

Union Calendar No. 485

110TH CONGRESS
2D SESSION

H. R. 1108

[Report No. 110-762]

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

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 15, 2007

Mr. WAXMAN (for himself, Mr. TOM DAVIS of Virginia, Mr. DINGELL, Mr. PALLONE, Mr. ABERCROMBIE, Mr. ACKERMAN, Mr. ALLEN, Ms. BALDWIN, Mr. BARTLETT of Maryland, Mr. BLUMENAUER, Ms. BORDALLO, Mrs. CAPPS, Mr. CAPUANO, Mr. CASTLE, Mrs. CHRISTENSEN, Mr. CUMMINGS, Mr. DAVIS of Illinois, Mrs. DAVIS of California, Ms. DEGETTE, Mr. DELAHUNT, Ms. DELAURO, Mr. ELLISON, Mr. EMANUEL, Mrs. EMERSON, Mr. ENGEL, Ms. ESHOO, Mr. FERGUSON, Mr. FINNER, Mr. FRANK of Massachusetts, Ms. GIFFORDS, Mr. GENE GREEN of Texas, Mr. GRIJALVA, Mr. GUTIERREZ, Mr. HIGGINS, Mr. HINCHEY, Ms. HIRONO, Mr. HOLT, Mr. HONDA, Mr. INSLEE, Mr. ISRAEL, Mr. JACKSON of Illinois, Ms. JACKSON-LEE of Texas, Mr. KENNEDY, Mr. KILDEE, Mr. KING of New York, Mr. KIRK, Mr. LAHOOD, Mr. LANTOS, Mr. LARSEN of Washington, Mr. LARSON of Connecticut, Ms. LEE, Mr. LEWIS of Georgia, Mr. LIPINSKI, Mr. LOBIONDO, Ms. ZOE LOFGREN of California, Mr. LYNCH, Mrs. MCCARTHY of New York, Ms. MCCOLLUM of Minnesota, Mr. McDERMOTT, Mr. MCGOVERN, Mr. McNULTY, Mrs. MALONEY of New York, Mr. MARKEY, Mr. MATHESON, Ms. MATSUI, Mr. MEEHAN, Mr. MICHAUD, Mrs. MILLER of Michigan, Mr. GEORGE MILLER of California, Mr. MOORE of Kansas, Mr. MORAN of Virginia, Mr. NADLER, Ms. NORTON, Mr. OBERSTAR, Mr. OLVER, Mr. PASCRELL, Mr. PAYNE, Mr. PLATTS, Ms. PRYCE of Ohio, Mr. RAMSTAD, Mr. REICHERT, Mr. ROTHMAN, Mr. RUSH, Ms. SCHAKOWSKY, Ms. SCHWARTZ, Mr. SHERMAN, Mr. SMITH of New Jersey, Ms. SOLIS, Mr. STARK, Mrs. TAUSCHER, Mr. TERRY, Mr. TIBERI, Mr. VAN HOLLEN, Mr. WALDEN of Oregon, Mr. WEINER, Mr. WELLER of Illinois, Mr. WEXLER, and Mr. WYNN) introduced the following bill; which was referred to the Committee on Energy and Commerce

JULY 17, 2008

Additional sponsors: Ms. HARMAN, Mr. FRELINGHUYSEN, Mr. COHEN, Mr. BAIRD, Ms. WOOLSEY, Mr. MURPHY of Connecticut, Mr. DENT, Mr. BOSWELL, Mr. FATAH, Mr. COURTNEY, Ms. WASSERMAN SCHULTZ, Mr. HARE, Mr. ROSKAM, Mr. TOWNS, Mr. UDALL of New Mexico, Mr. DOYLE, Mr. RAHALL, Mr. HALL of New York, Mr. ELLSWORTH, Mr. STUPAK, Mr. UPTON, Mr. MARSHALL, Mr. CROWLEY, Ms. HERSETH SANDLIN, Ms. CARSON, Mr. LAMPSON, Ms. SHEA-PORTER, Mr. MITCHELL, Mr. DEFAZIO, Mr. JOHNSON of Georgia, Mr. COSTELLO, Mr. BRALEY of Iowa, Mrs. BONO MACK, Ms. SUTTON, Mr. FARR, Mr. GONZALEZ, Mr. ARCURI, Mr. KAGEN, Mr. BERRY, Mr. THOMPSON of Mississippi, Mr. COSTA, Mr. HOLDEN, Mr. HINOJOSA, Mr. SMITH of Washington, Mr. WALZ of Minnesota, Mr. LOEBSACK, Mr. NEAL of Massachusetts, Mr. AL GREEN of Texas, Mr. RODRIGUEZ, Mr. KIND, Mr. CARNEY, Mrs. CAPITO, Mr. UDALL of Colorado, Mr. PATRICK J. MURPHY of Pennsylvania, Mr. WELCH of Vermont, Ms. SLAUGHTER, Mr. SCHIFF, Mr. RUPPERSBERGER, Mrs. LOWEY, Mr. GERLACH, Ms. HOOLEY, Mr. WALSH of New York, Mr. SARBANES, Mr. POMEROY, Mr. PRICE of North Carolina, Mr. GILCHREST, Mr. SAXTON, Mr. WU, Mrs. BOYDA of Kansas, Mr. MEEKS of New York, Mr. HODES, Mr. SERRANO, Ms. BEAN, Mrs. GILLIBRAND, Mr. SNYDER, Mr. ALEXANDER, Mr. CARNAHAN, Mr. BRADY of Pennsylvania, Mr. KUCINICH, Ms. BERKLEY, Ms. CLARKE, Ms. KILPATRICK, Mr. RYAN of Ohio, Ms. LORETTA SANCHEZ of California, Mrs. NAPOLITANO, Mr. BISHOP of New York, Ms. EDDIE BERNICE JOHNSON of Texas, Ms. ROYBAL-ALLARD, Mr. LANGEVIN, Mr. HASTINGS of Florida, Mr. ALTMIRE, Ms. CORRINE BROWN of Florida, Mr. BARROW, Mr. TIERNEY, Mr. CONYERS, Mr. KLEIN of Florida, Ms. LINDA T. SÁNCHEZ of California, Mr. LATOURETTE, Mr. BISHOP of Georgia, Mr. EDWARDS, Mr. ANDREWS, Mr. LEVIN, Mr. DICKS, Mr. JEFFERSON, Mr. MEEK of Florida, Mr. SESTAK, Mr. PASTOR, Ms. VELÁZQUEZ, Mr. ROSS, Ms. WATSON, Ms. TSONGAS, Ms. CASTOR, Mrs. JONES of Ohio, Mr. SCOTT of Virginia, Mr. MCNERNEY, Ms. MOORE of Wisconsin, Mr. FALEOMAVAEGA, Mr. PICKERING, Mr. REYES, Mr. CLEAVER, Mr. BILBRAY, Mr. SHAYS, Mr. THOMPSON of California, Mr. YARMUTH, Mr. DREIER, Mr. MURTHA, Mr. CARSON, Mr. RENZI, Ms. SPEIER, Mr. YOUNG of Alaska, Mr. CANTOR, Mr. FOSTER, Ms. GINNY BROWN-WAITE of Florida, Mr. KANJORSKI, Mr. BROWN of South Carolina, and Mr. MCCAUL of Texas

JULY 17, 2008

Deleted sponsor: Mr. PITTS (added March 1, 2007; deleted April 2, 2008)

JULY 17, 2008

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in italic]

[For text of introduced bill, see copy of bill as introduced on February 15, 2007]

A BILL

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

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

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

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

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

Sec. 1. Short title; table of contents.

Sec. 2. Findings.

Sec. 3. Purpose.

Sec. 4. Scope and effect.

Sec. 5. Severability.

TITLE I—AUTHORITY OF THE FOOD AND DRUG ADMINISTRATION

Sec. 101. Amendment of Federal Food, Drug, and Cosmetic Act.

Sec. 102. Final rule.

Sec. 103. Conforming and other amendments to general provisions.

Sec. 104. Study on raising the minimum age to purchase tobacco products.

Sec. 105. Tobacco industry concentration.

*TITLE II—TOBACCO PRODUCT WARNINGS; CONSTITUENT AND
 SMOKE CONSTITUENT DISCLOSURE*

Sec. 201. Cigarette label and advertising warnings.

Sec. 202. Authority to revise cigarette warning label statements.

Sec. 203. State regulation of cigarette advertising and promotion.

Sec. 204. Smokeless tobacco labels and advertising warnings.

Sec. 205. Authority to revise smokeless tobacco product warning label statements.

Sec. 206. Tar, nicotine, and other smoke constituent disclosure to the public.

TITLE III—PREVENTION OF ILLICIT TRADE IN TOBACCO PRODUCTS

Sec. 301. Labeling, recordkeeping, records inspection.

Sec. 302. Study and report.

1 **SEC. 2. FINDINGS.**

2 *The Congress finds the following:*

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

7 (2) *A consensus exists within the scientific and*
8 *medical communities that tobacco products are inher-*
9 *ently dangerous and cause cancer, heart disease, and*
10 *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, comprehen-*
21 *sive restrictions on the sale, promotion, and distribu-*
22 *tion of such products are needed.*

1 (7) *Federal and State Governments have lacked*
2 *the legal and regulatory authority and resources they*
3 *need to address comprehensively the public health and*
4 *societal problems caused by the use of tobacco prod-*
5 *ucts.*

6 (8) *Federal and State public health officials, the*
7 *public health community, and the public at large rec-*
8 *ognize that the tobacco industry should be subject to*
9 *ongoing oversight.*

10 (9) *Under article I, section 8 of the Constitution,*
11 *the Congress is vested with the responsibility for regu-*
12 *lating interstate commerce and commerce with Indian*
13 *tribes.*

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

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

24 (12) *It is in the public interest for Congress to*
25 *enact legislation that provides the Food and Drug Ad-*

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

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

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

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

1 (16) *In 2005, the cigarette manufacturers spent*
2 *more than \$13,000,000,000 to attract new users, re-*
3 *tain current users, increase current consumption, and*
4 *generate favorable long-term attitudes toward smoking*
5 *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 strongly*
15 *associated with sports and has become portrayed as*
16 *an integral part of sports and the healthy lifestyle as-*
17 *sociated with rigorous sporting activity.*

18 (20) *Children are exposed to substantial and un-*
19 *avoidable tobacco advertising that leads to favorable*
20 *beliefs about tobacco use, plays a role in leading*
21 *young people to overestimate the prevalence of tobacco*
22 *use, and increases the number of young people who*
23 *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 the*
4 *tobacco market by increasing consumption of tobacco*
5 *products including tobacco use by young people.*

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

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

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

20 *(26) Restrictions on advertising are necessary to*
21 *prevent unrestricted tobacco advertising from under-*
22 *mining legislation prohibiting access to young people*
23 *and providing for education about tobacco 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 and*
2 *young people’s use than weaker or less comprehensive*
3 *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 Fed.*
14 *Reg. 44615–44618) for inclusion as part 897 of title*
15 *21, Code of Federal Regulations, are consistent with*
16 *the first amendment to the United States Constitution*
17 *and with the standards set forth in the amendments*
18 *made by this subtitle for the regulation of tobacco*
19 *products by the Food and Drug Administration, and*
20 *the restriction on the sale and distribution of, includ-*
21 *ing access to and the advertising and promotion of,*
22 *tobacco products contained in such regulations are*
23 *substantially related to accomplishing the public*
24 *health goals of this Act.*

1 (31) *The regulations described in paragraph (30)*
2 *will directly and materially advance the Federal Gov-*
3 *ernment's substantial interest in reducing the number*
4 *of children and adolescents who use cigarettes and*
5 *smokeless tobacco and in preventing the life-threat-*
6 *ening health consequences associated with tobacco use.*
7 *An overwhelming majority of Americans who use to-*
8 *bacco products begin using such products while they*
9 *are minors and become addicted to the nicotine in*
10 *those products before reaching the age of 18. Tobacco*
11 *advertising and promotion play a crucial role in the*
12 *decision of these minors to begin using tobacco prod-*
13 *ucts. Less restrictive and less comprehensive ap-*
14 *proaches have not and will not be effective in reduc-*
15 *ing the problems addressed by such regulations. The*
16 *reasonable restrictions on the advertising and pro-*
17 *motion of tobacco products contained in such regula-*
18 *tions will lead to a significant decrease in the number*
19 *of minors using and becoming addicted to those prod-*
20 *ucts.*

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

1 to prevent the life-threatening health consequences as-
2 sociated with tobacco use. Such regulations are nar-
3 rowly tailored to restrict those advertising and pro-
4 motional practices which are most likely to be seen or
5 heard by youth and most likely to entice them into
6 tobacco use, while affording tobacco manufacturers
7 and sellers ample opportunity to convey information
8 about their products to adult consumers.

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

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

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

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

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

7 *(37) Unless tobacco products that purport to re-*
8 *duce the risks to the public of tobacco use actually re-*
9 *duce such risks, those products can cause substantial*
10 *harm to the public health to the extent that the indi-*
11 *viduals, who would otherwise not consume tobacco*
12 *products or would consume such products less, use to-*
13 *bacco products purporting to reduce risk. Those who*
14 *use products sold or distributed as modified risk prod-*
15 *ucts that do not in fact reduce risk, rather than quit-*
16 *ting or reducing their use of tobacco products, have*
17 *a substantially increased likelihood of suffering dis-*
18 *ability and premature death. The costs to society of*
19 *the widespread use of products sold or distributed as*
20 *modified risk products that do not in fact reduce risk*
21 *or that increase risk include thousands of unnecessary*
22 *deaths and injuries and huge costs to our health care*
23 *system.*

24 *(38) As the National Cancer Institute has found,*
25 *many smokers mistakenly believe that “low tar” and*

1 *“light” cigarettes cause fewer health problems than*
2 *other cigarettes. As the National Cancer Institute has*
3 *also found, mistaken beliefs about the health con-*
4 *sequences of smoking “low tar” and “light” cigarettes*
5 *can reduce the motivation to quit smoking entirely*
6 *and thereby lead to disease and death.*

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

12 *(40) The dangers of products sold or distributed*
13 *as modified risk tobacco products that do not in fact*
14 *reduce risk are so high that there is a compelling gov-*
15 *ernmental interest in ensuring that statements about*
16 *modified risk tobacco products are complete, accurate,*
17 *and relate to the overall disease risk of the product.*

18 *(41) As the Federal Trade Commission has*
19 *found, consumers have misinterpreted advertisements*
20 *in which one product is claimed to be less harmful*
21 *than a comparable product, even in the presence of*
22 *disclosures and advisories intended to provide clari-*
23 *fication.*

24 *(42) Permitting manufacturers to make unsub-*
25 *stantiated statements concerning modified risk to-*

1 *bacco products, whether express or implied, even if ac-*
2 *companied by disclaimers would be detrimental to the*
3 *public health.*

4 *(43) The only way to effectively protect the pub-*
5 *lic health from the dangers of unsubstantiated modi-*
6 *fied risk tobacco products is to empower the Food and*
7 *Drug Administration to require that products that to-*
8 *bacco manufacturers sold or distributed for risk re-*
9 *duction be reviewed in advance of marketing, and to*
10 *require that the evidence relied on to support claims*
11 *be fully verified.*

12 *(44) The Food and Drug Administration is a*
13 *regulatory agency with the scientific expertise to iden-*
14 *tify harmful substances in products to which con-*
15 *sumers are exposed, to design standards to limit expo-*
16 *sure to those substances, to evaluate scientific studies*
17 *supporting claims about the safety of products, and to*
18 *evaluate the impact of labels, labeling, and adver-*
19 *tising on consumer behavior in order to reduce the*
20 *risk of harm and promote understanding of the im-*
21 *port of the product on health. In connection with its*
22 *mandate to promote health and reduce the risk of*
23 *harm, the Food and Drug Administration routinely*
24 *makes decisions about whether and how products may*
25 *be marketed in the United States.*

1 (45) *The Federal Trade Commission was created*
2 *to protect consumers from unfair or deceptive acts or*
3 *practices, and to regulate unfair methods of competi-*
4 *tion. Its focus is on those marketplace practices that*
5 *deceive or mislead consumers, and those that give*
6 *some competitors an unfair advantage. Its mission is*
7 *to regulate activities in the marketplace. Neither the*
8 *Federal Trade Commission nor any other Federal*
9 *agency except the Food and Drug Administration*
10 *possesses the scientific expertise needed to implement*
11 *effectively all provisions of the Family Smoking Pre-*
12 *vention and Tobacco Control Act.*

13 (46) *If manufacturers state or imply in commu-*
14 *nications directed to consumers through the media or*
15 *through a label, labeling, or advertising, that a to-*
16 *bacco product is approved or inspected by the Food*
17 *and Drug Administration or complies with Food and*
18 *Drug Administration standards, consumers are likely*
19 *to be confused and misled. Depending upon the par-*
20 *ticular language used and its context, such a state-*
21 *ment could result in consumers being misled into be-*
22 *lieving that the product is endorsed by the Food and*
23 *Drug Administration for use or in consumers being*
24 *misled about the harmfulness of the product because*

1 of such regulation, inspection, approval, or compli-
2 ance.

