretary
6 to amend, in accordance with the Administrative
7 Procedures Act, the regulation promulgated pursu-
8 ant to this section.

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

17 (1) The preamble to the proposed rule in the
18 document entitled “Regulations Restricting the Sale
19 and Distribution of Cigarettes and Smokeless To-
20 bacco Products to Protect Children and Adoles-
21 cents” (60 Fed. Reg. 41314–41372 (August 11,
22 1995)).

23 (2) The document entitled “Nicotine in Ciga-
24 rettes and Smokeless Tobacco Products is a Drug
25 and These Products Are Nicotine Delivery Devices

1 Under the Federal Food, Drug, and Cosmetic Act”
2 (60 Fed. Reg. 41453–41787 (August 11, 1995)).

3 (3) The preamble to the final rule in the docu-
4 ment entitled “Regulations Restricting the Sale and
5 Distribution of Cigarettes and Smokeless Tobacco to
6 Protect Children and Adolescents” (61 Fed. Reg.
7 44396–44615 (August 28, 1996)).

8 (4) The document entitled “Nicotine in Ciga-
9 rettes and Smokeless Tobacco is a Drug and These
10 Products are Nicotine Delivery Devices Under the
11 Federal Food, Drug, and Cosmetic Act; Jurisdic-
12 tional Determination” (61 Fed. Reg. 44619–45318
13 (August 28, 1996)).

14 **SEC. 103. CONFORMING AND OTHER AMENDMENTS TO GEN-**
15 **ERAL PROVISIONS.**

16 (a) AMENDMENT OF FEDERAL FOOD, DRUG, AND
17 COSMETIC ACT.—Except as otherwise expressly provided,
18 whenever in this section an amendment is expressed in
19 terms of an amendment to, or repeal of, a section or other
20 provision, the reference is to a section or other provision
21 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
22 301 et seq.).

23 (b) SECTION 301.—Section 301 (21 U.S.C. 331) is
24 amended—

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

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

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

7 (4) in subsection (e), by striking “515(f), or
8 519” and inserting “515(f), 519, or 909”;

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

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

13 (7) in subsection (j), by striking “708, or 721”
14 and inserting “708, 721, 904, 905, 906, 907, 908,
15 909, or section 921(b)”;

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

18 (9) by striking subsection (p) and inserting the
19 following:

20 “(p) The failure to register in accordance with section
21 510 or 905, the failure to provide any information re-
22 quired by section 510(j), 510(k), 905(i), or 905(j), or the
23 failure to provide a notice required by section 510(j)(2)
24 or 905(i)(2).”;

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

3 “(q)(1) The failure or refusal—

4 “(A) to comply with any requirement prescribed
5 under section 518, 520(g), 903(b)(8), or 908, or
6 condition prescribed under section
7 903(b)(6)(B)(ii)(II);

8 “(B) to furnish any notification or other mate-
9 rial or information required by or under section 519,
10 520(g), 904, 909, or section 921; or

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

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

15 (12) in subsection (r), by inserting “or tobacco
16 product” after “device” each time that it appears;
17 and

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

19 “(aa) The sale of tobacco products in violation
20 of a no-tobacco-sale order issued under section
21 303(f).

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

1 “(cc)(1) Forging, counterfeiting, simulating, or
2 falsely representing, or without proper authority
3 using any mark, stamp (including tax stamp), tag,
4 label, or other identification device upon any tobacco
5 product or container or labeling thereof so as to
6 render such tobacco product a counterfeit tobacco
7 product.

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

17 “(3) The doing of any act that causes a tobacco
18 product to be a counterfeit tobacco product, or the
19 sale or dispensing, or the holding for sale or dis-
20 pensing, of a counterfeit tobacco product.

21 “(dd) The charitable distribution of tobacco
22 products.

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

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

3 (1) by striking the subsection heading and in-
4 serting the following:

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

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

9 (3) by redesignating paragraphs (3), (4), and
10 (5) as paragraphs (4), (5), and (6), and inserting
11 after paragraph (2) the following:

12 “(3) If the Secretary finds that a person has
13 committed repeated violations of restrictions promul-
14 gated under section 906(d) at a particular retail out-
15 let then the Secretary may impose a no-tobacco-sale
16 order on that person prohibiting the sale of tobacco
17 products in that outlet. A no-tobacco-sale order may
18 be imposed with a civil penalty under paragraph
19 (1).”;

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

21 (A) in subparagraph (A)—

22 (i) by striking “assessed” the first
23 time it appears and inserting “assessed, or
24 a no-tobacco-sale order may be imposed,”;