3 (47) *If manufacturers are permitted to state or*
4 *imply in communications directed to consumers that*
5 *a tobacco product is approved or inspected by the*
6 *Food and Drug Administration or complies with*
7 *Food and Drug Administration standards, consumers*
8 *are likely to be confused and misled. Such a statement*
9 *could result in consumers being misled into believing*
10 *that the product is endorsed by the Food and Drug*
11 *Administration for use or in consumers being misled*
12 *about the harmfulness of the product because of such*
13 *regulation, inspection, or compliance.*

14 (48) *In August 2006 a United States district*
15 *court judge found that the major United States ciga-*
16 *rette companies continue to target and market to*
17 *youth. USA v Philip Morris, USA, Inc., et al. (Civil*
18 *Action No. 99–2496 (GK), August 17, 2006).*

19 (49) *In August 2006 a United States district*
20 *court judge found that the major United States ciga-*
21 *rette companies dramatically increased their adver-*
22 *tising and promotional spending in ways that en-*
23 *courage youth to start smoking subsequent to the sign-*
24 *ing of the Master Settlement Agreement in 1998. USA*

1 *v Philip Morris, USA, Inc., et al. (Civil Action No.*
2 *99–2496 (GK), August 17, 2006).*

3 *(50) In August 2006 a United States district*
4 *court judge found that the major United States ciga-*
5 *rette companies have designed their cigarettes to pre-*
6 *cisely control nicotine delivery levels and provide*
7 *doses of nicotine sufficient to create and sustain ad-*
8 *diction while also concealing much of their nicotine-*
9 *related research. USA v Philip Morris, USA, Inc., et*
10 *al. (Civil Action No. 99–2496 (GK), August 17,*
11 *2006).*

12 **SEC. 3. PURPOSE.**

13 *The purposes of this Act are—*

14 *(1) to provide authority to the Food and Drug*
15 *Administration to regulate tobacco products under the*
16 *Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301*
17 *et seq.), by recognizing it as the primary Federal reg-*
18 *ulatory authority with respect to the manufacture,*
19 *marketing, and distribution of tobacco products as*
20 *provided for in this Act;*

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

1 (3) to authorize the Food and Drug Administra-
2 tion to set national standards controlling the manu-
3 facture of tobacco products and the identity, public
4 disclosure, and amount of ingredients used in such
5 products;

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

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

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

20 (7) to continue to permit the sale of tobacco
21 products to adults in conjunction with measures to
22 ensure that they are not sold or accessible to underage
23 purchasers;

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

1 (9) to promote cessation to reduce disease risk
2 and the social costs associated with tobacco-related
3 diseases; and

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

6 **SEC. 4. SCOPE AND EFFECT.**

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

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

12 (2) affect any action pending in Federal, State,
13 or tribal court, or any agreement, consent decree, or
14 contract of any kind.

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

22 (c) *REVENUE ACTIVITIES.*—The provisions of this Act
23 (or an amendment made by this Act) which authorize the
24 Secretary to take certain actions with regard to tobacco
25 products shall not be construed to affect any authority of

1 *the Secretary of the Treasury under chapter 52 of the Inter-*
2 *nal Revenue Code of 1986.*

3 **SEC. 5. SEVERABILITY.**

4 *If any provision of this Act, the amendments made by*
5 *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 shall*
10 *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 COS-**
15 **METIC ACT.**

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

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

1 “(2) *The term ‘tobacco product’ does not mean an arti-*
2 *cle that is a drug under subsection (g)(1), a device under*
3 *subsection (h), or a combination product described in sec-*
4 *tion 503(g).*”

5 “(3) *The products described in paragraph (2) shall be*
6 *subject to chapter V of this Act.*”

7 “(4) *A tobacco product may not be marketed in com-*
8 *bination with any other article or product regulated under*
9 *this Act (including a drug, biologic, food, cosmetic, medical*
10 *device, or a dietary supplement).*”

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

14 ***(1) by redesignating chapter IX as chapter X;***

15 ***(2) by redesignating sections 901 through 910 as***
16 ***sections 1001 through 1010; and***

17 ***(3) by inserting after chapter VIII the following:***

18 **“CHAPTER IX—TOBACCO PRODUCTS**

19 **“SEC. 900. DEFINITIONS.**

20 ***“In this chapter:***

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

1 *any substances intended for use as a flavoring or*
2 *coloring or in producing, manufacturing, packing,*
3 *processing, preparing, treating, packaging, trans-*
4 *porting, or holding), except that such term does not*
5 *include tobacco or a pesticide chemical residue in or*
6 *on raw tobacco or a pesticide chemical.*

7 “(2) *BRAND.*—*The term ‘brand’ means a variety*
8 *of tobacco product distinguished by the tobacco used,*
9 *tar content, nicotine content, flavoring used, size, fil-*
10 *tration, packaging, logo, registered trademark, brand*
11 *name, identifiable pattern of colors, or any combina-*
12 *tion of such attributes.*

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

14 “(A) *means a product that—*

15 “(i) *is a tobacco product; and*

16 “(ii) *meets the definition of the term*
17 *‘cigarette’ in section 3(1) of the Federal Cig-*
18 *arette Labeling and Advertising Act; and*

19 “(B) *includes tobacco, in any form, that is*
20 *functional in the product, which, because of its*
21 *appearance, the type of tobacco used in the filler,*
22 *or its packaging and labeling, is likely to be of-*
23 *fered to, or purchased by, consumers as a ciga-*
24 *rette or as roll-your-own tobacco.*

1 “(4) *CIGARETTE TOBACCO.*—*The term ‘cigarette*
2 *tobacco’ means any product that consists of loose to-*
3 *bacco that is intended for use by consumers in a ciga-*
4 *rette. Unless otherwise stated, the requirements appli-*
5 *cable to cigarettes under this chapter shall also apply*
6 *to cigarette tobacco.*

7 “(5) *COMMERCE.*—*The term ‘commerce’ has the*
8 *meaning given that term by section 3(2) of the Fed-*
9 *eral Cigarette Labeling and Advertising Act.*

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

17 “(7) *DISTRIBUTOR.*—*The term ‘distributor’ as*
18 *regards a tobacco product means any person who fur-*
19 *thers the distribution of a tobacco product, whether*
20 *domestic or imported, at any point from the original*
21 *place of manufacture to the person who sells or dis-*
22 *tributes the product to individuals for personal con-*
23 *sumption. Common carriers are not considered dis-*
24 *tributors for purposes of this chapter.*

1 “(8) *ILLICIT TRADE*.—The term ‘illicit trade’
2 means any practice or conduct prohibited by law
3 which relates to production, shipment, receipt, posses-
4 sion, distribution, sale, or purchase of tobacco prod-
5 ucts including any practice or conduct intended to fa-
6 cilitate such activity.

7 “(9) *INDIAN TRIBE*.—The term ‘Indian tribe’ has
8 the meaning given such term in section 4(e) of the In-
9 dian Self-Determination and Education Assistance
10 Act.

11 “(10) *LITTLE CIGAR*.—The term ‘little cigar’
12 means a product that—

13 “(A) is a tobacco product; and

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

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

21 “(12) *PACKAGE*.—The term ‘package’ means a
22 pack, box, carton, or container of any kind or, if no
23 other container, any wrapping (including cellophane),
24 in which a tobacco product is offered for sale, sold, or
25 otherwise distributed to consumers.

1 “(13) *RETAILER.*—*The term ‘retailer’ means any*
2 *person, government, or entity who sells tobacco prod-*
3 *ucts to individuals for personal consumption, or who*
4 *operates a facility where self-service displays of to-*
5 *bacco products are permitted.*

6 “(14) *ROLL-YOUR-OWN TOBACCO.*—*The term*
7 *‘roll-your-own tobacco’ means any tobacco product*
8 *which, because of its appearance, type, packaging, or*
9 *labeling, is suitable for use and likely to be offered to,*
10 *or purchased by, consumers as tobacco for making*
11 *cigarettes.*

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

21 “(16) *SMOKE CONSTITUENT.*—*The term ‘smoke*
22 *constituent’ means any chemical or chemical com-*
23 *pound in mainstream or sidestream tobacco smoke*
24 *that either transfers from any component of the ciga-*
25 *rette to the smoke or that is formed by the combustion*

1 *or heating of tobacco, additives, or other component of*
2 *the tobacco product.*

3 “(17) *SMOKELESS TOBACCO.*—*The term ‘smoke-*
4 *less tobacco’ means any tobacco product that consists*
5 *of cut, ground, powdered, or leaf tobacco and that is*
6 *intended to be placed in the oral or nasal cavity.*

7 “(18) *STATE; TERRITORY.*—*The terms ‘State’*
8 *and ‘Territory’ shall have the meanings given to such*
9 *terms in section 201.*

10 “(19) *TOBACCO PRODUCT MANUFACTURER.*—*The*
11 *term ‘tobacco product manufacturer’ means any per-*
12 *son, including any repacker or relabeler, who—*

13 “(A) *manufactures, fabricates, assembles,*
14 *processes, or labels a tobacco product; or*

15 “(B) *imports a finished tobacco product for*
16 *sale or distribution in the United States.*

17 “(20) *TOBACCO WAREHOUSE.*—

18 “(A) *Subject to subparagraphs (B) and (C),*
19 *the term ‘tobacco warehouse’ includes any per-*
20 *son—*

21 “(i) *who—*

22 “(I) *removes foreign material*
23 *from tobacco leaf through nothing other*
24 *than a mechanical process;*

1 “(II) humidifies tobacco leaf with
2 nothing other than potable water in the
3 form of steam or mist; or

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

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

8 “(iii) who provides to any manufac-
9 turer to whom the person sells tobacco all
10 information related to the person’s actions
11 described in clause (i) that is necessary for
12 compliance with this Act.

13 “(B) The term ‘tobacco warehouse’ excludes
14 any person who—

15 “(i) reconstitutes tobacco leaf;

16 “(ii) is a manufacturer, distributor, or
17 retailer of a tobacco product; or

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

21 “(C) The definition of the term ‘tobacco
22 warehouse’ in subparagraph (A) shall not apply
23 to the extent to which the Secretary determines,
24 through rulemaking, that regulation under this
25 chapter of the actions described in such subpara-

1 *graph is appropriate for the protection of the*
2 *public health.*

3 “(21) *UNITED STATES.*—*The term ‘United*
4 *States’ means the 50 States of the United States of*
5 *America and the District of Columbia, the Common-*
6 *wealth of Puerto Rico, Guam, the Virgin Islands,*
7 *American Samoa, Wake Island, Midway Islands,*
8 *Kingman Reef, Johnston Atoll, the Northern Mariana*
9 *Islands, and any other trust territory or possession of*
10 *the United States.*

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

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

17 “(b) *APPLICABILITY.*—*This chapter shall apply to all*
18 *cigarettes, cigarette tobacco, and smokeless tobacco and to*
19 *any other tobacco products that the Secretary by regulation*
20 *deems to be subject to this chapter.*

21 “(c) *SCOPE.*—

22 “(1) *IN GENERAL.*—*Nothing in this chapter, or*
23 *any policy issued or regulation promulgated there-*
24 *under, or in sections 101(a), 102, or 103 of title I,*
25 *title II, or title III of the Family Smoking Prevention*

1 *and Tobacco Control Act, shall be construed to affect,*
2 *expand, or limit the Secretary’s authority over (in-*
3 *cluding the authority to determine whether products*
4 *may be regulated), or the regulation of, products*
5 *under this Act that are not tobacco products under*
6 *chapter V or any other chapter.*

7 “(2) *LIMITATION OF AUTHORITY.*—

8 “(A) *IN GENERAL.*—*The provisions of this*
9 *chapter shall not apply to tobacco leaf that is not*
10 *in the possession of a manufacturer of tobacco*
11 *products, or to the producers of tobacco leaf, in-*
12 *cluding tobacco growers, tobacco warehouses, and*
13 *tobacco grower cooperatives, nor shall any em-*
14 *ployee of the Food and Drug Administration*
15 *have any authority to enter onto a farm owned*
16 *by a producer of tobacco leaf without the written*
17 *consent of such producer.*

18 “(B) *EXCEPTION.*—*Notwithstanding sub-*
19 *paragraph (A), if a producer of tobacco leaf is*
20 *also a tobacco product manufacturer or con-*
21 *trolled by a tobacco product manufacturer, the*
22 *producer shall be subject to this chapter in the*
23 *producer’s capacity as a manufacturer. The ex-*
24 *ception in this subparagraph shall not apply to*
25 *a producer of tobacco leaf who grows tobacco*

1 *under a contract with a tobacco product manu-*
2 *facturer and who is not otherwise engaged in the*
3 *manufacturing process.*

4 “(C) *RULE OF CONSTRUCTION.*—*Nothing in*
5 *this chapter shall be construed to grant the Sec-*
6 *retary authority to promulgate regulations on*
7 *any matter that involves the production of to-*
8 *bacco leaf or a producer thereof, other than ac-*
9 *tivities by a manufacturer affecting production.*

10 “(d) *RULEMAKING PROCEDURES.*—*Each rulemaking*
11 *under this chapter shall be in accordance with chapter 5*
12 *of title 5, United States Code. This subsection shall not be*
13 *construed to affect the rulemaking provisions of section*
14 *102(a) of the Family Smoking Prevention and Tobacco*
15 *Control Act.*

16 “(e) *CENTER FOR TOBACCO PRODUCTS.*—*Not later*
17 *than 90 days after the date of enactment of this chapter,*
18 *the Secretary shall establish within the Food and Drug Ad-*
19 *ministration the Center for Tobacco Products, which shall*
20 *report to the Commissioner of Food and Drugs in the same*
21 *manner as the other agency centers within the Food and*
22 *Drug Administration. The Center shall be responsible for*
23 *the implementation of this chapter and related matters as-*
24 *signed by the Commissioner.*

1 “(f) *OFFICE TO ASSIST SMALL TOBACCO PRODUCT*
2 *MANUFACTURERS.*—*The Secretary shall establish within*
3 *the Food and Drug Administration an identifiable office*
4 *to provide technical and other nonfinancial assistance to*
5 *small tobacco product manufacturers to assist them in com-*
6 *plying with the requirements of this Act.*

7 “(g) *CONSULTATION PRIOR TO RULEMAKING.*—*Prior*
8 *to promulgating rules under this chapter, the Secretary*
9 *shall endeavor to consult with other Federal agencies as ap-*
10 *propriate.*

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

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

14 “(1) *it consists in whole or in part of any filthy,*
15 *putrid, or decomposed substance, or is otherwise con-*
16 *taminated by any added poisonous or added deleter-*
17 *ious substance that may render the product injurious*
18 *to health;*

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

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

1 “(4) *the manufacturer or importer of the tobacco*
2 *product fails to pay a user fee assessed to such manu-*
3 *facturer or importer pursuant to section 919 by the*
4 *date specified in section 919 or by the 30th day after*
5 *final agency action on a resolution of any dispute as*
6 *to the amount of such fee;*

7 “(5) *it is, or purports to be or is represented as,*
8 *a tobacco product which is subject to a tobacco prod-*
9 *uct standard established under section 907 unless such*
10 *tobacco product is in all respects in conformity with*
11 *such standard;*

12 “(6)(A) *it is required by section 910(a) to have*
13 *premarket review and does not have an order in effect*
14 *under section 910(c)(1)(A)(i); or*

15 “(B) *it is in violation of an order under section*
16 *910(c)(1)(A);*

17 “(7) *the methods used in, or the facilities or con-*
18 *trols used for, its manufacture, packing, or storage*
19 *are not in conformity with applicable requirements*
20 *under section 906(e)(1) or an applicable condition*
21 *prescribed by an order under section 906(e)(2); or*

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

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

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

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

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

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

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

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

15 “(D) the statement required under section
16 920(a),
17 except that under subparagraph (B) reasonable vari-
18 ations shall be permitted, and exemptions as to small
19 packages shall be established, by regulations pre-
20 scribed by the Secretary;

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

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

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

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

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

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

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

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

5 “(8) *unless, in the case of any tobacco product*
6 *distributed or offered for sale in any State, the manu-*
7 *facturer, packer, or distributor thereof includes in all*
8 *advertisements and other descriptive printed matter*
9 *issued or caused to be issued by the manufacturer,*
10 *packer, or distributor with respect to that tobacco*
11 *product—*

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

15 “(B) *a brief statement of—*

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

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

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

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

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

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

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

14 “(b) *PRIOR APPROVAL OF LABEL STATEMENTS.—The*
15 *Secretary may, by regulation, require prior approval of*
16 *statements made on the label of a tobacco product. No regu-*
17 *lation issued under this subsection may require prior ap-*
18 *proval by the Secretary of the content of any advertisement,*
19 *except for modified risk tobacco products as provided in sec-*
20 *tion 911. No advertisement of a tobacco product published*
21 *after the date of enactment of the Family Smoking Preven-*
22 *tion and Tobacco Control Act shall, with respect to the lan-*
23 *guage of label statements as prescribed under section 4 of*
24 *the Federal Cigarette Labeling and Advertising Act and sec-*
25 *tion 3 of the Comprehensive Smokeless Tobacco Health Edu-*

1 *tion Act of 1986 or the regulations issued under such sec-*
2 *tions, be subject to the provisions of sections 12 through 15*
3 *of the Federal Trade Commission Act.*

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

6 *“(a) REQUIREMENT.—Each tobacco product manufac-*
7 *turer or importer, or agents thereof, shall submit to the Sec-*
8 *retary the following information:*

9 *“(1) Not later than 6 months after the date of*
10 *enactment of the Family Smoking Prevention and To-*
11 *bacco Control Act, a listing of all ingredients, includ-*
12 *ing tobacco, substances, compounds, and additives*
13 *that are, as of such date, added by the manufacturer*
14 *to the tobacco, paper, filter, or other part of each to-*
15 *bacco product by brand and by quantity in each*
16 *brand and subbrand.*

17 *“(2) A description of the content, delivery, and*
18 *form of nicotine in each tobacco product measured in*
19 *milligrams of nicotine in accordance with regulations*
20 *promulgated by the Secretary in accordance with sec-*
21 *tion 4(e) of the Federal Cigarette Labeling and Adver-*
22 *tising Act.*

23 *“(3) Beginning 3 years after the date of enact-*
24 *ment of this Act, a listing of all constituents, includ-*
25 *ing smoke constituents as applicable, identified by the*

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

10 *“(4) Beginning 6 months after the date of enact-*
11 *ment of the Family Smoking Prevention and Tobacco*
12 *Control Act, all documents developed after the date of*
13 *enactment of the Family Smoking Prevention and To-*
14 *bacco Control Act that relate to health, toxicological,*
15 *behavioral, or physiologic effects of current or future*
16 *tobacco products, their constituents (including smoke*
17 *constituents), ingredients, components, and additives.*

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

22 *“(1) Any or all documents (including underlying*
23 *scientific information) relating to research activities,*
24 *and research findings, conducted, supported, or pos-*
25 *sessed by the manufacturer (or agents thereof) on the*

1 *health, toxicological, behavioral, or physiologic effects*
2 *of tobacco products and their constituents (including*
3 *smoke constituents), ingredients, components, and ad-*
4 *ditives.*

5 *“(2) Any or all documents (including underlying*
6 *scientific information) relating to research activities,*
7 *and research findings, conducted, supported, or pos-*
8 *sessed by the manufacturer (or agents thereof) that re-*
9 *late to the issue of whether a reduction in risk to*
10 *health from tobacco products can occur upon the em-*
11 *ployment of technology available or known to the*
12 *manufacturer.*

13 *“(3) Any or all documents (including underlying*
14 *scientific or financial information) relating to mar-*
15 *keting research involving the use of tobacco products*
16 *or marketing practices and the effectiveness of such*
17 *practices used by tobacco manufacturers and distribu-*
18 *tors.*

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

22 *“(c) TIME FOR SUBMISSION.—*

23 *“(1) IN GENERAL.—At least 90 days prior to the*
24 *delivery for introduction into interstate commerce of*
25 *a tobacco product not on the market on the date of*

1 *enactment of the Family Smoking Prevention and To-*
2 *bacco Control Act, the manufacturer of such product*
3 *shall provide the information required under sub-*
4 *section (a).*

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

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

21 “(d) *DATA LIST.*—

22 “(1) *IN GENERAL.*—*Not later than 3 years after*
23 *the date of enactment of the Family Smoking Preven-*
24 *tion and Tobacco Control Act, and annually there-*
25 *after, the Secretary shall publish in a format that is*

1 *understandable and not misleading to a lay person,*
2 *and place on public display (in a manner determined*
3 *by the Secretary) the list established under subsection*
4 *(e).*

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

15 *“(e) DATA COLLECTION.—Not later than 24 months*
16 *after the date of enactment of the Family Smoking Preven-*
17 *tion and Tobacco Control Act, the Secretary shall establish,*
18 *and periodically revise as appropriate, a list of harmful*
19 *and potentially harmful constituents, including smoke con-*
20 *stituents, to health in each tobacco product by brand and*
21 *by quantity in each brand and subbrand. The Secretary*
22 *shall publish a public notice requesting the submission by*
23 *interested persons of scientific and other information con-*
24 *cerning the harmful and potentially harmful constituents*
25 *in tobacco products and tobacco smoke.*

1 **“SEC. 905. ANNUAL REGISTRATION.**

2 “(a) *DEFINITIONS.*—*In this section:*

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

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

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

1 *quent calendar year by which registration pursuant to this*
2 *subsection shall occur.*

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

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

17 “(e) *UNIFORM PRODUCT IDENTIFICATION SYSTEM.—*
18 *The Secretary may by regulation prescribe a uniform sys-*
19 *tem for the identification of tobacco products and may re-*
20 *quire that persons who are required to list such tobacco*
21 *products under subsection (i) shall list such tobacco prod-*
22 *ucts in accordance with such system.*

23 “(f) *PUBLIC ACCESS TO REGISTRATION INFORMA-*
24 *TION.—The Secretary shall make available for inspection,*

1 to any person so requesting, any registration filed under
2 this section.