25 and

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

4 (B) in subparagraph (B)—

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

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

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

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

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

21 (A) by striking “(3)(A)” as redesignated,
22 and inserting “(4)(A)”;

23 (B) by inserting “or the imposition of a
24 no-tobacco-sale order” after “penalty” the first
25 2 places it appears; and

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

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

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

9 (1) in subsection (a)(2)—

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

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

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

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

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

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

23 (1) by inserting “(1)” after “(a)”;

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

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

5 (f) SECTION 703.—Section 703 (21 U.S.C. 373) is
6 amended—

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

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

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

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

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

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

21 (h) SECTION 705.—Section 705(b) (21 U.S.C.
22 375(b)) is amended by inserting “tobacco products,” after
23 “devices,”.

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

1 (j) SECTION 801.—Section 801 (21 U.S.C. 381) is
2 amended—

3 (1) in subsection (a)—

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

6 (B) by inserting “or section 905(j)” after
7 “section 510”; and

8 (C) by striking “drugs or devices” each
9 time it appears and inserting “drugs, devices,
10 or tobacco products”;

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

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

14 “(p)(1) Not later than 2 years after the date of enact-
15 ment of the Family Smoking Prevention and Tobacco
16 Control Act, and annually thereafter, the Secretary shall
17 submit to the Committee on Health, Education, Labor,
18 and Pensions of the Senate and the Committee on Energy
19 and Commerce of the House of Representatives, a report
20 regarding—

21 “(A) the nature, extent, and destination of
22 United States tobacco product exports that do not
23 conform to tobacco product standards established
24 pursuant to this Act;

1 “(B) the public health implications of such ex-
2 ports, including any evidence of a negative public
3 health impact; and

4 “(C) recommendations or assessments of policy
5 alternatives available to Congress and the Executive
6 Branch to reduce any negative public health impact
7 caused by such exports.

8 “(2) The Secretary is authorized to establish appro-
9 priate information disclosure requirements to carry out
10 this subsection.”.

11 (k) SECTION 1003.—Section 1003(d)(2)(C) (as re-
12 designated by section 101(a)) is amended—

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

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

16 (l) EFFECTIVE DATE FOR NO-TOBACCO-SALE
17 ORDER AMENDMENTS.—The amendments made by sub-
18 section (c), other than the amendment made by paragraph
19 (2) of such subsection, shall take effect upon the issuance
20 of guidance by the Secretary of Health and Human
21 Services—

22 (1) defining the term “repeated violation”, as
23 used in section 303(f) of the Federal Food, Drug,
24 and Cosmetic Act (21 U.S.C. 333(f)) as amended by
25 subsection (c), by identifying the number of viola-

1 tions of particular requirements over a specified pe-
2 riod of time at a particular retail outlet that con-
3 stitute a repeated violation;

4 (2) providing for timely and effective notice to
5 the retailer of each alleged violation at a particular
6 retail outlet and an expedited procedure for the ad-
7 ministrative appeal of an alleged violation;

8 (3) providing that a person may not be charged
9 with a violation at a particular retail outlet unless
10 the Secretary has provided notice to the retailer of
11 all previous violations at that outlet;

12 (4) establishing a period of time during which,
13 if there are no violations by a particular retail out-
14 let, that outlet will not be considered to have been
15 the site of repeated violations when the next viola-
16 tion occurs; and

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

24 (A) adopting and enforcing a written policy
25 against sales to minors;

1 (B) informing its employees of all applica-
2 ble laws;

3 (C) establishing disciplinary sanctions for
4 employee noncompliance; and

5 (D) requiring its employees to verify age
6 by way of photographic identification or elec-
7 tronic scanning device.

8 **TITLE II—TOBACCO PRODUCT**
9 **WARNINGS; CONSTITUENT**
10 **AND SMOKE CONSTITUENT**
11 **DISCLOSURE**

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

13 Section 4 of the Federal Cigarette Labeling and Ad-
14 vertising Act (15 U.S.C. 1333) is amended to read as fol-
15 lows:

16 **“SEC. 4. LABELING.**

17 **“(a) LABEL REQUIREMENTS.—**

18 **“(1) IN GENERAL.—**It shall be unlawful for any
19 person to manufacture, package, sell, offer to sell,
20 distribute, or import for sale or distribution within
21 the United States any cigarettes the package of
22 which fails to bear, in accordance with the require-
23 ments of this section, one of the following labels:

24 **‘WARNING: Cigarettes are addictive’.**

1 'WARNING: Tobacco smoke can harm your chil-
2 dren'.