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

14 “(h) *REGISTRATION BY FOREIGN ESTABLISHMENTS.*—
15 *Any establishment within any foreign country engaged in*
16 *the manufacture, preparation, compounding, or processing*
17 *of a tobacco product or tobacco products, shall register*
18 *under this section under regulations promulgated by the*
19 *Secretary. Such regulations shall require such establishment*
20 *to provide the information required by subsection (i) and*
21 *shall include provisions for registration of any such estab-*
22 *lishment upon condition that adequate and effective means*
23 *are available, by arrangement with the government of such*
24 *foreign country or otherwise, to enable the Secretary to de-*
25 *termine from time to time whether tobacco products manu-*

1 *factured, prepared, compounded, or processed in such estab-*
2 *lishment, if imported or offered for import into the United*
3 *States, shall be refused admission on any of the grounds*
4 *set forth in section 801(a).*

5 “(i) *REGISTRATION INFORMATION.*—

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

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

1 “(B) *in the case of any other tobacco prod-*
2 *uct contained in an applicable list, a copy of all*
3 *consumer information and other labeling for*
4 *such tobacco product, a representative sampling*
5 *of advertisements for such tobacco product, and,*
6 *upon request made by the Secretary for good*
7 *cause, a copy of all advertisements for a par-*
8 *ticular tobacco product; and*

9 “(C) *if the registrant filing a list has deter-*
10 *mined that a tobacco product contained in such*
11 *list is not subject to a tobacco product standard*
12 *established under section 907, a brief statement*
13 *of the basis upon which the registrant made such*
14 *determination if the Secretary requests such a*
15 *statement with respect to that particular tobacco*
16 *product.*

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

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

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

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

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

23 *“(C) If since the date the registrant reported*
24 *under subparagraph (B) a notice of discontinu-*
25 *ance that person has resumed the manufacture,*

1 *preparation, compounding, or processing for*
2 *commercial distribution of the tobacco product*
3 *with respect to which such notice of discontinu-*
4 *ance was reported, notice of such resumption, the*
5 *date of such resumption, the identity of such to-*
6 *bacco product by established name, and other in-*
7 *formation required by paragraph (1), unless the*
8 *registrant has previously reported such resump-*
9 *tion to the Secretary under this subparagraph.*

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

13 *“(j) REPORT PRECEDING INTRODUCTION OF CERTAIN*
14 *SUBSTANTIALLY EQUIVALENT PRODUCTS INTO INTER-*
15 *STATE COMMERCE.—*

16 *“(1) IN GENERAL.—Each person who is required*
17 *to register under this section and who proposes to*
18 *begin the introduction or delivery for introduction*
19 *into interstate commerce for commercial distribution*
20 *of a tobacco product intended for human use that was*
21 *not commercially marketed (other than for test mar-*
22 *keting) in the United States as of February 15, 2007,*
23 *shall, at least 90 days prior to making such introduc-*
24 *tion or delivery, report to the Secretary (in such form*
25 *and manner as the Secretary shall prescribe)—*

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

3 “(i) the tobacco product is substan-
4 tially equivalent, within the meaning of sec-
5 tion 910, to a tobacco product commercially
6 marketed (other than for test marketing) in
7 the United States as of February 15, 2007,
8 or to a tobacco product that the Secretary
9 has previously determined, pursuant to sub-
10 section (a)(3) of section 910, is substantially
11 equivalent and that is in compliance with
12 the requirements of this Act; or

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

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

24 “(2) APPLICATION TO CERTAIN POST-FEBRUARY
25 15, 2007, PRODUCTS.—A report under this subsection

1 *for a tobacco product that was first introduced or de-*
2 *livered for introduction into interstate commerce for*
3 *commercial distribution in the United States after*
4 *February 15, 2007, and prior to the date that is 21*
5 *months after the date of enactment of the Family*
6 *Smoking Prevention and Tobacco Control Act shall be*
7 *submitted to the Secretary not later than 21 months*
8 *after such date of enactment.*

9 “(3) *EXEMPTIONS.*—

10 “(A) *IN GENERAL.*—*The Secretary may ex-*
11 *empt from the requirements of this subsection re-*
12 *lating to the demonstration that a tobacco prod-*
13 *uct is substantially equivalent within the mean-*
14 *ing of section 910, tobacco products that are*
15 *modified by adding or deleting a tobacco addi-*
16 *tive, or increasing or decreasing the quantity of*
17 *an existing tobacco additive, if the Secretary de-*
18 *termines that—*

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

22 “(ii) *a report under this subsection is*
23 *not necessary to ensure that permitting the*
24 *tobacco product to be marketed would be ap-*

1 *appropriate for protection of the public health;*
2 *and*

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

5 *“(B) REGULATIONS.—Not later than 15*
6 *months after the date of enactment of the Family*
7 *Smoking Prevention and Tobacco Control Act,*
8 *the Secretary shall issue regulations to imple-*
9 *ment this paragraph.*

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

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

23 *“(b) INFORMATION ON PUBLIC ACCESS AND COM-*
24 *MENT.—Each notice of proposed rulemaking or other notifi-*
25 *cation under section 907, 908, 909, 910, or 911 or under*

1 *this section, any other notice which is published in the Fed-*
2 *eral Register with respect to any other action taken under*
3 *any such section and which states the reasons for such ac-*
4 *tion, and each publication of findings required to be made*
5 *in connection with rulemaking under any such section shall*
6 *set forth—*

7 “(1) *the manner in which interested persons may*
8 *examine data and other information on which the no-*
9 *tice or findings is based; and*

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

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

1 *cers or employees concerned with carrying out this chapter,*
2 *or when relevant in any proceeding under this chapter.*

3 “(d) *RESTRICTIONS.*—

4 “(1) *IN GENERAL.*—*The Secretary may by regu-*
5 *lation require restrictions on the sale and distribution*
6 *of a tobacco product, including restrictions on the ac-*
7 *cess to, and the advertising and promotion of, the to-*
8 *bacco product, if the Secretary determines that such*
9 *regulation would be appropriate for the protection of*
10 *the public health. The Secretary may by regulation*
11 *impose restrictions on the advertising and promotion*
12 *of a tobacco product consistent with and to full extent*
13 *permitted by the first amendment to the Constitution.*
14 *The finding as to whether such regulation would be*
15 *appropriate for the protection of the public health*
16 *shall be determined with respect to the risks and bene-*
17 *fits to the population as a whole, including users and*
18 *nonusers of the tobacco product, and taking into ac-*
19 *count—*

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

5 “(2) *LABEL STATEMENTS.*—*The label of a to-*
6 *bacco product shall bear such appropriate statements*
7 *of the restrictions required by a regulation under sub-*
8 *section (a) as the Secretary may in such regulation*
9 *prescribe.*

10 “(3) *LIMITATIONS.*—

11 “(A) *IN GENERAL.*—*No restrictions under*
12 *paragraph (1) may—*

13 “(i) *prohibit the sale of any tobacco*
14 *product in face-to-face transactions by a*
15 *specific category of retail outlets; or*

16 “(ii) *establish a minimum age of sale*
17 *of tobacco products to any person older than*
18 *18 years of age.*

19 “(B) *MATCHBOOKS.*—*For purposes of any*
20 *regulations issued by the Secretary, matchbooks*
21 *of conventional size containing not more than 20*
22 *paper matches, and which are customarily given*
23 *away for free with the purchase of tobacco prod-*
24 *ucts, shall be considered as adult-written publi-*
25 *cations which shall be permitted to contain ad-*

1 *vertising. Notwithstanding the preceding sen-*
2 *tence, if the Secretary finds that such treatment*
3 *of matchbooks is not appropriate for the protec-*
4 *tion of the public health, the Secretary may de-*
5 *termine by regulation that matchbooks shall not*
6 *be considered adult-written publications.*

7 “(4) *REMOTE SALES.*—

8 “(A) *IN GENERAL.*—*The Secretary shall—*

9 “(i) *within 18 months after the date of*
10 *enactment of this chapter, promulgate regu-*
11 *lations regarding the sale and distribution*
12 *of tobacco products that occur through*
13 *means other than a direct, face-to-face ex-*
14 *change between a retailer and a consumer*
15 *in order to prevent the sale and distribution*
16 *of tobacco products to individuals who have*
17 *not attained the minimum age established*
18 *by applicable law for the purchase of such*
19 *products, including requirements for age*
20 *verification; and*

21 “(ii) *within 2 years after such date of*
22 *enactment, issue regulations to address the*
23 *promotion and marketing of tobacco prod-*
24 *ucts that are sold or distributed through*
25 *means other than a direct, face-to-face ex-*

1 *change between a retailer and a consumer*
2 *in order to protect individuals who have not*
3 *attained the minimum age established by*
4 *applicable law for the purchase of such*
5 *products.*

6 “(B) *RELATION TO OTHER AUTHORITY.—*
7 *Nothing in this paragraph limits the authority*
8 *of the Secretary to take additional actions under*
9 *the other paragraphs of this subsection.*

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

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

14 “(A) *IN GENERAL.—In applying manufac-*
15 *turing restrictions to tobacco, the Secretary shall,*
16 *in accordance with subparagraph (B), prescribe*
17 *regulations (which may differ based on the type*
18 *of tobacco product involved) requiring that the*
19 *methods used in, and the facilities and controls*
20 *used for, the manufacture, preproduction design*
21 *validation (including a process to assess the per-*
22 *formance of a tobacco product), packing, and*
23 *storage of a tobacco product conform to current*
24 *good manufacturing practice, or hazard analysis*
25 *and critical control point methodology, as pre-*

1 *scribed in such regulations to assure that the*
2 *public health is protected and that the tobacco*
3 *product is in compliance with this chapter. Such*
4 *regulations may provide for the testing of raw*
5 *tobacco for pesticide chemical residues regardless*
6 *of whether a tolerance for such chemical residues*
7 *has been established.*

8 “(B) *REQUIREMENTS.—The Secretary*
9 *shall—*

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

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

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

24 “(iv) *in establishing the effective date*
25 *of a regulation promulgated under this sub-*

1 *section, take into account the differences in*
2 *the manner in which the different types of*
3 *tobacco products have historically been pro-*
4 *duced, the financial resources of the dif-*
5 *ferent tobacco product manufacturers, and*
6 *the state of their existing manufacturing fa-*
7 *cilities, and shall provide for a reasonable*
8 *period of time for such manufacturers to*
9 *conform to good manufacturing practices;*
10 *and*

11 *“(v) not require any small tobacco*
12 *product manufacturer to comply with a reg-*
13 *ulation under subparagraph (A) for at least*
14 *4 years following the effective date estab-*
15 *lished by the Secretary for such regulation.*

16 *“(2) EXEMPTIONS; VARIANCES.—*

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

24 *“(i) in the case of a petition for an ex-*
25 *emption from a requirement, set forth the*

1 *basis for the petitioner’s determination that*
2 *compliance with the requirement is not re-*
3 *quired to assure that the tobacco product*
4 *will be in compliance with this chapter;*

5 “(ii) *in the case of a petition for a*
6 *variance from a requirement, set forth the*
7 *methods proposed to be used in, and the fa-*
8 *ilities and controls proposed to be used for,*
9 *the manufacture, packing, and storage of*
10 *the tobacco product in lieu of the methods,*
11 *facilities, and controls prescribed by the re-*
12 *quirement; and*

13 “(iii) *contain such other information*
14 *as the Secretary shall prescribe.*

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

1 “(i) the date the petition was sub-
2 mitted to the Secretary under subparagraph
3 (A); or

4 “(ii) the day after the petition was re-
5 ferred to the Tobacco Products Scientific
6 Advisory Committee,

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

9 “(C) APPROVAL.—The Secretary may ap-
10 prove—

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

17 “(ii) a petition for a variance for a to-
18 bacco product from a requirement if the
19 Secretary determines that the methods to be
20 used in, and the facilities and controls to be
21 used for, the manufacture, packing, and
22 storage of the tobacco product in lieu of the
23 methods, facilities, and controls prescribed
24 by the requirement are sufficient to assure

1 that the tobacco product will be in compli-
2 ance with this chapter.

3 “(D) *CONDITIONS.*—An order of the Sec-
4 retary approving a petition for a variance shall
5 prescribe such conditions respecting the methods
6 used in, and the facilities and controls used for,
7 the manufacture, packing, and storage of the to-
8 bacco product to be granted the variance under
9 the petition as may be necessary to assure that
10 the tobacco product will be in compliance with
11 this chapter.

12 “(E) *HEARING.*—After the issuance of an
13 order under subparagraph (B) respecting a peti-
14 tion, the petitioner shall have an opportunity for
15 an informal hearing on such order.

16 “(3) *COMPLIANCE.*—Compliance with require-
17 ments under this subsection shall not be required be-
18 fore the end of the 3-year period following the date of
19 enactment of the Family Smoking Prevention and To-
20 bacco Control Act.

21 “(f) *RESEARCH AND DEVELOPMENT.*—The Secretary
22 may enter into contracts for research, testing, and dem-
23 onstrations respecting tobacco products and may obtain to-
24 bacco products for research, testing, and demonstration pur-
25 poses.

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

2 “(a) *IN GENERAL.*—

3 “(1) *SPECIAL RULES.*—

4 “(A) *SPECIAL RULE FOR CIGARETTES.*—*Be-*
5 *ginning 3 months after the date of enactment of*
6 *the Family Smoking Prevention and Tobacco*
7 *Control Act, a cigarette or any of its component*
8 *parts (including the tobacco, filter, or paper)*
9 *shall not contain, as a constituent (including a*
10 *smoke constituent) or additive, an artificial or*
11 *natural flavor (other than tobacco or menthol) or*
12 *an herb or spice, including strawberry, grape,*
13 *orange, clove, cinnamon, pineapple, vanilla, co-*
14 *conut, licorice, cocoa, chocolate, cherry, or coffee,*
15 *that is a characterizing flavor of the tobacco*
16 *product or tobacco smoke. Nothing in this sub-*
17 *paragraph shall be construed to limit the Sec-*
18 *retary’s authority to take action under this sec-*
19 *tion or other sections of this Act applicable to*
20 *menthol or any artificial or natural flavor, herb,*
21 *or spice not specified in this subparagraph. For*
22 *purposes of this section, a cigarette or any of its*
23 *component parts has a characterizing flavor if*
24 *the cigarette, its tobacco smoke, or the component*
25 *part imparts a distinguishable taste or aroma*
26 *other than tobacco or menthol either prior to*

1 *consumption or during consumption, or is adver-*
2 *tised or marketed as having or producing a fla-*
3 *vor, taste, or aroma other than tobacco or men-*
4 *thol.*

5 “(B) *ADDITIONAL SPECIAL RULE.—No to-*
6 *bacco product manufactured in or imported into*
7 *the United States shall contain foreign-grown to-*
8 *bacco that—*

9 *“(i) contains a level of any pesticide*
10 *chemical residue in excess of any maximum*
11 *permissible residue level that is applicable*
12 *to domestically grown tobacco; or*

13 *“(ii) was grown or processed using any*
14 *pesticide chemical not approved under Fed-*
15 *eral law for use in domestic tobacco farm-*
16 *ing or processing.*

17 “(2) *REVISION OF TOBACCO PRODUCT STAND-*
18 *ARDS.—The Secretary may revise the tobacco product*
19 *standards in paragraph (1) in accordance with sub-*
20 *section (c).*

21 “(3) *TOBACCO PRODUCT STANDARDS.—*

22 *“(A) IN GENERAL.—The Secretary may*
23 *adopt tobacco product standards in addition to*
24 *those in paragraph (1) if the Secretary finds*

1 *that a tobacco product standard is appropriate*
2 *for the protection of the public health.*

3 “(B) DETERMINATIONS.—

4 “(i) CONSIDERATIONS.—*In making a*
5 *finding described in subparagraph (A), the*
6 *Secretary shall consider scientific evidence*
7 *concerning—*

8 “(I) *the risks and benefits to the*
9 *population as a whole, including users*
10 *and nonusers of tobacco products, of*
11 *the proposed standard;*

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

16 “(III) *the increased or decreased*
17 *likelihood that those who do not use to-*
18 *bacco products will start using such*
19 *products.*

20 “(ii) ADDITIONAL CONSIDERATIONS.—

21 *In the event that the Secretary makes a de-*
22 *termination, set forth in a proposed tobacco*
23 *product standard in a proposed rule, that it*
24 *is appropriate for the protection of public*
25 *health to require the reduction or elimi-*

1 *nation of an additive, constituent (includ-*
2 *ing a smoke constituent), or other compo-*
3 *nent of a tobacco product because the Sec-*
4 *retary has found that the additive, con-*
5 *stituent, or other component is or may be*
6 *harmful, any party objecting to the pro-*
7 *posed standard on the ground that the pro-*
8 *posed standard will not reduce or eliminate*
9 *the risk of illness or injury may provide for*
10 *the Secretary's consideration scientific evi-*
11 *dence that demonstrates that the proposed*
12 *standard will not reduce or eliminate the*
13 *risk of illness or injury.*

14 *“(4) CONTENT OF TOBACCO PRODUCT STAND-*
15 *ARDS.—A tobacco product standard established under*
16 *this section for a tobacco product—*

17 *“(A) shall include provisions that are ap-*
18 *propriate for the protection of the public health,*
19 *including provisions, where appropriate—*

20 *“(i) for nicotine yields of the product;*

21 *“(ii) for the reduction or elimination*
22 *of other constituents, including smoke con-*
23 *stituents, or harmful components of the*
24 *product; or*

1 “(iii) relating to any other require-
2 ment under subparagraph (B);

3 “(B) shall, where appropriate for the protec-
4 tion of the public health, include—

5 “(i) provisions respecting the construc-
6 tion, components, ingredients, additives,
7 constituents, including smoke constituents,
8 and properties of the tobacco product;

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

12 “(iii) provisions for the measurement
13 of the tobacco product characteristics of the
14 tobacco product;

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

22 “(v) a provision requiring that the sale
23 and distribution of the tobacco product be
24 restricted but only to the extent that the sale
25 and distribution of a tobacco product may

1 *be restricted under a regulation under sec-*
2 *tion 906(d);*

3 “(C) shall, where appropriate, require the
4 *use and prescribe the form and content of label-*
5 *ing for the proper use of the tobacco product; and*

6 “(D) shall require tobacco products con-
7 *taining foreign-grown tobacco to meet the same*
8 *standards applicable to tobacco products con-*
9 *taining domestically grown tobacco.*

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

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

21 “(A) *use personnel, facilities, and other*
22 *technical support available in other Federal*
23 *agencies;*

24 “(B) *consult with other Federal agencies*
25 *concerned with standard setting and other na-*

1 *tionally or internationally recognized standard-*
2 *setting entities; and*

3 “(C) *invite appropriate participation,*
4 *through joint or other conferences, workshops, or*
5 *other means, by informed persons representative*
6 *of scientific, professional, industry, agricultural,*
7 *or consumer organizations who in the Secretary’s*
8 *judgment can make a significant contribution.*

9 “(b) *CONSIDERATIONS BY SECRETARY.—*

10 “(1) *TECHNICAL ACHIEVABILITY.—The Secretary*
11 *shall consider information submitted in connection*
12 *with a proposed standard regarding the technical*
13 *achievability of compliance with such standard.*

14 “(2) *OTHER CONSIDERATIONS.—The Secretary*
15 *shall consider all other information submitted in con-*
16 *nection with a proposed standard, including informa-*
17 *tion concerning the countervailing effects of the to-*
18 *bacco product standard on the health of adolescent to-*
19 *bacco users, adult tobacco users, or nontobacco users,*
20 *such as the creation of a significant demand for con-*
21 *traband or other tobacco products that do not meet*
22 *the requirements of this chapter and the significance*
23 *of such demand.*

24 “(c) *PROPOSED STANDARDS.—*

1 “(1) *IN GENERAL.*—*The Secretary shall publish*
2 *in the Federal Register a notice of proposed rule-*
3 *making for the establishment, amendment, or revoca-*
4 *tion of any tobacco product standard.*

5 “(2) *REQUIREMENTS OF NOTICE.*—*A notice of*
6 *proposed rulemaking for the establishment or amend-*
7 *ment of a tobacco product standard for a tobacco*
8 *product shall—*

9 “(A) *set forth a finding with supporting*
10 *justification that the tobacco product standard is*
11 *appropriate for the protection of the public*
12 *health;*

13 “(B) *invite interested persons to submit a*
14 *draft or proposed tobacco product standard for*
15 *consideration by the Secretary;*

16 “(C) *invite interested persons to submit*
17 *comments on structuring the standard so that it*
18 *does not advantage foreign-grown tobacco over*
19 *domestically grown tobacco; and*

20 “(D) *invite the Secretary of Agriculture to*
21 *provide any information or analysis which the*
22 *Secretary of Agriculture believes is relevant to*
23 *the proposed tobacco product standard.*

24 “(3) *FINDING.*—*A notice of proposed rulemaking*
25 *for the revocation of a tobacco product standard shall*

1 *set forth a finding with supporting justification that*
2 *the tobacco product standard is no longer appropriate*
3 *for the protection of the public health.*

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

6 *“(d) PROMULGATION.—*

7 *“(1) IN GENERAL.—After the expiration of the*
8 *period for comment on a notice of proposed rule-*
9 *making published under subsection (c) respecting a*
10 *tobacco product standard and after consideration of*
11 *comments submitted under subsections (b) and (c)*
12 *and any report from the Tobacco Products Scientific*
13 *Advisory Committee, if the Secretary determines that*
14 *the standard would be appropriate for the protection*
15 *of the public health, the Secretary shall—*

16 *“(A) promulgate a regulation establishing a*
17 *tobacco product standard and publish in the*
18 *Federal Register findings on the matters referred*
19 *to in subsection (c); or*

20 *“(B) publish a notice terminating the pro-*
21 *ceeding for the development of the standard to-*
22 *gether with the reasons for such termination.*

23 *“(2) EFFECTIVE DATE.—A regulation estab-*
24 *lishing a tobacco product standard shall set forth the*
25 *date or dates upon which the standard shall take ef-*

1 *fect, but no such regulation may take effect before 1*
2 *year after the date of its publication unless the Sec-*
3 *retary determines that an earlier effective date is nec-*
4 *essary for the protection of the public health. Such*
5 *date or dates shall be established so as to minimize,*
6 *consistent with the public health, economic loss to,*
7 *and disruption or dislocation of, domestic and inter-*
8 *national trade. In establishing such effective date or*
9 *dates, the Secretary shall consider information sub-*
10 *mitted in connection with a proposed product stand-*
11 *ard by interested parties, including manufacturers*
12 *and tobacco growers, regarding the technical*
13 *achievability of compliance with the standard, and*
14 *including information concerning the existence of pat-*
15 *ents that make it impossible to comply in the time-*
16 *frame envisioned in the proposed standard. If the Sec-*
17 *retary determines, based on the Secretary's evaluation*
18 *of submitted comments, that a product standard can*
19 *be met only by manufacturers requiring substantial*
20 *changes to the methods of farming the domestically*
21 *grown tobacco used by the manufacturer, the effective*
22 *date of that product standard shall be not less than*
23 *2 years after the date of publication of the final regu-*
24 *lation establishing the standard.*

1 “(3) *LIMITATION ON POWER GRANTED TO THE*
2 *FOOD AND DRUG ADMINISTRATION.—Because of the*
3 *importance of a decision of the Secretary to issue a*
4 *regulation—*

5 “(A) *banning all cigarettes, all smokeless to-*
6 *bacco products, all little cigars, all cigars other*
7 *than little cigars, all pipe tobacco, or all roll-*
8 *your-own tobacco products; or*

9 “(B) *requiring the reduction of nicotine*
10 *yields of a tobacco product to zero,*
11 *the Secretary is prohibited from taking such actions*
12 *under this Act.*

13 “(4) *AMENDMENT; REVOCATION.—*

14 “(A) *AUTHORITY.—The Secretary, upon the*
15 *Secretary’s own initiative or upon petition of an*
16 *interested person, may by a regulation, promul-*
17 *gated in accordance with the requirements of*
18 *subsection (c) and paragraph (2), amend or re-*
19 *voke a tobacco product standard.*

20 “(B) *EFFECTIVE DATE.—The Secretary*
21 *may declare a proposed amendment of a tobacco*
22 *product standard to be effective on and after its*
23 *publication in the Federal Register and until the*
24 *effective date of any final action taken on such*

1 *amendment if the Secretary determines that*
2 *making it so effective is in the public interest.*

3 “(5) *REFERRAL TO ADVISORY COMMITTEE.*—

4 “(A) *IN GENERAL.*—*The Secretary may*
5 *refer a proposed regulation for the establishment,*
6 *amendment, or revocation of a tobacco product*
7 *standard to the Tobacco Products Scientific Ad-*
8 *visory Committee for a report and recommenda-*
9 *tion with respect to any matter involved in the*
10 *proposed regulation which requires the exercise of*
11 *scientific judgment.*

12 “(B) *INITIATION OF REFERRAL.*—*The Sec-*
13 *retary may make a referral under this para-*
14 *graph—*

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

16 *or*

17 “(ii) *upon the request of an interested*
18 *person that—*

19 “(I) *demonstrates good cause for*
20 *the referral; and*

21 “(II) *is made before the expira-*
22 *tion of the period for submission of*
23 *comments on the proposed regulation.*

24 “(C) *PROVISION OF DATA.*—*If a proposed*
25 *regulation is referred under this paragraph to*

1 *the Tobacco Products Scientific Advisory Com-*
2 *mittee, the Secretary shall provide the Advisory*
3 *Committee with the data and information on*
4 *which such proposed regulation is based.*

5 “(D) *REPORT AND RECOMMENDATION.*—*The*
6 *Tobacco Products Scientific Advisory Committee*
7 *shall, within 60 days after the referral of a pro-*
8 *posed regulation under this paragraph and after*
9 *independent study of the data and information*
10 *furnished to it by the Secretary and other data*
11 *and information before it, submit to the Sec-*
12 *retary a report and recommendation respecting*
13 *such regulation, together with all underlying*
14 *data and information and a statement of the*
15 *reason or basis for the recommendation.*

16 “(E) *PUBLIC AVAILABILITY.*—*The Secretary*
17 *shall make a copy of each report and rec-*
18 *ommendation under subparagraph (D) publicly*
19 *available.*

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

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

23 “(1) *a tobacco product which is introduced or de-*
24 *livered for introduction into interstate commerce for*

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

3 “(2) *notification under this subsection is nec-*
4 *essary to eliminate the unreasonable risk of such*
5 *harm and no more practicable means is available*
6 *under the provisions of this chapter (other than this*
7 *section) to eliminate such risk,*
8 *the Secretary may issue such order as may be necessary*
9 *to assure that adequate notification is provided in an ap-*
10 *propriate form, by the persons and means best suited under*
11 *the circumstances involved, to all persons who should prop-*
12 *erly receive such notification in order to eliminate such*
13 *risk. The Secretary may order notification by any appro-*
14 *priate means, including public service announcements. Be-*
15 *fore issuing an order under this subsection, the Secretary*
16 *shall consult with the persons who are to give notice under*
17 *the order.*

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

25 “(c) *RECALL AUTHORITY.—*

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

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

22 “(A) *IN GENERAL.*—*If, after providing an*
23 *opportunity for an informal hearing under*
24 *paragraph (1), the Secretary determines that the*
25 *order should be amended to include a recall of*

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

8 “(B) NOTICE.—*An amended order under*
9 *subparagraph (A)—*

10 “(i) *shall not include recall of a to-*
11 *bacco product from individuals; and*

12 “(ii) *shall provide for notice to persons*
13 *subject to the risks associated with the use*
14 *of such tobacco product.*

15 *In providing the notice required by clause (ii),*
16 *the Secretary may use the assistance of retailers*
17 *and other persons who distributed such tobacco*
18 *product. If a significant number of such persons*
19 *cannot be identified, the Secretary shall notify*
20 *such persons under section 705(b).*

21 “(3) REMEDY NOT EXCLUSIVE.—*The remedy pro-*
22 *vided by this subsection shall be in addition to rem-*
23 *edies provided by subsection (a).*

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

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

11 “(1) *may require a tobacco product manufac-*
12 *turer or importer to report to the Secretary whenever*
13 *the manufacturer or importer receives or otherwise be-*
14 *comes aware of information that reasonably suggests*
15 *that one of its marketed tobacco products may have*
16 *caused or contributed to a serious unexpected adverse*
17 *experience associated with the use of the product or*
18 *any significant increase in the frequency of a serious,*
19 *expected adverse product experience;*

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

23 “(3) *shall not impose requirements unduly bur-*
24 *densome to a tobacco product manufacturer or im-*
25 *porter, taking into account the cost of complying with*
26 *such requirements and the need for the protection of*

1 *the public health and the implementation of this*
2 *chapter;*

3 *“(4) when prescribing the procedure for making*
4 *requests for reports or information, shall require that*
5 *each request made under such regulations for submis-*
6 *sion of a report or information to the Secretary state*
7 *the reason or purpose for such request and identify to*
8 *the fullest extent practicable such report or informa-*
9 *tion;*

10 *“(5) when requiring submission of a report or*
11 *information to the Secretary, shall state the reason or*
12 *purpose for the submission of such report or informa-*
13 *tion and identify to the fullest extent practicable such*
14 *report or information; and*

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

22 *In prescribing regulations under this subsection, the Sec-*
23 *retary shall have due regard for the professional ethics of*
24 *the medical profession and the interests of patients. The*
25 *prohibitions of paragraph (6) continue to apply to records,*

1 *reports, and information concerning any individual who*
2 *has been a patient, irrespective of whether or when he ceases*
3 *to be a patient.*

4 “(b) *REPORTS OF REMOVALS AND CORRECTIONS.—*

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

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

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

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

23 “(2) *EXCEPTION.—No report of the corrective ac-*
24 *tion or removal of a tobacco product may be required*
25 *under paragraph (1) if a report of the corrective ac-*

1 “(i) the manufacturer has submitted a
2 report under section 905(j); and the Sec-
3 retary has issued an order that the tobacco
4 product—

5 “(I) is substantially equivalent to
6 a tobacco product commercially mar-
7 keted (other than for test marketing) in
8 the United States as of February 15,
9 2007; and

10 “(II) is in compliance with the re-
11 quirements of this Act; or

12 “(ii) the tobacco product is exempt
13 from the requirements of section 905(j) pur-
14 suant to a regulation issued under section
15 905(j)(3).

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

19 “(i) that was first introduced or deliv-
20 ered for introduction into interstate com-
21 merce for commercial distribution in the
22 United States after February 15, 2007, and
23 prior to the date that is 21 months after the
24 date of enactment of the Family Smoking
25 Prevention and Tobacco Control Act; and

1 “(ii) for which a report was submitted
2 under section 905(j) within such 21-month
3 period,

4 except that subparagraph (A) shall apply to the
5 tobacco product if the Secretary issues an order
6 that the tobacco product is not substantially
7 equivalent.

8 “(3) *SUBSTANTIALLY EQUIVALENT DEFINED.*—

9 “(A) *IN GENERAL.*—*In this section and sec-*
10 *tion 905(j), the term ‘substantially equivalent’ or*
11 *‘substantial equivalence’ means, with respect to*
12 *the tobacco product being compared to the predi-*
13 *cate tobacco product, that the Secretary by order*
14 *has found that the tobacco product—*

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

17 “(ii) *has different characteristics and*
18 *the information submitted contains infor-*
19 *mation, including clinical data if deemed*
20 *necessary by the Secretary, that dem-*
21 *onstrates that it is not appropriate to regu-*
22 *late the product under this section because*
23 *the product does not raise different ques-*
24 *tions of public health.*

1 “(B) *CHARACTERISTICS.*—*In subparagraph*
2 *(A), the term ‘characteristics’ means the mate-*
3 *rials, ingredients, design, composition, heating*
4 *source, or other features of a tobacco product.*

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

11 “(4) *HEALTH INFORMATION.*—

12 “(A) *SUMMARY.*—*As part of a submission*
13 *under section 905(j) respecting a tobacco prod-*
14 *uct, the person required to file a premarket noti-*
15 *fication under such section shall provide an ade-*
16 *quate summary of any health information re-*
17 *lated to the tobacco product or state that such in-*
18 *formation will be made available upon request*
19 *by any person.*

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

1 *termination that such tobacco product is sub-*
2 *stantially equivalent to another tobacco product.*

3 “(b) *APPLICATION.*—

4 “(1) *CONTENTS.*—*An application under this sec-*
5 *tion 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 investiga-*
9 *tions which have been made to show the health*
10 *risks of such tobacco product and whether such*
11 *tobacco product presents less risk than other to-*
12 *bacco products;*

13 “(B) *a full statement of the components, in-*
14 *gredients, additives, and properties, and of the*
15 *principle or principles of operation, of such to-*
16 *bacco 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 tobacco*
23 *product standard under section 907 which would*
24 *be applicable to any aspect of such tobacco prod-*
25 *uct, and either adequate information to show*

1 *that such aspect of such tobacco product fully*
2 *meets such tobacco product standard or adequate*
3 *information to justify any deviation from such*
4 *standard;*

5 *“(E) such samples of such tobacco product*
6 *and of components thereof as the Secretary may*
7 *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 the*
11 *subject matter of the application as the Secretary*
12 *may require.*

13 *“(2) REFERRAL 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 initiative;*
18 *or*

19 *“(B) may, upon the request of an applicant,*
20 *refer such application to the Tobacco Products Sci-*
21 *entific Advisory Committee for reference and for sub-*
22 *mission (within such period as the Secretary may es-*
23 *tablish) of a report and recommendation respecting*
24 *the application, together with all underlying data*
25 *and the reasons or basis for the recommendation.*

1 “(c) *ACTION ON APPLICATION.*—

2 “(1) *DEADLINE.*—

3 “(A) *IN GENERAL.*—*As promptly as possible, but in no event later than 180 days after*
4 *the receipt of an application under subsection*
5 *(b), the Secretary, after considering the report*
6 *and recommendation submitted under subsection*
7 *(b)(2), shall—*

8 “(i) *issue an order that the new prod-*
9 *uct may be introduced or delivered for in-*
10 *troduction into interstate commerce if the*
11 *Secretary finds that none of the grounds*
12 *specified in paragraph (2) of this subsection*
13 *applies; or*