3 'WARNING: Cigarettes cause fatal lung disease'.

4 'WARNING: Cigarettes cause cancer'.

5 'WARNING: Cigarettes cause strokes and heart dis-
6 ease'.

7 'WARNING: Smoking during pregnancy can harm
8 your baby'.

9 'WARNING: Smoking can kill you'.

10 'WARNING: Tobacco smoke causes fatal lung dis-
11 ease in non-smokers'.

12 'WARNING: Quitting smoking now greatly reduces
13 serious risks to your health'.

14 "(2) PLACEMENT; TYPOGRAPHY; ETC.—

15 "(A) IN GENERAL.—Each label statement
16 required by paragraph (1) shall be located in
17 the upper portion of the front and rear panels
18 of the package, directly on the package under-
19 neath the cellophane or other clear wrapping.
20 Except as provided in subparagraph (B), each
21 label statement shall comprise at least the top
22 30 percent of the front and rear panels of the
23 package. The word 'WARNING' shall appear in
24 capital letters and all text shall be in con-
25 spicuous and legible 17-point type, unless the

1 text of the label statement would occupy more
2 than 70 percent of such area, in which case the
3 text may be in a smaller conspicuous and leg-
4 ible type size, provided that at least 60 percent
5 of such area is occupied by required text. The
6 text shall be black on a white background, or
7 white on a black background, in a manner that
8 contrasts, by typography, layout, or color, with
9 all other printed material on the package, in an
10 alternating fashion under the plan submitted
11 under subsection (b)(4).

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

23 “(3) DOES NOT APPLY TO FOREIGN DISTRIBU-
24 TION.—The provisions of this subsection do not
25 apply to a tobacco product manufacturer or dis-

1 tributor of cigarettes which does not manufacture,
2 package, or import cigarettes for sale or distribution
3 within the United States.

4 “(4) APPLICABILITY TO RETAILERS.—A retailer
5 of cigarettes shall not be in violation of this sub-
6 section for packaging that is supplied to the retailer
7 by a tobacco product manufacturer, importer, or dis-
8 tributor and is not altered by the retailer in a way
9 that is material to the requirements of this sub-
10 section except that this paragraph shall not relieve
11 a retailer of liability if the retailer sells or distributes
12 tobacco products that are not labeled in accordance
13 with this subsection.

14 “(b) ADVERTISING REQUIREMENTS.—

15 “(1) IN GENERAL.—It shall be unlawful for any
16 tobacco product manufacturer, importer, distributor,
17 or retailer of cigarettes to advertise or cause to be
18 advertised within the United States any cigarette
19 unless its advertising bears, in accordance with the
20 requirements of this section, one of the labels speci-
21 fied in subsection (a) of this section.

22 “(2) TYPOGRAPHY, ETC.—Each label statement
23 required by subsection (a) of this section in cigarette
24 advertising shall comply with the standards set forth
25 in this paragraph. For press and poster advertise-

1 ments, each such statement and (where applicable)
2 any required statement relating to tar, nicotine, or
3 other constituent (including a smoke constituent)
4 yield shall comprise at least 20 percent of the area
5 of the advertisement and shall appear in a con-
6 spicuous and prominent format and location at the
7 top of each advertisement within the trim area. The
8 Secretary may revise the required type sizes in such
9 area in such manner as the Secretary determines ap-
10 propriate. The word 'WARNING' shall appear in
11 capital letters, and each label statement shall appear
12 in conspicuous and legible type. The text of the label
13 statement shall be black if the background is white
14 and white if the background is black, under the plan
15 submitted under paragraph (4) of this subsection.
16 The label statements shall be enclosed by a rectan-
17 gular border that is the same color as the letters of
18 the statements and that is the width of the first
19 downstroke of the capital 'W' of the word 'WARN-
20 ING' in the label statements. The text of such label
21 statements shall be in a typeface pro rata to the fol-
22 lowing requirements: 45-point type for a whole-page
23 broadsheet newspaper advertisement; 39-point type
24 for a half-page broadsheet newspaper advertisement;
25 39-point type for a whole-page tabloid newspaper ad-

1 advertisement; 27-point type for a half-page tabloid
2 newspaper advertisement; 31.5-point type for a dou-
3 ble page spread magazine or whole-page magazine
4 advertisement; 22.5-point type for a 28 centimeter
5 by 3 column advertisement; and 15-point type for a
6 20 centimeter by 2 column advertisement. The label
7 statements shall be in English, except that in the
8 case of—

9 “(A) an advertisement that appears in a
10 newspaper, magazine, periodical, or other publi-
11 cation that is not in English, the statements
12 shall appear in the predominant language of the
13 publication; and

14 “(B) in the case of any other advertise-
15 ment that is not in English, the statements
16 shall appear in the same language as that prin-
17 cipally used in the advertisement.