14 “(ii) *issue an order that the new prod-*
15 *uct may not be introduced or delivered for*
16 *introduction into interstate commerce if the*
17 *Secretary finds (and sets forth the basis for*
18 *such finding as part of or accompanying*
19 *such denial) that 1 or more grounds for de-*
20 *negial specified in paragraph (2) of this sub-*
21 *section apply.*

22 “(B) *RESTRICTIONS ON SALE AND DIS-*
23 *TRIBUTION.*—*An order under subparagraph*
24 *(A)(i) may require that the sale and distribution*
25

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

5 “(2) *DENIAL OF APPLICATION.*—*The Secretary*
6 *shall deny an application submitted under subsection*
7 *(b) if, upon the basis of the information submitted to*
8 *the Secretary as part of the application and any*
9 *other information before the Secretary with respect to*
10 *such tobacco product, the Secretary finds that—*

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

15 “(B) *the methods used in, or the facilities or*
16 *controls used for, the manufacture, processing, or*
17 *packing of such tobacco product do not conform*
18 *to the requirements of section 906(e);*

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

22 “(D) *such tobacco product is not shown to*
23 *conform in all respects to a tobacco product*
24 *standard in effect under section 907, and there*

1 *is a lack of adequate information to justify the*
2 *deviation from such standard.*

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

11 “(4) *BASIS FOR FINDING.*—*For purposes of this*
12 *section, the finding as to whether the marketing of a*
13 *tobacco product for which an application has been*
14 *submitted is appropriate for the protection of the pub-*
15 *lic health shall be determined with respect to the risks*
16 *and benefits to the population as a whole, including*
17 *users and nonusers of the tobacco product, and taking*
18 *into account—*

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

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

25 “(5) *BASIS FOR ACTION.*—

1 “(A) *INVESTIGATIONS.*—*For purposes of*
2 *paragraph (2)(A), whether permitting a tobacco*
3 *product to be marketed would be appropriate for*
4 *the protection of the public health shall, when*
5 *appropriate, be determined on the basis of well-*
6 *controlled investigations, which may include 1 or*
7 *more clinical investigations by experts qualified*
8 *by training and experience to evaluate the to-*
9 *bacco product.*

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

18 “(d) *WITHDRAWAL AND TEMPORARY SUSPENSION.*—

19 “(1) *IN GENERAL.*—*The Secretary shall, upon*
20 *obtaining, where appropriate, advice on scientific*
21 *matters from the Tobacco Products Scientific Advi-*
22 *sory Committee, and after due notice and opportunity*
23 *for informal hearing for a tobacco product for which*
24 *an order was issued under subsection (c)(1)(A)(i),*

1 *issue an order withdrawing the order if the Secretary*
2 *finds—*

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

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

9 “(C) *that the applicant—*

10 “(i) *has failed to establish a system for*
11 *maintaining records, or has repeatedly or*
12 *deliberately failed to maintain records or to*
13 *make reports, required by an applicable reg-*
14 *ulation under section 909;*

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

18 “(iii) *has not complied with the re-*
19 *quirements of section 905;*

20 “(D) *on the basis of new information before*
21 *the Secretary with respect to such tobacco prod-*
22 *uct, evaluated together with the evidence before*
23 *the Secretary when the application was reviewed,*
24 *that the methods used in, or the facilities and*
25 *controls used for, the manufacture, processing,*

1 *packing, or installation of such tobacco product*
2 *do not conform with the requirements of section*
3 *906(e) and were not brought into conformity*
4 *with such requirements within a reasonable time*
5 *after receipt of written notice from the Secretary*
6 *of nonconformity;*

7 *“(E) on the basis of new information before*
8 *the Secretary, evaluated together with the evi-*
9 *dence before the Secretary when the application*
10 *was reviewed, that the labeling of such tobacco*
11 *product, based on a fair evaluation of all mate-*
12 *rial facts, is false or misleading in any par-*
13 *ticular and was not corrected within a reason-*
14 *able time after receipt of written notice from the*
15 *Secretary of such fact; or*

16 *“(F) on the basis of new information before*
17 *the Secretary, evaluated together with the evi-*
18 *dence before the Secretary when such order was*
19 *issued, that such tobacco product is not shown to*
20 *conform in all respects to a tobacco product*
21 *standard which is in effect under section 907,*
22 *compliance with which was a condition to the*
23 *issuance of an order relating to the application,*
24 *and that there is a lack of adequate information*
25 *to justify the deviation from such standard.*

1 “(2) *APPEAL.*—*The holder of an application sub-*
2 *ject to an order issued under paragraph (1) with-*
3 *drawing an order issued pursuant to subsection*
4 *(c)(1)(A)(i) may, by petition filed on or before the*
5 *30th day after the date upon which such holder re-*
6 *ceives notice of such withdrawal, obtain review thereof*
7 *in accordance with section 912.*

8 “(3) *TEMPORARY SUSPENSION.*—*If, after pro-*
9 *viding an opportunity for an informal hearing, the*
10 *Secretary determines there is reasonable probability*
11 *that the continuation of distribution of a tobacco*
12 *product under an order would cause serious, adverse*
13 *health consequences or death, that is greater than or-*
14 *dinarily caused by tobacco products on the market,*
15 *the Secretary shall by order temporarily suspend the*
16 *authority of the manufacturer to market the product.*
17 *If the Secretary issues such an order, the Secretary*
18 *shall proceed expeditiously under paragraph (1) to*
19 *withdraw such application.*

20 “(e) *SERVICE OF ORDER.*—*An order issued by the Sec-*
21 *retary under this section shall be served—*

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

24 “(2) *by mailing the order by registered mail or*
25 *certified mail addressed to the applicant at the appli-*

1 *cant's last known address in the records of the Sec-*
2 *retary.*

3 “(f) *RECORDS.*—

4 “(1) *ADDITIONAL INFORMATION.*—*In the case of*
5 *any tobacco product for which an order issued pursu-*
6 *ant to subsection (c)(1)(A)(i) for an application filed*
7 *under subsection (b) is in effect, the applicant shall*
8 *establish and maintain such records, and make such*
9 *reports to the Secretary, as the Secretary may by reg-*
10 *ulation, or by order with respect to such application,*
11 *prescribe on the basis of a finding that such records*
12 *and reports are necessary in order to enable the Sec-*
13 *retary to determine, or facilitate a determination of,*
14 *whether there is or may be grounds for withdrawing*
15 *or temporarily suspending such order.*

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

23 “(g) *INVESTIGATIONAL TOBACCO PRODUCT EXEMP-*
24 *TION FOR INVESTIGATIONAL USE.*—*The Secretary may ex-*
25 *empt tobacco products intended for investigational use from*

1 *the provisions of this chapter under such conditions as the*
2 *Secretary may by regulation prescribe.*

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

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

8 “(b) *DEFINITIONS.*—*In this section:*

9 “(1) *MODIFIED RISK TOBACCO PRODUCT.*—*The*
10 *term ‘modified risk tobacco product’ means any to-*
11 *bacco product that is sold or distributed for use to re-*
12 *duce harm or the risk of tobacco-related disease asso-*
13 *ciated with commercially marketed tobacco products.*

14 “(2) *SOLD OR DISTRIBUTED.*—

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

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

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

1 *other commercially marketed tobacco*
2 *products;*

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

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

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

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

1 *presents a reduced exposure to, or does not*
2 *contain or is free of, a substance or sub-*
3 *stances.*

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

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

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

1 scribed in such paragraph on such date of enactment.

2 The effective date shall be with respect to the date of
3 manufacture, provided that, in any case, 30 days
4 after such effective date, a manufacturer shall not in-
5 troduce into the domestic commerce of the United
6 States any product that is not in conformance with
7 paragraph (2)(A)(ii).

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

14 “(d) *FILING.*—Any person may file with the Secretary
15 an application for a modified risk tobacco product. Such
16 application shall include—

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

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

20 “(3) the formulation of the product;

21 “(4) sample product labels and labeling;

22 “(5) all documents (including underlying sci-
23 entific information) relating to research findings con-
24 ducted, supported, or possessed by the tobacco product
25 manufacturer relating to the effect of the product on

1 tobacco-related diseases and health-related conditions,
2 including information both favorable and unfavorable
3 to the ability of the product to reduce risk or exposure
4 and relating to human health;

5 “(6) data and information on how consumers ac-
6 tually use the tobacco product; and

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

9 “(e) *PUBLIC AVAILABILITY.*—The Secretary shall make
10 the application described in subsection (d) publicly avail-
11 able (except matters in the application which are trade se-
12 crets or otherwise confidential, commercial information)
13 and shall request comments by interested persons on the in-
14 formation contained in the application and on the label,
15 labeling, and advertising accompanying such application.

16 “(f) *ADVISORY COMMITTEE.*—

17 “(1) *IN GENERAL.*—The Secretary shall refer to
18 the Tobacco Products Scientific Advisory Committee
19 any application submitted under this section.

20 “(2) *RECOMMENDATIONS.*—Not later than 60
21 days after the date an application is referred to the
22 Tobacco Products Scientific Advisory Committee
23 under paragraph (1), the Advisory Committee shall
24 report its recommendations on the application to the
25 Secretary.

1 “(g) *MARKETING.*—

2 “(1) *MODIFIED RISK PRODUCTS.*—*Except as pro-*
3 *vided in paragraph (2), the Secretary shall, with re-*
4 *spect to an application submitted under this section,*
5 *issue an order that a modified risk product may be*
6 *commercially marketed only if the Secretary deter-*
7 *mines that the applicant has demonstrated that such*
8 *product, as it is actually used by consumers, will—*

9 “(A) *significantly reduce harm and the risk*
10 *of tobacco-related disease to individual tobacco*
11 *users; and*

12 “(B) *benefit the health of the population as*
13 *a whole taking into account both users of tobacco*
14 *products and persons who do not currently use*
15 *tobacco products.*

16 “(2) *SPECIAL RULE FOR CERTAIN PRODUCTS.*—

17 “(A) *IN GENERAL.*—*The Secretary may*
18 *issue an order that a tobacco product may be in-*
19 *troduced or delivered for introduction into inter-*
20 *state commerce, pursuant to an application*
21 *under this section, with respect to a tobacco*
22 *product that may not be commercially marketed*
23 *under paragraph (1) if the Secretary makes the*
24 *findings required under this paragraph and de-*

1 *termines that the applicant has demonstrated*
2 *that—*

3 *“(i) such order would be appropriate*
4 *to promote the public health;*

5 *“(ii) any aspect of the label, labeling,*
6 *and advertising for such product that would*
7 *cause the tobacco product to be a modified*
8 *risk tobacco product under subsection (b) is*
9 *limited to an explicit or implicit represen-*
10 *tation that such tobacco product or its*
11 *smoke does not contain or is free of a sub-*
12 *stance or contains a reduced level of a sub-*
13 *stance, or presents a reduced exposure to a*
14 *substance in tobacco smoke;*

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

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

1 *tobacco users is reasonably likely in subse-*
2 *quent studies.*

3 “(B) *ADDITIONAL FINDINGS REQUIRED.*—
4 *To issue an order under subparagraph (A) the*
5 *Secretary must also find that the applicant has*
6 *demonstrated that—*

7 “(i) *the magnitude of the overall reduc-*
8 *tions in exposure to the substance or sub-*
9 *stances which are the subject of the applica-*
10 *tion is substantial, such substance or sub-*
11 *stances are harmful, and the product as ac-*
12 *tually used exposes consumers to the speci-*
13 *fied reduced level of the substance or sub-*
14 *stances;*

15 “(ii) *the product as actually used by*
16 *consumers will not expose them to higher*
17 *levels of other harmful substances compared*
18 *to the similar types of tobacco products then*
19 *on the market unless such increases are*
20 *minimal and the reasonably likely overall*
21 *impact of use of the product remains a sub-*
22 *stantial and measurable reduction in over-*
23 *all morbidity and mortality among indi-*
24 *vidual tobacco users;*

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

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

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

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

18 “(C) CONDITIONS OF MARKETING.—

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

1 “(ii) *AGREEMENTS BY APPLICANT.*—
2 *An order under this paragraph shall be con-*
3 *ditioned on the applicant’s agreement to*
4 *conduct postmarket surveillance and studies*
5 *and to submit to the Secretary the results of*
6 *such surveillance and studies to determine*
7 *the impact of the order on consumer percep-*
8 *tion, behavior, and health and to enable the*
9 *Secretary to review the accuracy of the de-*
10 *terminations upon which the order was*
11 *based in accordance with a protocol ap-*
12 *proved by the Secretary.*

13 “(iii) *ANNUAL SUBMISSION.*—*The re-*
14 *sults of such postmarket surveillance and*
15 *studies described in clause (ii) shall be sub-*
16 *mitted annually.*

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

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

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

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

1 *minations under paragraphs (1) and (2), the Sec-*
2 *retary shall take into account—*

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

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

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

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

20 *“(E) comments, data, and information sub-*
21 *mitted by interested persons.*

22 *“(h) ADDITIONAL CONDITIONS FOR MARKETING.—*

23 *“(1) MODIFIED RISK PRODUCTS.—The Secretary*
24 *shall require for the marketing of a product under*
25 *this section that any advertising or labeling con-*

1 *cerning modified risk products enable the public to*
2 *comprehend the information concerning modified risk*
3 *and to understand the relative significance of such in-*
4 *formation in the context of total health and in rela-*
5 *tion to all of the diseases and health-related condi-*
6 *tions associated with the use of tobacco products.*

7 *“(2) COMPARATIVE CLAIMS.—*

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

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

1 “(3) *LABEL DISCLOSURE.*—

2 “(A) *IN GENERAL.*—*The Secretary may re-*
3 *quire the disclosure on the label of other sub-*
4 *stances in the tobacco product, or substances that*
5 *may be produced by the consumption of that to-*
6 *bacco product, that may affect a disease or*
7 *health-related condition or may increase the risk*
8 *of other diseases or health-related conditions as-*
9 *sociated with the use of tobacco products.*

10 “(B) *CONDITIONS OF USE.*—*If the condi-*
11 *tions of use of the tobacco product may affect the*
12 *risk of the product to human health, the Sec-*
13 *retary may require the labeling of conditions of*
14 *use.*

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

17 “(5) *ADVERTISING.*—*The Secretary may require,*
18 *with respect to a product for which an applicant ob-*
19 *tained an order under subsection (g)(1), that the*
20 *product comply with requirements relating to adver-*
21 *tising and promotion of the tobacco product.*

22 “(i) *POSTMARKET SURVEILLANCE AND STUDIES.*—

23 “(1) *IN GENERAL.*—*The Secretary shall require,*
24 *with respect to a product for which an applicant ob-*
25 *tained an order under subsection (g)(1), that the ap-*

1 *plicant conduct postmarket surveillance and studies*
2 *for such a tobacco product to determine the impact of*
3 *the order issuance on consumer perception, behavior,*
4 *and health, to enable the Secretary to review the accu-*
5 *racy of the determinations upon which the order was*
6 *based, and to provide information that the Secretary*
7 *determines is otherwise necessary regarding the use or*
8 *health risks involving the tobacco product. The results*
9 *of postmarket surveillance and studies shall be sub-*
10 *mitted to the Secretary on an annual basis.*

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

24 *“(j) WITHDRAWAL OF AUTHORIZATION.—The Sec-*
25 *retary, after an opportunity for an informal hearing, shall*

1 *withdraw an order under subsection (g) if the Secretary de-*
2 *termines that—*

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

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

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

14 “(A) *a tobacco product standard is estab-*
15 *lished pursuant to section 907;*

16 “(B) *an action is taken that affects the risks*
17 *presented by other commercially marketed to-*
18 *bacco products that were compared to the prod-*
19 *uct that is the subject of the application; or*

20 “(C) *any postmarket surveillance or studies*
21 *reveal that the order is no longer consistent with*
22 *the protection of the public health;*

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

1 “(5) the applicant failed to meet a condition im-
2 posed under subsection (h).

3 “(k) CHAPTER IV OR V.—A product for which the Sec-
4 retary has issued an order pursuant to subsection (g) shall
5 not be subject to chapter IV or V.

6 “(l) IMPLEMENTING REGULATIONS OR GUIDANCE.—

7 “(1) SCIENTIFIC EVIDENCE.—Not later than 2
8 years after the date of enactment of the Family Smok-
9 ing Prevention and Tobacco Control Act, the Sec-
10 retary shall issue regulations or guidance (or any
11 combination thereof) on the scientific evidence re-
12 quired for assessment and ongoing review of modified
13 risk tobacco products. Such regulations or guidance
14 shall—

15 “(A) to the extent that adequate scientific
16 evidence exists, establish minimum standards for
17 scientific studies needed prior to issuing an
18 order under subsection (g) to show that a sub-
19 stantial reduction in morbidity or mortality
20 among individual tobacco users occurs for prod-
21 ucts described in subsection (g)(1) or is reason-
22 ably likely for products described in subsection
23 (g)(2);

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

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

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

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

18 “(F) establish a reasonable timetable for the
19 Secretary to review an application under this
20 section.

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

1 *experts, on the design and conduct of such studies and*
2 *surveillance.*

3 “(3) *REVISION.*—*The regulations or guidance*
4 *under paragraph (1) shall be revised on a regular*
5 *basis as new scientific information becomes available.*

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

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

24 **“SEC. 912. JUDICIAL REVIEW.**

25 “(a) *RIGHT TO REVIEW.*—

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

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

6 “(B) *a denial of an application under sec-*
7 *tion 910(c),*
8 *any person adversely affected by such regulation or*
9 *denial may file a petition for judicial review of such*
10 *regulation or denial with the United States Court of*
11 *Appeals for the District of Columbia Circuit or for*
12 *the circuit in which such person resides or has their*
13 *principal place of business.*

14 “(2) *REQUIREMENTS.*—

15 “(A) *COPY OF PETITION.*—*A copy of the pe-*
16 *tition filed under paragraph (1) shall be trans-*
17 *mitted by the clerk of the court involved to the*
18 *Secretary.*

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

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

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

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

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

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

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

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

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

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

1 *cluding interim relief, as provided for in such chapter. A*
2 *regulation or denial described in subsection (a) shall be re-*
3 *viewed in accordance with section 706(2)(A) of title 5,*
4 *United States Code.*

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

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

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

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

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

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

3 “(a) *JURISDICTION.*—

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

10 “(2) *ENFORCEMENT.*—*Any advertising that vio-*
11 *lates this chapter or a provision of the regulations re-*
12 *ferred to in section 102 of the Family Smoking Pre-*
13 *vention and Tobacco Control Act, is an unfair or de-*
14 *ceptive act or practice under section 5(a) of the Fed-*
15 *eral Trade Commission Act and shall be considered a*
16 *violation of a rule promulgated under section 18 of*
17 *that Act.*

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

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

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

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

6 **“SEC. 915. REGULATION REQUIREMENT.**

7 *“(a) TESTING, REPORTING, AND DISCLOSURE.—Not*
8 *later than 36 months after the date of enactment of the*
9 *Family Smoking Prevention and Tobacco Control Act, the*
10 *Secretary shall promulgate regulations under this Act that*
11 *meet the requirements of subsection (b).*

12 *“(b) CONTENTS OF RULES.—The regulations promul-*
13 *gated under subsection (a)—*

14 *“(1) shall require testing and reporting of to-*
15 *bacco product constituents, ingredients, and additives,*
16 *including smoke constituents, by brand and subbrand*
17 *that the Secretary determines should be tested to pro-*
18 *tect the public health; and*

19 *“(2) may require that tobacco product manufac-*
20 *turers, packagers, or importers make disclosures relat-*
21 *ing to the results of the testing of tar and nicotine*
22 *through labels or advertising or other appropriate*
23 *means, and make disclosures regarding the results of*
24 *the testing of other constituents, including smoke con-*
25 *stituents, ingredients, or additives, that the Secretary*

1 *determines should be disclosed to the public to protect*
2 *the public health and will not mislead consumers*
3 *about the risk of tobacco-related disease.*

4 “(c) *AUTHORITY.*—*The Secretary shall have the au-*
5 *thority under this chapter to conduct or to require the test-*
6 *ing, reporting, or disclosure of tobacco product constituents,*
7 *including smoke constituents.*

8 “(d) *SMALL TOBACCO PRODUCT MANUFACTURERS.*—

9 “(1) *FIRST COMPLIANCE DATE.*—*The initial regu-*
10 *lations promulgated under subsection (a) shall not*
11 *impose requirements on small tobacco product manu-*
12 *facturers before the later of—*

13 “(A) *the end of the 2-year period following*
14 *the final promulgation of such regulations; and*

15 “(B) *the initial date set by the Secretary for*
16 *compliance with such regulations by manufac-*
17 *turers that are not small tobacco product manu-*
18 *facturers.*

19 “(2) *TESTING AND REPORTING INITIAL COMPLI-*
20 *ANCE PERIOD.*—

21 “(A) *4-YEAR PERIOD.*—*The initial regula-*
22 *tions promulgated under subsection (a) shall give*
23 *each small tobacco product manufacturer a 4-*
24 *year period over which to conduct testing and re-*
25 *porting for all of its tobacco products. Subject to*

1 paragraph (1), the end of the first year of such
2 4-year period shall coincide with the initial date
3 of compliance under this section set by the Sec-
4 retary with respect to manufacturers that are
5 not small tobacco product manufacturers or the
6 end of the 2-year period following the final pro-
7 mulgation of such regulations, as described in
8 paragraph (1)(A). A small tobacco product man-
9 ufacturer shall be required—

10 “(i) to conduct such testing and report-
11 ing for 25 percent of its tobacco products
12 during each year of such 4-year period; and

13 “(ii) to conduct such testing and re-
14 porting for its largest-selling tobacco prod-
15 ucts (as determined by the Secretary) before
16 its other tobacco products, or in such other
17 order of priority as determined by the Sec-
18 retary.

19 “(B) CASE-BY-CASE DELAY.—Notwith-
20 standing subparagraph (A), the Secretary may,
21 on a case-by-case basis, delay the date by which
22 an individual small tobacco product manufac-
23 turer must conduct testing and reporting for its
24 tobacco products under this section based upon a
25 showing of undue hardship to such manufac-

1 *turer. Notwithstanding the preceding sentence,*
2 *the Secretary shall not extend the deadline for a*
3 *small tobacco product manufacturer to conduct*
4 *testing and reporting for all of its tobacco prod-*
5 *ucts beyond a total of 5 years after the initial*
6 *date of compliance under this section set by the*
7 *Secretary with respect to manufacturers that are*
8 *not small tobacco product manufacturers.*

9 *“(3) SUBSEQUENT AND ADDITIONAL TESTING*
10 *AND REPORTING.—The regulations promulgated under*
11 *subsection (a) shall provide that, with respect to any*
12 *subsequent or additional testing and reporting of to-*
13 *bacco products required under this section, such test-*
14 *ing and reporting by a small tobacco product manu-*
15 *facturer shall be conducted in accordance with the*
16 *timeframes described in paragraph (2)(A), except*
17 *that, in the case of a new product, or if there has been*
18 *a modification described in section 910(a)(1)(B) of*
19 *any product of a small tobacco product manufacturer*
20 *since the last testing and reporting required under*
21 *this section, the Secretary shall require that any sub-*
22 *sequent or additional testing and reporting be con-*
23 *ducted in accordance with the same timeframe appli-*
24 *cable to manufacturers that are not small tobacco*
25 *product manufacturers.*

1 “(4) *JOINT LABORATORY TESTING SERVICES.*—
2 *The Secretary shall allow any 2 or more small to-*
3 *bacco product manufacturers to join together to pur-*
4 *chase laboratory testing services required by this sec-*
5 *tion on a group basis in order to ensure that such*
6 *manufacturers receive access to, and fair pricing of,*
7 *such testing services.*

8 “(e) *EXTENSIONS FOR LIMITED LABORATORY CAPAC-*
9 *ITY.*—

10 “(1) *IN GENERAL.*—*The regulations promulgated*
11 *under subsection (a) shall provide that a small to-*
12 *bacco product manufacturer shall not be considered to*
13 *be in violation of this section before the deadline ap-*
14 *plicable under paragraphs (3) and (4), if—*

15 “(A) *the tobacco products of such manufac-*
16 *turer are in compliance with all other require-*
17 *ments of this chapter; and*

18 “(B) *the conditions described in paragraph*
19 *(2) are met.*

20 “(2) *CONDITIONS.*—*Notwithstanding the require-*
21 *ments of this section, the Secretary may delay the*
22 *date by which a small tobacco product manufacturer*
23 *must be in compliance with the testing and reporting*
24 *required by this section until such time as the testing*
25 *is reported if, not later than 90 days before the dead-*

1 *line for reporting in accordance with this section, a*
2 *small tobacco product manufacturer provides evidence*
3 *to the Secretary demonstrating that—*

4 *“(A) the manufacturer has submitted the re-*
5 *quired products for testing to a laboratory and*
6 *has done so sufficiently in advance of the dead-*
7 *line to create a reasonable expectation of comple-*
8 *tion by the deadline;*

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

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

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

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

8 “(4) *ADDITIONAL EXTENSION.—In addition to*
9 *the time that may be provided under paragraph (3),*
10 *the Secretary may provide further extensions of time,*
11 *in increments of no more than 1 year, for required*
12 *testing and reporting to occur if the Secretary deter-*
13 *mines, based on evidence properly and timely sub-*
14 *mitted by a small tobacco product manufacturer in*
15 *accordance with paragraph (2), that a lack of avail-*
16 *able laboratory capacity prevents the manufacturer*
17 *from completing the required testing during the pe-*
18 *riod described in paragraph (3).*

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

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

3 “(a) *IN GENERAL.*—

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

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

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

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

9 “(B) *EXCEPTION.*—*Subparagraph (A) does*
10 *not apply to requirements relating to the sale,*
11 *distribution, possession, information reporting to*
12 *the State, exposure to, access to, the advertising*
13 *and promotion of, or use of, tobacco products by*
14 *individuals of any age, or relating to fire safety*
15 *standards for tobacco products. Information dis-*
16 *closed to a State under subparagraph (A) that is*
17 *exempt from disclosure under section 552(b)(4)*
18 *of title 5, United States Code, shall be treated as*
19 *a trade secret and confidential information by*
20 *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 af-*
24 *fect any action or the liability of any person under the*
25 *product liability law of any State.*

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

3 “(a) *ESTABLISHMENT.*—Not later than 1 year after the
4 date of enactment of the Family Smoking Prevention and
5 Tobacco Control Act, the Secretary shall establish a 12-
6 member advisory committee, to be known as the Tobacco
7 Products Scientific Advisory Committee (in this section re-
8 ferred to as the ‘Advisory Committee’).

9 “(b) *MEMBERSHIP.*—

10 “(1) *IN GENERAL.*—

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

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

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

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

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

9 “(v) 1 individual as a representative of
10 the interests of the small business tobacco
11 manufacturing industry, which position
12 may be filled on a rotating, sequential basis
13 by representatives of different small business
14 tobacco manufacturers based on areas of ex-
15 pertise relevant to the topics being consid-
16 ered by the Advisory Committee; and

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

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

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

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

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

21 “(c) *DUTIES.*—The Tobacco Products Scientific Advi-
22 sory Committee shall provide advice, information, and rec-
23 ommendations to the Secretary—

24 “(1) as provided in this chapter;

1 “(2) on the effects of the alteration of the nicotine
2 yields from tobacco products;

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

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

9 “(d) COMPENSATION; SUPPORT; FACA.—

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

1 “(2) *ADMINISTRATIVE SUPPORT.*—*The Secretary*
2 *shall furnish the Advisory Committee clerical and*
3 *other assistance.*

4 “(3) *NONAPPLICATION OF FAC.*—*Section 14 of*
5 *the Federal Advisory Committee Act does not apply*
6 *to the Advisory Committee.*

7 “(e) *PROCEEDINGS OF ADVISORY PANELS AND COM-*
8 *MITTEES.*—*The Advisory Committee shall make and main-*
9 *tain a transcript of any proceeding of the panel or com-*
10 *mittee. Each such panel and committee shall delete from*
11 *any transcript made under this subsection information*
12 *which is exempt from disclosure under section 552(b) of title*
13 *5, United States Code.*

14 “**SEC. 918. DRUG PRODUCTS USED TO TREAT TOBACCO DE-**
15 **PENDENCE.**

16 “(a) *IN GENERAL.*—*The Secretary shall—*

17 “(1) *at the request of the applicant, consider des-*
18 *ignating products for smoking cessation, including*
19 *nicotine replacement products as fast track research*
20 *and approval products within the meaning of section*
21 *506;*

22 “(2) *consider approving the extended use of nico-*
23 *tine replacement products (such as nicotine patches,*
24 *nicotine gum, and nicotine lozenges) for the treatment*
25 *of tobacco dependence; and*

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

4 “(b) *REPORT ON INNOVATIVE PRODUCTS.*—

5 “(1) *IN GENERAL.*—Not later than 3 years after
6 the date of enactment of the Family Smoking Preven-
7 tion and Tobacco Control Act, the Secretary, after
8 consultation with recognized scientific, medical, and
9 public health experts (including both Federal agencies
10 and nongovernmental entities, the Institute of Medi-
11 cine of the National Academy of Sciences, and the So-
12 ciety for Research on Nicotine and Tobacco), shall
13 submit to the Congress a report that examines how
14 best to regulate, promote, and encourage the develop-
15 ment of innovative products and treatments (includ-
16 ing nicotine-based and non-nicotine-based products
17 and treatments) to better achieve, in a manner that
18 best protects and promotes the public health—

19 “(A) total abstinence from tobacco use;

20 “(B) reductions in consumption of tobacco;

21 and

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

24 “(2) *RECOMMENDATIONS.*—The report under
25 paragraph (1) shall include the recommendations of

1 *the Secretary on how the Food and Drug Administra-*
2 *tion should coordinate and facilitate the exchange of*
3 *information on such innovative products and treat-*
4 *ments among relevant offices and centers within the*
5 *Administration and within the National Institutes of*
6 *Health, the Centers for Disease Control and Preven-*
7 *tion, and other relevant agencies.*

8 **“SEC. 919. USER FEE.**

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

15 “(b) *FUNDING OF FDA REGULATION OF TOBACCO*
16 *PRODUCTS.—*

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

1 “(2) *AVAILABILITY.*—Subject to paragraph (1),
2 *fees collected pursuant to subsection (c)(1) shall be*
3 *available to the Secretary without further appropria-*
4 *tion in the following amounts:*

5 “(A) *For fiscal year 2008, \$85,000,000.*

6 “(B) *For fiscal year 2009, \$235,000,000.*

7 “(C) *For fiscal year 2010, \$450,000,000.*

8 “(D) *For fiscal year 2011, \$477,000,000.*

9 “(E) *For fiscal year 2012, \$505,000,000.*

10 “(F) *For fiscal year 2013, \$534,000,000.*

11 “(G) *For fiscal year 2014, \$566,000,000.*

12 “(H) *For fiscal year 2015, \$599,000,000.*

13 “(I) *For fiscal year 2016, \$635,000,000.*

14 “(J) *For fiscal year 2017, \$672,000,000.*

15 “(K) *For fiscal year 2018 and each subse-*
16 *quent fiscal year, \$712,000,000.*

17 *Fees made available to the Secretary under this para-*
18 *graph shall remain available until expended.*

19 “(3) *OFFSETTING RECEIPTS.*—*Fees collected pur-*
20 *suant to subsection (c)(1) shall be recorded as offset-*
21 *ting receipts.*

22 “(4) *PROHIBITION AGAINST USE OF OTHER*
23 *FUNDS.*—

24 “(A) *IN GENERAL.*—*Except as provided in*
25 *subparagraph (B), fees collected pursuant to this*

1 *section shall be the only funds used to pay the*
2 *costs of the activities of the Food and Drug Ad-*
3 *ministration related to the regulation of tobacco*
4 *products under this chapter and the Family*
5 *Smoking Prevention and Tobacco Control Act.*

6 “(B) *STARTUP COSTS.*—*Subparagraph (A)*
7 *shall not apply until the date on which the Sec-*
8 *retary has collected fees pursuant to this section*
9 *for 2 fiscal year quarters. Until such date,*
10 *amounts available to the Food and Drug Admin-*
11 *istration (other than fees collected pursuant to*
12 *this section) may be used to pay the costs de-*
13 *scribed in subparagraph (A), provided that such*
14 *amounts are reimbursed through such fees.*

15 “(c) *ASSESSMENT OF USER FEE.*—

16 “(1) *AMOUNT OF ASSESSMENT.*—*The assessment*
17 *under this section for—*

18 “(A) *fiscal year 2008 shall be \$90,100,000;*

19 “(B) *fiscal year 2009 shall be \$249,100,000;*

20 “(C) *fiscal year 2010 shall be \$477,000,000;*

21 “(D) *fiscal year 2011 shall be \$505,620,000;*

22 “(E) *fiscal year 2012 shall be \$535,300,000;*

23 “(F) *fiscal year 2013 shall be \$566,040,000;*

24 “(G) *fiscal year 2014 shall be \$599,960,000;*

25 “(H) *fiscal year 2015 shall be \$634,940,000;*

1 “(I) fiscal year 2016 shall be \$673,100,000;

2 “(J) fiscal year 2017 shall be \$712,320,000;

3 and

4 “(K) fiscal year 2018 and each subsequent
5 fiscal year shall be \$754,720,000.

6 “(2) ALLOCATIONS OF ASSESSMENT BY CLASS OF
7 TOBACCO PRODUCTS.—

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

14 “(B) APPLICABLE PERCENTAGE.—

15 “(i) IN GENERAL.—For purposes of
16 subparagraph (A), the applicable percentage
17 for a fiscal year for each of the following
18 classes of tobacco products shall be deter-
19 mined in accordance with clause (ii):

20 “(I) Cigarettes.

21 “(II) Cigars, including small ci-
22 gars and cigars other than small ci-
23 gars.

24 “(III) Snuff.

25 “(IV) Chewing tobacco.

1 “(V) *Pipe tobacco.*

2 “(VI) *Roll-your-own tobacco.*

3 “(ii) *ALLOCATIONS.—The applicable*
4 *percentage of each class of tobacco product*
5 *described in clause (i) for a fiscal year shall*
6 *be the percentage determined under section*
7 *625(c) of Public Law 108–357 for each such*
8 *class of product for such fiscal year.*

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

17 “(iv) *REALLOCATIONS.—In the case of*
18 *a class of tobacco products that is not listed*
19 *in section 901(b) or deemed by the Sec-*
20 *retary in a regulation under section 901(b)*
21 *to be subject to this chapter, the amount of*
22 *user fees that would otherwise be assessed to*
23 *such class of tobacco products shall be re-*
24 *allocated to such other classes of tobacco*
25 *products that are subject to this chapter in*

1 *the same manner and based on the same*
2 *relative percentages otherwise determined*
3 *under clause (i).*

4 “(3) *DETERMINATION OF USER FEE BY COM-*
5 *PANY.—*

6 “(A) *IN GENERAL.—The total user fee to be*
7 *paid by each manufacturer or importer of a par-*
8 *ticular class of tobacco products shall be deter-*
9 *mined in each quarter by multiplying—*

10 “(i) *such manufacturer’s or importer’s*
11 *percentage share as determined under para-*
12 *graph (4); by*

13 “(ii) *the portion of the user fee amount*
14 *for the current quarter to be assessed on all*
15 *manufacturers and importers of such class*
16 *of tobacco products as determined under*
17 *paragraph (2).*

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

23 “(4) *ALLOCATION OF ASSESSMENT WITHIN EACH*
24 *CLASS OF TOBACCO PRODUCT.—The percentage share*
25 *of each manufacturer or importer of a particular*

1 *class of tobacco products of the total user fee to be*
2 *paid by all manufacturers or importers of that class*
3 *of tobacco products shall be the percentage determined*
4 *for purposes of allocations under subsections (e)*
5 *through (h) of section 625 of Public Law 108–357.*

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

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

21 “(e) *MEMORANDUM OF UNDERSTANDING.*—

22 “(1) *IN GENERAL.*—*The Secretary shall request*
23 *the appropriate Federal agency to enter into a memo-*
24 *randum of understanding that provides for the reg-*
25 *ular and timely transfer from the head of such agency*

1 to the Secretary of the information described in para-
2 graphs (2)(B)(ii) and (4) of subsection (c) and all
3 necessary information regarding all tobacco product
4 manufacturers and importers required to pay user
5 fees. The Secretary shall maintain all disclosure re-
6 strictions established by the head of such agency re-
7 garding the information provided under the memo-
8 randum of understanding.