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

24 “(4) ADJUSTMENT BY SECRETARY.—The Sec-
25 retary may, through a rulemaking under section 553

1 of title 5, United States Code, adjust the format and
2 type sizes for the label statements required by this
3 section or the text, format, and type sizes of any re-
4 quired tar, nicotine yield, or other constituent (in-
5 cluding smoke constituent) disclosures, or to estab-
6 lish the text, format, and type sizes for any other
7 disclosures required under the Federal Food, Drug,
8 and Cosmetic Act (21 U.S.C. 301 et. seq.). The text
9 of any such label statements or disclosures shall be
10 required to appear only within the 20 percent area
11 of cigarette advertisements provided by paragraph
12 (2) of this subsection. The Secretary shall promul-
13 gate regulations which provide for adjustments in
14 the format and type sizes of any text required to ap-
15 pear in such area to ensure that the total text re-
16 quired to appear by law will fit within such area.

17 “(5) MARKETING REQUIREMENTS.—

18 “(A) The label statements specified in sub-
19 section (a)(1) shall be randomly displayed in
20 each 12-month period, in as equal a number of
21 times as is possible on each brand of the prod-
22 uct and be randomly distributed in all areas of
23 the United States in which the product is mar-
24 keted in accordance with a plan submitted by
25 the tobacco product manufacturer, importer,

1 distributor, or retailer and approved by the Sec-
2 retary.

3 “(B) The label statements specified in sub-
4 section (a)(1) shall be rotated quarterly in al-
5 ternating sequence in advertisements for each
6 brand of cigarettes in accordance with a plan
7 submitted by the tobacco product manufacturer,
8 importer, distributor, or retailer to, and ap-
9 proved by, the Secretary.

10 “(C) The Secretary shall review each plan
11 submitted under subparagraph (B) and approve
12 it if the plan—

13 “(i) will provide for the equal distribu-
14 tion and display on packaging and the ro-
15 tation required in advertising under this
16 subsection; and

17 “(ii) assures that all of the labels re-
18 quired under this section will be displayed
19 by the tobacco product manufacturer, im-
20 porter, distributor, or retailer at the same
21 time.

22 “(6) APPLICABILITY TO RETAILERS.—This sub-
23 section applies to a retailer only if that retailer is re-
24 sponsible for or directs the label statements required
25 under this section except that this paragraph shall

1 not relieve a retailer of liability if the retailer dis-
2 plays, in a location open to the public, an advertise-
3 ment that is not labeled in accordance with the re-
4 quirements of this subsection.”.

5 **SEC. 202. AUTHORITY TO REVISE CIGARETTE WARNING**
6 **LABEL STATEMENTS.**

7 Section 4 of the Federal Cigarette Labeling and Ad-
8 vertising Act (15 U.S.C. 1333), as amended by section
9 201, is further amended by adding at the end the fol-
10 lowing:

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

1 **SEC. 203. STATE REGULATION OF CIGARETTE ADVER-**
 2 **TISING AND PROMOTION.**

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

6 “(c) EXCEPTION.—Notwithstanding subsection (b), a
 7 State or locality may enact statutes and promulgate regu-
 8 lations, based on smoking and health, that take effect
 9 after the effective date of the Family Smoking Prevention
 10 and Tobacco Control Act, imposing specific bans or re-
 11 strictions on the time, place, and manner, but not content,
 12 of the advertising or promotion of any cigarettes.”.

13 **SEC. 204. SMOKELESS TOBACCO LABELS AND ADVERTISING**
 14 **WARNINGS.**

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

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

19 “(a) GENERAL RULE.—

20 “(1) It shall be unlawful for any person to man-
 21 ufacture, package, sell, offer to sell, distribute, or
 22 import for sale or distribution within the United
 23 States any smokeless tobacco product unless the
 24 product package bears, in accordance with the re-
 25 quirements of this Act, one of the following labels:
 26 ‘WARNING: This product can cause mouth cancer’.

1 ‘WARNING: This product can cause gum disease
2 and tooth loss’.

3 ‘WARNING: This product is not a safe alternative
4 to cigarettes’.