9 “(2) ASSURANCES.—Beginning not later than
10 fiscal year 2015, and for each subsequent fiscal year,
11 the Secretary shall ensure that the Food and Drug
12 Administration is able to determine the applicable
13 percentages described in subsection (c)(2) and the per-
14 centage shares described in subsection (c)(4). The Sec-
15 retary may carry out this paragraph by entering into
16 a contract with the head of the Federal agency re-
17 ferred to in paragraph (1) to continue to provide the
18 necessary information.

19 “(f) EFFECTIVE DATE.—

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

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

1 *user fees for the portion of the quarter that occurs*
2 *after such date of enactment shall be assessed during*
3 *the next full quarter.*

4 *“(g) STUDY BY GAO.—*

5 *“(1) IN GENERAL.—The Comptroller General of*
6 *the United States shall conduct a study on—*

7 *“(A) the prevalence of youth tobacco use*
8 *and the brands and subbrands that individuals*
9 *under the age of 18 consume;*

10 *“(B) the feasibility of structuring the user*
11 *fees or a portion of the user fees collected under*
12 *this section on the youth market share of a man-*
13 *ufacturer or year to year changes in a manufac-*
14 *turer’s share of youth market; and*

15 *“(C) the potential effects of tobacco mar-*
16 *keting to youth audiences if user fees were cal-*
17 *culated in whole or in part on youth market*
18 *share.*

19 *“(2) REPORT.—The Comptroller General shall*
20 *submit to the Energy and Commerce Committee of the*
21 *House of Representatives and the Health, Education,*
22 *Labor, and Pensions Committee of the Senate a re-*
23 *port on the study conducted under paragraph (1) by*
24 *not later than 3 years after the date of enactment of*

1 *the Family Smoking Prevention and Tobacco Control*
2 *Act.”.*

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

4 *(a) CIGARETTES AND SMOKELESS TOBACCO.—*

5 *(1) IN GENERAL.—On the first day of publica-*
6 *tion of the Federal Register that is 180 days or more*
7 *after the date of enactment of this Act, the Secretary*
8 *of Health and Human Services shall publish in the*
9 *Federal Register a final rule regarding cigarettes and*
10 *smokeless tobacco, which—*

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

14 *(B) shall be deemed to be in compliance*
15 *with all applicable provisions of chapter 5 of*
16 *title 5, United States Code, and all other provi-*
17 *sions of law relating to rulemaking procedures.*

18 *(2) CONTENTS OF RULE.—Except as provided in*
19 *this subsection, the final rule published under para-*
20 *graph (1), shall be identical in its provisions to part*
21 *897 of the regulations promulgated by the Secretary*
22 *of Health and Human Services in the August 28,*
23 *1996, issue of the Federal Register (61 Fed. Reg.,*
24 *44615–44618). Such rule shall—*

1 (A) provide for the designation of jurisdic-
2 tional authority that is in accordance with this
3 subsection in accordance with this Act and the
4 amendments made by this Act;

5 (B) strike Subpart C—Labels and section
6 897.32(c);

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

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

15 (E) become effective on the date that is 1
16 year after the date of enactment of this Act; and

17 (F) amend paragraph (d) of section 897.16
18 to read as follows:

19 “(d)(1) Except as provided in subparagraph (2), no
20 manufacturer, distributor, or retailer may distribute or
21 cause to be distributed any free samples of cigarettes, smoke-
22 less tobacco, or other tobacco products (as such term is de-
23 fined in section 201 of the Federal Food, Drug, and Cos-
24 metic Act).

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

5 “(B) This subparagraph does not affect the authority
6 *of a State or local government to prohibit or otherwise re-*
7 *strict the distribution of free samples of smokeless tobacco.*

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

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

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

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

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

1 “(v) is enclosed by a barrier that—

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

4 “(II) extends from no more than 12 inches
5 above the ground or floor (which area at the bot-
6 tom of the barrier must be covered with material
7 that restricts visibility but may allow airflow) to
8 at least 8 feet above the ground or floor (or to
9 the ceiling); and

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

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

15 “(I) any tobacco product advertising;

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

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

23 “(D) Distribution of samples of smokeless tobacco
24 under this subparagraph permitted to be taken out of the
25 qualified adult-only facility shall be limited to 1 package

1 *per adult consumer containing no more than 0.53 ounces*
2 *(15 grams) of smokeless tobacco. If such package of smoke-*
3 *less tobacco contains individual portions of smokeless to-*
4 *bacco, the individual portions of smokeless tobacco shall not*
5 *exceed 8 individual portions and the collective weight of*
6 *such individual portions shall not exceed 0.53 ounces (15*
7 *grams). Any manufacturer, distributor, or retailer who dis-*
8 *tributes or causes to be distributed free samples also shall*
9 *take reasonable steps to ensure that the above amounts are*
10 *limited to one such package per adult consumer per day.*

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

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

15 “(B) *at any football, basketball, baseball, soccer,*
16 *or hockey event or any other sporting or entertain-*
17 *ment event determined by the Secretary to be covered*
18 *by this subparagraph.*

19 “(4) *The Secretary shall implement a program to en-*
20 *sure compliance with this paragraph and submit a report*
21 *to the Congress on such compliance not later than 18*
22 *months after the date of enactment of the Family Smoking*
23 *Prevention and Tobacco Control Act.*

24 “(5) *Nothing in this paragraph shall be construed to*
25 *authorize any person to distribute or cause to be distributed*

1 *any sample of a tobacco product to any individual who has*
2 *not attained the minimum age established by applicable*
3 *law for the purchase of such product.”.*

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

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

16 (5) *ENFORCEMENT OF RETAIL SALE PROVI-*
17 *SIONS.—The Secretary of Health and Human Serv-*
18 *ices shall ensure that the provisions of this Act, the*
19 *amendments made by this Act, and the implementing*
20 *regulations (including such provisions, amendments,*
21 *and regulations relating to the retail sale of tobacco*
22 *products) are enforced with respect to the United*
23 *States and Indian tribes.*

24 (6) *QUALIFIED ADULT-ONLY FACILITY.—A quali-*
25 *fied adult-only facility (as such term is defined in*

1 *section 897.16(d) of the final rule published under*
2 *paragraph (1)) that is also a retailer and that com-*
3 *mits a violation as a retailer shall not be subject to*
4 *the limitations in section 103(q) and shall be subject*
5 *to penalties applicable to a qualified adult-only facil-*
6 *ity.*

7 (7) *CONGRESSIONAL REVIEW PROVISIONS.—Sec-*
8 *tion 801 of title 5, United States Code, shall not*
9 *apply to the final rule published under paragraph*
10 *(1).*

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

19 (1) *The preamble to the proposed rule in the doc-*
20 *ument titled “Regulations Restricting the Sale and*
21 *Distribution of Cigarettes and Smokeless Tobacco*
22 *Products to Protect Children and Adolescents” (60*
23 *Fed. Reg. 41314–41372 (August 11, 1995)).*

24 (2) *The document titled “Nicotine in Cigarettes*
25 *and Smokeless Tobacco Products is a Drug and These*

1 *Products Are Nicotine Delivery Devices Under the*
2 *Federal Food, Drug, and Cosmetic Act*” (60 Fed. Reg.
3 41453–41787 (August 11, 1995)).

4 (3) *The preamble to the final rule in the docu-*
5 *ment titled “Regulations Restricting the Sale and*
6 *Distribution of Cigarettes and Smokeless Tobacco to*
7 *Protect Children and Adolescents*” (61 Fed. Reg.
8 44396–44615 (August 28, 1996)).

9 (4) *The document titled “Nicotine in Cigarettes*
10 *and Smokeless Tobacco is a Drug and These Products*
11 *are Nicotine Delivery Devices Under the Federal*
12 *Food, Drug, and Cosmetic Act; Jurisdictional Deter-*
13 *mination*” (61 Fed. Reg. 44619–45318 (August 28,
14 1996)).

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

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

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

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

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

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

7 (4) in subsection (e)—

8 (A) by striking the period after “572(i)”;
9 and

10 (B) by striking “or 761 or the refusal to
11 permit access to” and inserting “761, 909, or
12 921 or the refusal to permit access to”;

13 (5) in subsection (g), by inserting “tobacco prod-
14 uct,” after “device,”;

15 (6) in subsection (h), by inserting “tobacco prod-
16 uct,” after “device,”;

17 (7) in subsection (j)—

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

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

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

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

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

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

8 “(q)(1) *The failure or refusal—*

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

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

14 “(C) *to comply with a requirement under section*
15 *522 or 913.”;*

16 (11) *in subsection (q)(2), by striking “device,”*
17 *and inserting “device or tobacco product,”;*

18 (12) *in subsection (r), by inserting “or tobacco*
19 *product” after the term “device” each time that such*
20 *term appears; and*

21 (13) *by adding at the end the following:*

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

1 “(pp) *The introduction or delivery for introduction*
2 *into interstate commerce of a tobacco product in violation*
3 *of section 911.*

4 “(qq)(1) *Forging, counterfeiting, simulating, or falsely*
5 *representing, or without proper authority using any mark,*
6 *stamp (including tax stamp), tag, label, or other identifica-*
7 *tion device upon any tobacco product or container or label-*
8 *ing thereof so as to render such tobacco product a counterfeit*
9 *tobacco product.*

10 “(2) *Making, selling, disposing of, or keeping in posses-*
11 *sion, control, or custody, or concealing any punch, die,*
12 *plate, stone, or other item that is designed to print, imprint,*
13 *or reproduce the trademark, trade name, or other identi-*
14 *fying mark, imprint, or device of another or any likeness*
15 *of any of the foregoing upon any tobacco product or con-*
16 *tainer or labeling thereof so as to render such tobacco prod-*
17 *uct a counterfeit tobacco product.*

18 “(3) *The doing of any act that causes a tobacco prod-*
19 *uct to be a counterfeit tobacco product, or the sale or dis-*
20 *persing, or the holding for sale or dispensing, of a counter-*
21 *feit tobacco product.*

22 “(rr) *The charitable distribution of tobacco products.*

23 “(ss) *The failure of a manufacturer or distributor to*
24 *notify the Attorney General and the Secretary of the Treas-*

1 *ury of their knowledge of tobacco products used in illicit*
2 *trade.*

3 “(tt) *With respect to a tobacco product, any statement*
4 *directed to consumers through the media or through the*
5 *label, labeling, or advertising that would reasonably be ex-*
6 *pected to result in consumers believing that the product is*
7 *regulated, inspected or approved by the Food and Drug Ad-*
8 *ministration, or that the product complies with the require-*
9 *ments of the Food and Drug Administration, including a*
10 *statement or implication in the label, labeling, or adver-*
11 *tising of such product, and that could result in consumers*
12 *believing that the product is endorsed for use by the Food*
13 *and Drug Administration or in consumers being misled*
14 *about the harmfulness of the product because of such regula-*
15 *tion, inspection, or compliance.”.*

16 (c) *SECTION 303.—Section 303(f) (21 U.S.C. 333(f))*
17 *is amended—*

18 (1) *in paragraph (1)(A), by inserting “or to-*
19 *bacco products” after the term “devices” each place*
20 *such term appears;*

21 (2) *in paragraph (5)—*

22 (A) *in subparagraph (A)—*

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

1 (ii) by striking “penalty” the second
2 time it appears and inserting “penalty, or
3 upon whom a no-tobacco-sale order is to be
4 imposed,”;

5 (B) in subparagraph (B)—

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

9 (ii) by adding at the end the following:
10 “A no-tobacco-sale order permanently pro-
11 hibiting an individual retail outlet from
12 selling tobacco products shall include provi-
13 sions that allow the outlet, after a specified
14 period of time, to request that the Secretary
15 compromise, modify, or terminate the
16 order.”; and

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

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

21 (3) in paragraph (6)—

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

1 (B) 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 (4) by adding at the end the following:

5 “(8) If the Secretary finds that a person has
6 committed repeated violations of restrictions promul-
7 gated under section 906(d) at a particular retail out-
8 let then the Secretary may impose a no-tobacco-sale
9 order on that person prohibiting the sale of tobacco
10 products in that outlet. A no-tobacco-sale order may
11 be imposed with a civil penalty under paragraph (1).
12 Prior to the entry of a no-sale order under this para-
13 graph, a person shall be entitled to a hearing pursu-
14 ant to the procedures established through regulations
15 of the Food and Drug Administration for assessing
16 civil money penalties, including at a retailer’s request
17 a hearing by telephone, or at the nearest regional or
18 field office of the Food and Drug Administration, or
19 at a Federal, State, or county facility within 100
20 miles from the location of the retail outlet, if such a
21 facility is available.”.

22 (d) SECTION 304.—Section 304 (21 U.S.C. 334) is
23 amended—

24 (1) in subsection (a)(2)—

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

1 (B) by striking “device.” and inserting the
2 following: “device, and (E) Any adulterated or
3 misbranded tobacco product.”;

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

6 (3) in subsection (g)(1), by inserting “or tobacco
7 product” after the term “device” each place such term
8 appears; and

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

11 (e) SECTION 505.—Section 505(n)(2) (21 U.S.C.
12 355(n)(2)) is amended by striking “section 904” and insert-
13 ing “section 1004”.

14 (f) SECTION 523.—Section 523(b)(2)(D) (21 U.S.C.
15 360m(b)(2)(D)) is amended by striking “section 903(g)”
16 and inserting “section 1003(g)”.

17 (g) SECTION 702.—Section 702(a) (21 U.S.C. 372(a))
18 is amended by adding at the end of paragraph (1) the fol-
19 lowing: “For a tobacco product, to the extent feasible, the
20 Secretary shall contract with the States in accordance with
21 this paragraph to carry out inspections of retailers within
22 that State in connection with the enforcement of this Act.”.

23 (h) SECTION 703.—Section 703 (21 U.S.C. 373) is
24 amended—

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

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

5 (i) SECTION 704.—Section 704 (21 U.S.C. 374) is
6 amended—

7 (1) in subsection (a)(1)(A), by inserting “tobacco
8 products,” after the term “devices,” each place such
9 term appears;

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

13 (3) in subsection (b), by inserting “tobacco prod-
14 uct,” after “device,”; and

15 (4) in subsection (g)(13), by striking “section
16 903(g)” and inserting “section 1003(g)”.

17 (j) SECTION 705.—Section 705(b) (21 U.S.C. 375(b))
18 is amended by inserting “tobacco products,” after “de-
19 vices,”.

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

22 (l) SECTION 801.—Section 801 (21 U.S.C. 381) is
23 amended—

24 (1) in subsection (a)—

1 (A) by inserting “tobacco products,” after
2 the term “devices,” ;

3 (B) by inserting “or section 905(h)” after
4 “section 510”; and

5 (C) by striking the term “drugs or devices”
6 each time such term appears and inserting
7 “drugs, devices, or tobacco products”;

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

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

11 “(p)(1) Not later than 36 months after the date of en-
12 actment of the Family Smoking Prevention and Tobacco
13 Control Act, and annually thereafter, the Secretary shall
14 submit to the Committee on Health, Education, Labor, and
15 Pensions of the Senate and the Committee on Energy and
16 Commerce of the House of Representatives, a report regard-
17 ing—

18 “(A) the nature, extent, and destination of
19 United States tobacco product exports that do not
20 conform to tobacco product standards established pur-
21 suant to this Act;

22 “(B) the public health implications of such ex-
23 ports, including any evidence of a negative public
24 health impact; and

1 “(C) recommendations or assessments of policy
2 alternatives available to Congress and the executive
3 branch to reduce any negative public health impact
4 caused by such exports.

5 “(2) The Secretary is authorized to establish appro-
6 priate information disclosure requirements to carry out this
7 subsection.”.

8 (m) SECTION 1003.—Section 1003(d)(2)(C) (as redес-
9 igned by section 101(b)) is amended—

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

11 (2) inserting “, and tobacco products” after “de-
12 vices”.

13 (n) SECTION 1009.—Section 1009(b) (as redesignated
14 by section 101(b)) is amended by striking “section 908” and
15 inserting “section 1008”.

16 (o) SECTION 409 OF THE FEDERAL MEAT INSPECTION
17 ACT.—Section 409(a) of the Federal Meat Inspection Act
18 (21 U.S.C. 679(a)) is amended by striking “section 902(b)”
19 and inserting “section 1002(b)”.

20 (p) RULE OF CONSTRUCTION.—Nothing in this section
21 is intended or shall be construed to expand, contract, or
22 otherwise modify or amend the existing limitations on State
23 government authority over tribal restricted fee or trust
24 lands.

25 (q) GUIDANCE AND EFFECTIVE DATES.—

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

3 (A) *defining the term “repeated violation”,*
4 *as used in section 303(f)(8) of the Federal Food,*
5 *Drug, and Cosmetic Act (21 U.S.C. 333(f)(8)) as*
6 *amended by subsection (c), as including at least*
7 *5 violations of particular requirements over a*
8 *36-month period at a particular retail outlet*
9 *that constitute a repeated violation and pro-*
10 *viding for civil penalties in accordance with*
11 *paragraph (2);*

12 (B) *providing for timely and effective notice*
13 *by certified or registered mail or personal deliv-*
14 *ery to the retailer of each alleged violation at a*
15 *particular retail outlet prior to conducting a fol-*
16 *lowup compliance check, such notice to be sent to*
17 *the location specified on the retailer’s registra-*
18 *tion or to the retailer’s registered agent if the re-*
19 *tailer has provider such agent information to the*
20 *Food and Drug Administration prior to the vio-*
21 *lation;*

22 (C) *providing for a hearing pursuant to the*
23 *procedures established through regulations of the*
24 *Food and Drug Administration for assessing*
25 *civil money penalties, including at a retailer’s*

1 *request a hearing by telephone or at the nearest*
2 *regional or field office of the Food and Drug Ad-*
3 *ministration, and providing for an expedited*
4 *procedure for the administrative appeal of an al-*
5 *leged violation;*

6 *(D) providing that a person may not be*
7 *charged with a violation at a particular retail*
8 *outlet unless the Secretary has provided notice to*
9 *the retailer of all previous violations at that out-*
10 *let;*

11 *(E) establishing that civil money penalties*
12 *for multiple violations shall increase from one*
13 *violation to the next violation pursuant to para-*
14 *graph (2) within the time periods provided for*
15 *in such paragraph;*

16 *(F) providing that good faith reliance on*
17 *the presentation of a false government-issued*
18 *photographic identification that contains a date*
19 *of birth does not constitute a violation of any*
20 *minimum age requirement for the sale of tobacco*
21 *products if the retailer has taken effective steps*
22 *to prevent such violations, including—*

23 *(i) adopting and enforcing a written*
24 *policy against sales to minors;*

1 (ii) informing its employees of all ap-
2 plicable laws;

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

5 (iv) requiring its employees to verify
6 age by way of photographic identification
7 or electronic scanning device; and

8 (G) providing for the Secretary, in deter-
9 mining whether to impose a no-tobacco-sale order
10 and in determining whether to compromise,
11 modify, or terminate such an order, to consider
12 whether the retailer has taken effective steps to
13 prevent violations of the minimum age require-
14 ments for the sale of tobacco products, including
15 the steps listed in subparagraph (F).