5 ‘WARNING: Smokeless tobacco is addictive’.

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

8 “(A) located on the 2 principal display
9 panels of the package, and each label statement
10 shall comprise at least 30 percent of each such
11 display panel; and

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

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

6 “(4) The provisions of this subsection do not
7 apply to a tobacco product manufacturer or dis-
8 tributor of any smokeless tobacco product that does
9 not manufacture, package, or import smokeless to-
10 bacco products for sale or distribution within the
11 United States.

12 “(5) A retailer of smokeless tobacco products
13 shall not be in violation of this subsection for pack-
14 aging that is supplied to the retailer by a tobacco
15 products manufacturer, importer, or distributor and
16 that is not altered by the retailer unless the retailer
17 offers for sale, sells, or distributes a smokeless to-
18 bacco product that is not labeled in accordance with
19 this subsection.

20 “(b) REQUIRED LABELS.—

21 “(1) It shall be unlawful for any tobacco prod-
22 uct manufacturer, packager, importer, distributor, or
23 retailer of smokeless tobacco products to advertise or
24 cause to be advertised within the United States any
25 smokeless tobacco product unless its advertising

1 bears, in accordance with the requirements of this
2 section, one of the labels specified in subsection (a).

3 “(2) Each label statement required by sub-
4 section (a) in smokeless tobacco advertising shall
5 comply with the standards set forth in this para-
6 graph. For press and poster advertisements, each
7 such statement and (where applicable) any required
8 statement relating to tar, nicotine, or other con-
9 stituent yield shall—

10 “(A) comprise at least 20 percent of the
11 area of the advertisement, and the warning area
12 shall be delineated by a dividing line of con-
13 trasting color from the advertisement; and

14 “(B) the word ‘WARNING’ shall appear in
15 capital letters and each label statement shall
16 appear in conspicuous and legible type. The text
17 of the label statement shall be black on a white
18 background, or white on a black background, in
19 an alternating fashion under the plan submitted
20 under paragraph (3).

21 “(3)(A) The label statements specified in sub-
22 section (a)(1) shall be randomly displayed in each
23 12-month period, in as equal a number of times as
24 is possible on each brand of the product and be ran-
25 domly distributed in all areas of the United States

1 in which the product is marketed in accordance with
2 a plan submitted by the tobacco product manufac-
3 turer, importer, distributor, or retailer and approved
4 by the Secretary.

5 “(B) The label statements specified in sub-
6 section (a)(1) shall be rotated quarterly in alter-
7 nating sequence in advertisements for each brand of
8 smokeless tobacco product in accordance with a plan
9 submitted by the tobacco product manufacturer, im-
10 porter, distributor, or retailer to, and approved by,
11 the Secretary.

12 “(C) The Secretary shall review each plan sub-
13 mitted under subparagraph (B) and approve it if the
14 plan—

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

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

22 “(D) This paragraph applies to a retailer only
23 if that retailer is responsible for or directs the label
24 statements under this section, unless the retailer dis-
25 plays in a location open to the public, an advertise-

1 ment that is not labeled in accordance with the re-
2 quirements of this subsection.

3 “(c) TELEVISION AND RADIO ADVERTISING.—It is
4 unlawful to advertise smokeless tobacco on any medium
5 of electronic communications subject to the jurisdiction of
6 the Federal Communications Commission.”.

7 **SEC. 205. AUTHORITY TO REVISE SMOKELESS TOBACCO**
8 **PRODUCT WARNING LABEL STATEMENTS.**

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

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

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

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

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

21 “(B) Any differences between the requirements
22 established by the Secretary under subparagraph (A)
23 and tar and nicotine yield reporting requirements es-
24 tablished by the Federal Trade Commission shall be
25 resolved by a memorandum of understanding be-

1 tween the Secretary and the Federal Trade Commis-
2 sion.

3 “(C) In addition to the disclosures required by
4 subparagraph (A) of this paragraph, the Secretary
5 may, under a rulemaking conducted under section
6 553 of title 5, United States Code, prescribe disclo-
7 sure requirements regarding the level of any ciga-
8 rette or other tobacco product constituent including
9 any smoke constituent. Any such disclosure may be
10 required if the Secretary determines that disclosure
11 would be of benefit to the public health, or otherwise
12 would increase consumer awareness of the health
13 consequences of the use of tobacco products, except
14 that no such prescribed disclosure shall be required
15 on the face of any cigarette package or advertise-
16 ment. Nothing in this section shall prohibit the Sec-
17 retary from requiring such prescribed disclosure
18 through a cigarette or other tobacco product pack-
19 age or advertisement insert, or by any other means
20 under the Federal Food, Drug, and Cosmetic Act
21 (21 U.S.C. 301 et seq.).

22 “(D) This paragraph applies to a retailer only
23 if that retailer is responsible for or directs the label
24 statements required under this section, except that
25 this paragraph shall not relieve a retailer of liability

1 if the retailer sells or distributes tobacco products
 2 that are not labeled in accordance with the require-
 3 ments of this subsection.”.

4 **TITLE III—PREVENTION OF IL-**
 5 **LICIT TRADE IN TOBACCO**
 6 **PRODUCTS**

7 **SEC. 301. LABELING, RECORDKEEPING, RECORDS INSPEC-**
 8 **TION.**

9 Chapter IX of the Federal Food, Drug, and Cosmetic
 10 Act, as added by section 101, is further amended by add-
 11 ing at the end the following:

12 **“SEC. 921. LABELING, RECORDKEEPING, RECORDS INSPEC-**
 13 **TION.**

14 “(a) **ORIGIN LABELING.**—The label, packaging, and
 15 shipping containers of tobacco products for introduction
 16 or delivery for introduction into interstate commerce shall
 17 bear the statement ‘sale only allowed in the United
 18 States.’

19 “(b) **REGULATIONS CONCERNING RECORDKEEPING**
 20 **FOR TRACKING AND TRACING.**—

21 “(1) **IN GENERAL.**—Not later than 9 months
 22 after the date of enactment of the Family Smoking
 23 Prevention and Tobacco Control Act, the Secretary
 24 shall promulgate regulations regarding the establish-
 25 ment and maintenance of records by any person who

1 manufactures, processes, transports, distributes, re-
2 ceives, packages, holds, exports, or imports tobacco
3 products.

4 “(2) INSPECTION.—In promulgating the regula-
5 tions described in paragraph (1), the Secretary shall
6 consider which records are needed for inspection to
7 monitor the movement of tobacco products from the
8 point of manufacture through distribution to retail
9 outlets to assist in investigating potential illicit
10 trade, smuggling or counterfeiting of tobacco prod-
11 ucts.

12 “(3) CODES.—The Secretary may require codes
13 on the labels of tobacco products or other designs or
14 devices for the purpose of tracking or tracing the to-
15 bacco product through the distribution system.

16 “(4) SIZE OF BUSINESS.—The Secretary shall
17 take into account the size of a business in promul-
18 gating regulations under this section.

19 “(5) RECORDKEEPING BY RETAILERS.—The
20 Secretary shall not require any retailer to maintain
21 records relating to individual purchasers of tobacco
22 products for personal consumption.

23 “(c) RECORDS INSPECTION.—If the Secretary has a
24 reasonable belief that a tobacco product is part of an illicit
25 trade or smuggling or is a counterfeit product, each person

1 who manufactures, processes, transports, distributes, re-
2 ceives, holds, packages, exports, or imports tobacco prod-
3 ucts shall, at the request of an officer or employee duly
4 designated by the Secretary, permit such officer or em-
5 ployee, at reasonable times and within reasonable limits
6 and in a reasonable manner, upon the presentation of ap-
7 propriate credentials and a written notice to such person,
8 to have access to and copy all records (including financial
9 records) relating to such article that are needed to assist
10 the Secretary in investigating potential illicit trade, smug-
11 gling or counterfeiting of tobacco products.

12 “(d) KNOWLEDGE OF ILLEGAL TRANSACTION.—If
13 the manufacturer or distributor of a tobacco product has
14 knowledge which reasonably supports the conclusion that
15 a tobacco product manufactured or distributed by such
16 manufacturer or distributor that has left the control of
17 such person may be or has been—

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

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

24 the manufacturer or distributor shall promptly notify the
25 Attorney General of such knowledge.

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

4 “(A) the actual knowledge that the manu-
5 facturer or distributor had; or

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

10 **SEC. 302. STUDY AND REPORT.**

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

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

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

1 (b) REPORT.—Not later than 18 months after the
2 date of enactment of this Act, the Comptroller General
3 of the United States shall submit to the Committee on
4 Health, Education, Labor, and Pensions of the Senate and
5 the Committee on Energy and Commerce of the House
6 of Representatives a report on the study described in sub-
7 section (a).

Passed the Senate October 10, 2004.

Attest:

Secretary.

108TH CONGRESS
2^D SESSION

S. 2974

AN ACT

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