16 (2) *PENALTIES FOR VIOLATIONS.*—

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

21 (i) With respect to a retailer with an
22 approved training program, the amount of
23 the civil penalty shall not exceed—

1 (I) *in the case of the first viola-*
2 *tion, \$0.00 together with the issuance*
3 *of a warning letter to the retailer;*

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

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

8 (IV) *in the case of a fourth viola-*
9 *tion within a 24-month period, \$2,000;*

10 (V) *in the case of a fifth violation*
11 *within a 36-month period, \$5,000; and*

12 (VI) *in the case of a sixth or sub-*
13 *sequent violation within a 48-month*
14 *period, \$10,000 as determined by the*
15 *Secretary on a case-by-case basis.*

16 (ii) *With respect to a retailer that does*
17 *not have an approved training program, the*
18 *amount of the civil penalty shall not ex-*
19 *ceed—*

20 (I) *in the case of the first viola-*
21 *tion, \$250;*

22 (II) *in the case of a second viola-*
23 *tion within a 12-month period, \$500;*

24 (III) *in the case of a third viola-*
25 *tion within a 24-month period, \$1,000;*

1 (IV) *in the case of a fourth viola-*
2 *tion within a 24-month period, \$2,000;*

3 (V) *in the case of a fifth violation*
4 *within a 36-month period, \$5,000; and*

5 (VI) *in the case of a sixth or sub-*
6 *sequent violation within a 48-month*
7 *period, \$10,000 as determined by the*
8 *Secretary on a case-by-case basis.*

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

14 (C) *CONSIDERATION OF STATE PEN-*
15 *ALTIES.—The Secretary shall coordinate with the*
16 *States in enforcing the provisions of this Act*
17 *and, for purposes of mitigating a civil penalty*
18 *to be applied for a violation by a retailer of any*
19 *restriction promulgated under section 906(d),*
20 *shall consider the amount of any penalties paid*
21 *by the retailer to a State for the same violation.*

22 (3) *GENERAL EFFECTIVE DATE.—The amend-*
23 *ments made by paragraphs (2), (3), and (4) of sub-*
24 *section (c) shall take effect upon the issuance of guid-*
25 *ance described in paragraph (1) of this subsection.*

1 (4) *SPECIAL EFFECTIVE DATE.*—*The amendment*
2 *made by subsection (c)(1) shall take effect on the date*
3 *of enactment of this Act.*

4 (5) *PACKAGE LABEL REQUIREMENTS.*—*The pack-*
5 *age label requirements of paragraphs (2), (3), and (4)*
6 *of section 903(a) of the Federal Food, Drug, and Cos-*
7 *metic Act (as amended by this Act) shall take effect*
8 *on the date that is 12 months after the date of enact-*
9 *ment of this Act. The effective date shall be with re-*
10 *spect to the date of manufacture, provided that, in*
11 *any case, 30 days after such effective date, a manu-*
12 *facturer shall not introduce into the domestic com-*
13 *merce of the United States any product that is not in*
14 *conformance with section 903(a)(2), (3), and (4) and*
15 *section 920(a) of the Federal Food, Drug, and Cos-*
16 *metic Act.*

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

22 **SEC. 104. STUDY ON RAISING THE MINIMUM AGE TO PUR-**
23 **CHASE TOBACCO PRODUCTS.**

24 *The Secretary of Health and Human Services shall—*

1 (1) *convene an expert panel to conduct a study*
2 *on the public health implications of raising the min-*
3 *imum age to purchase tobacco products; and*

4 (2) *not later than 5 years after the date of the*
5 *enactment of this Act, submit a report to the Congress*
6 *on the results of such study.*

7 **SEC. 105. TOBACCO INDUSTRY CONCENTRATION.**

8 (a) *STUDY.*—*The Federal Trade Commission shall*
9 *conduct a study on the causes and effects of concentration*
10 *in the tobacco industry.*

11 (b) *PUBLIC REPORT.*—*The Federal Trade Commission*
12 *shall transmit to Congress a report not later than 5 years*
13 *after the date of enactment of this Act, and a subsequent*
14 *report on the date that is 10 years after the date of enact-*
15 *ment of this Act. Such reports shall include—*

16 (1) *an analysis of trends in the market share of*
17 *any dominant tobacco product manufacturer in any*
18 *class of tobacco products; or*

19 (2) *an analysis of trends in competition or the*
20 *emergence of a monopoly; and*

21 (3) *recommendations to Congress on any correc-*
22 *tive actions that should be taken to address tobacco*
23 *industry concentration.*

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

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

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

9 **“SEC. 4. LABELING.**

10 *“(a) LABEL REQUIREMENTS.—*

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

17 *“WARNING: Cigarettes are addictive.*

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

20 *“WARNING: Cigarettes cause fatal lung*
21 *disease.*

22 *“WARNING: Cigarettes cause cancer.*

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

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

3 “WARNING: *Smoking can kill you.*

4 “WARNING: *Tobacco smoke causes fatal*
5 *lung disease in nonsmokers.*

6 “WARNING: *Quitting smoking now greatly*
7 *reduces serious risks to your health.*

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

1 *in an alternating fashion under the plan submitted*
2 *under subsection (c).*

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

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

12 “(A) *contains a warning label;*

13 “(B) *is supplied to the retailer by a license-*
14 *or permit-holding tobacco product manufacturer,*
15 *importer, or distributor; and*

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

19 “(b) *ADVERTISING REQUIREMENTS.*—

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

1 *ments of this section, one of the labels specified in*
2 *subsection (a).*

3 *“(2) TYPOGRAPHY, ETC.—Each label statement*
4 *required by subsection (a) in cigarette advertising*
5 *shall comply with the standards set forth in this*
6 *paragraph. For press and poster advertisements, each*
7 *such statement and (where applicable) any required*
8 *statement relating to tar, nicotine, or other con-*
9 *stituent (including a smoke constituent) yield shall*
10 *comprise at least 20 percent of the area of the adver-*
11 *tisement and shall appear in a conspicuous and*
12 *prominent format and location at the top of each ad-*
13 *vertisement within the trim area. The Secretary may*
14 *revise the required type sizes in such area in such*
15 *manner as the Secretary determines appropriate. The*
16 *word ‘WARNING’ shall appear in capital letters, and*
17 *each label statement shall appear in conspicuous and*
18 *legible type. The text of the label statement shall be*
19 *black if the background is white and white if the*
20 *background is black, under the plan submitted under*
21 *subsection (c). The label statements shall be enclosed*
22 *by a rectangular border that is the same color as the*
23 *letters of the statements and that is the width of the*
24 *first downstroke of the capital ‘W’ of the word*
25 *‘WARNING’ in the label statements. The text of such*

1 *label statements shall be in a typeface pro rata to the*
2 *following requirements: 45-point type for a whole-*
3 *page broadsheet newspaper advertisement; 39-point*
4 *type for a half-page broadsheet newspaper advertise-*
5 *ment; 39-point type for a whole-page tabloid news-*
6 *paper advertisement; 27-point type for a half-page*
7 *tabloid newspaper advertisement; 31.5-point type for*
8 *a double page spread magazine or whole-page maga-*
9 *zine advertisement; 22.5-point type for a 28 centi-*
10 *meter by 3 column advertisement; and 15-point type*
11 *for a 20 centimeter by 2 column advertisement. The*
12 *label statements shall be in English, except that—*

13 *“(A) in the case of an advertisement that*
14 *appears in a newspaper, magazine, periodical,*
15 *or other publication that is not in English, the*
16 *statements shall appear in the predominant lan-*
17 *guage of the publication; and*

18 *“(B) in the case of any other advertisement*
19 *that is not in English, the statements shall ap-*
20 *pear in the same language as that principally*
21 *used in the advertisement.*

22 *“(3) MATCHBOOKS.—Notwithstanding para-*
23 *graph (2), for matchbooks (defined as containing not*
24 *more than 20 matches) customarily given away with*
25 *the purchase of tobacco products, each label statement*

1 *required by subsection (a) may be printed on the in-*
2 *side cover of the matchbook.*

3 “(4) *ADJUSTMENT BY SECRETARY.*—*The Sec-*
4 *retary may, through a rulemaking under section 553*
5 *of title 5, United States Code, adjust the format and*
6 *type sizes for the label statements required by this sec-*
7 *tion; the text, format, and type sizes of any required*
8 *tar, nicotine yield, or other constituent (including*
9 *smoke constituent) disclosures; or the text, format,*
10 *and type sizes for any other disclosures required*
11 *under the Federal Food, Drug, and Cosmetic Act. The*
12 *text of any such label statements or disclosures shall*
13 *be required to appear only within the 20 percent area*
14 *of cigarette advertisements provided by paragraph*
15 *(2). The Secretary shall promulgate regulations which*
16 *provide for adjustments in the format and type sizes*
17 *of any text required to appear in such area to ensure*
18 *that the total text required to appear by law will fit*
19 *within such area.*

20 “(c) *MARKETING REQUIREMENTS.*—

21 “(1) *RANDOM DISPLAY.*—*The label statements*
22 *specified in subsection (a)(1) shall be randomly dis-*
23 *played in each 12-month period, in as equal a num-*
24 *ber of times as is possible on each brand of the prod-*
25 *uct and be randomly distributed in all areas of the*

1 *United States in which the product is marketed in ac-*
2 *cordance with a plan submitted by the tobacco prod-*
3 *uct manufacturer, importer, distributor, or retailer*
4 *and approved by the Secretary.*

5 *“(2) ROTATION.—The label statements specified*
6 *in subsection (a)(1) shall be rotated quarterly in al-*
7 *ternating sequence in advertisements for each brand*
8 *of cigarettes in accordance with a plan submitted by*
9 *the tobacco product manufacturer, importer, dis-*
10 *tributor, or retailer to, and approved by, the Sec-*
11 *retary.*

12 *“(3) REVIEW.—The Secretary shall review each*
13 *plan submitted under paragraph (2) and approve it*
14 *if the plan—*

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

18 *“(B) 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 *“(4) APPLICABILITY TO RETAILERS.—This sub-*
23 *section and subsection (b) apply to a retailer only if*
24 *that retailer is responsible for or directs the label*
25 *statements required under this section except that this*

1 *such a change would promote greater public understanding*
2 *of the risks associated with the use of tobacco products.”.*

3 **SEC. 203. STATE REGULATION OF CIGARETTE ADVERTISING**
4 **AND PROMOTION.**

5 *Section 5 of the Federal Cigarette Labeling and Adver-*
6 *tising Act (15 U.S.C. 1334) is amended by adding at the*
7 *end the following:*

8 *“(c) EXCEPTION.—Notwithstanding subsection (b), a*
9 *State or locality may enact statutes and promulgate regula-*
10 *tions, based on smoking and health, that take effect after*
11 *the effective date of the Family Smoking Prevention and*
12 *Tobacco Control Act, imposing specific bans or restrictions*
13 *on the time, place, and manner, but not content, of the ad-*
14 *vertising or promotion of any cigarettes.”.*

15 **SEC. 204. SMOKELESS TOBACCO LABELS AND ADVERTISING**
16 **WARNINGS.**

17 *(a) AMENDMENT.—Section 3 of the Comprehensive*
18 *Smokeless Tobacco Health Education Act of 1986 (15*
19 *U.S.C. 4402) is amended to read as follows:*

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

21 *“(a) GENERAL RULE.—*

22 *“(1) It shall be unlawful for any person to man-*
23 *ufacture, package, sell, offer to sell, distribute, or im-*
24 *port for sale or distribution within the United States*
25 *any smokeless tobacco product unless the product*

1 *package bears, in accordance with the requirements of*
2 *this Act, one of the following labels:*

3 *“WARNING: This product can cause mouth*
4 *cancer.*

5 *“WARNING: This product can cause gum*
6 *disease and tooth loss.*

7 *“WARNING: This product is not a safe al-*
8 *ternative to cigarettes.*

9 *“WARNING: Smokeless tobacco is addictive.*

10 *“(2) Each label statement required by paragraph*
11 *(1) shall be—*

12 *“(A) located on the 2 principal display*
13 *panels of the package, and each label statement*
14 *shall comprise at least 30 percent of each such*
15 *display panel; and*

16 *“(B) in 17-point conspicuous and legible*
17 *type and in black text on a white background, or*
18 *white text on a black background, in a manner*
19 *that contrasts by typography, layout, or color,*
20 *with all other printed material on the package,*
21 *in an alternating fashion under the plan sub-*
22 *mitted under subsection (b)(3), except that if the*
23 *text of a label statement would occupy more than*
24 *70 percent of the area specified by subparagraph*
25 *(A), such text may appear in a smaller type size,*

1 *so long as at least 60 percent of such warning*
2 *area is occupied by the label statement.*

3 “(3) *The label statements required by paragraph*
4 *(1) shall be introduced by each tobacco product manu-*
5 *facturer, packager, importer, distributor, or retailer of*
6 *smokeless tobacco products concurrently into the dis-*
7 *tribution chain of such products.*

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

14 “(5) *A retailer of smokeless tobacco products*
15 *shall not be in violation of this subsection for pack-*
16 *aging that—*

17 “(A) *contains a warning label;*

18 “(B) *is supplied to the retailer by a license-*
19 *or permit-holding tobacco product manufacturer,*
20 *importer, or distributor; and*

21 “(C) *is not altered by the retailer in a way*
22 *that is material to the requirements of this sub-*
23 *section.*

24 “(b) *REQUIRED LABELS.—*

1 “(1) It shall be unlawful for any tobacco product
2 manufacturer, packager, importer, distributor, or re-
3 tailer of smokeless tobacco products to advertise or
4 cause to be advertised within the United States any
5 smokeless tobacco product unless its advertising bears,
6 in accordance with the requirements of this section,
7 one of the labels specified in subsection (a).

8 “(2) Each label statement required by subsection
9 (a) in smokeless tobacco advertising shall comply with
10 the standards set forth in this paragraph. For press
11 and poster advertisements, each such statement and
12 (where applicable) any required statement relating to
13 tar, nicotine, or other constituent yield shall—

14 “(A) comprise at least 20 percent of the
15 area of the advertisement, and the warning area
16 shall be delineated by a dividing line of con-
17 trasting color from the advertisement; and

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

1 “(3)(A) *The label statements specified in sub-*
2 *section (a)(1) shall be randomly displayed in each 12-*
3 *month period, in as equal a number of times as is*
4 *possible on each brand of the product and be ran-*
5 *domly distributed in all areas of the United States in*
6 *which the product is marketed in accordance with a*
7 *plan submitted by the tobacco product manufacturer,*
8 *importer, distributor, or retailer and approved by the*
9 *Secretary.*

10 “(B) *The label statements specified in subsection*
11 *(a)(1) shall be rotated quarterly in alternating se-*
12 *quence in advertisements for each brand of smokeless*
13 *tobacco product in accordance with a plan submitted*
14 *by the tobacco product manufacturer, importer, dis-*
15 *tributor, or retailer to, and approved by, the Sec-*
16 *retary.*

17 “(C) *The Secretary shall review each plan sub-*
18 *mitted under subparagraphs (A) and (B) and ap-*
19 *prove it if the plan—*

20 “(i) *will provide for the equal distribution*
21 *and display on packaging and the rotation re-*
22 *quired in advertising under this subsection; and*

23 “(ii) *assures that all of the labels required*
24 *under this section will be displayed by the to-*

1 *bacco product manufacturer, importer, dis-*
2 *tributor, or retailer at the same time.*

3 “(D) *This paragraph applies to a retailer only*
4 *if that retailer is responsible for or directs the label*
5 *statements under this section, unless the retailer dis-*
6 *plays, in a location open to the public, an advertise-*
7 *ment that does not contain a warning label or has*
8 *been altered by the retailer in a way that is material*
9 *to the requirements of this subsection.*

10 “(4) *The Secretary may, through a rulemaking*
11 *under section 553 of title 5, United States Code, ad-*
12 *just the format and type sizes for the label statements*
13 *required by this section; the text, format, and type*
14 *sizes of any required tar, nicotine yield, or other con-*
15 *stituent disclosures; or the text, format, and type sizes*
16 *for any other disclosures required under the Federal*
17 *Food, Drug, and Cosmetic Act. The text of any such*
18 *label statements or disclosures shall be required to ap-*
19 *pear only within the 20 percent area of advertise-*
20 *ments provided by paragraph (2). The Secretary shall*
21 *promulgate regulations which provide for adjustments*
22 *in the format and type sizes of any text required to*
23 *appear in such area to ensure that the total text re-*
24 *quired to appear by law will fit within such area.*

1 “(c) *TELEVISION AND RADIO ADVERTISING.*—*It is un-*
2 *lawful to advertise smokeless tobacco on any medium of elec-*
3 *tronic communications subject to the jurisdiction of the*
4 *Federal Communications Commission.*”.

5 (b) *EFFECTIVE DATE.*—*The amendments made by this*
6 *title to section 3 of the Comprehensive Smokeless Tobacco*
7 *Health Education Act of 1986 (15 U.S.C. 4402) shall take*
8 *effect on the date that is 1 year after the date of enactment*
9 *of this Act.*

10 **SEC. 205. AUTHORITY TO REVISE SMOKELESS TOBACCO**
11 **PRODUCT WARNING LABEL STATEMENTS.**

12 (a) *IN GENERAL.*—*Section 3 of the Comprehensive*
13 *Smokeless Tobacco Health Education Act of 1986 (15*
14 *U.S.C. 4402), as amended by section 204, is further amend-*
15 *ed by adding at the end the following:*

16 “(d) *AUTHORITY TO REVISE WARNING LABEL STATE-*
17 *MENTS.*—*The Secretary may, by a rulemaking conducted*
18 *under section 553 of title 5, United States Code, adjust the*
19 *format, type size, and text of any of the label requirements,*
20 *require color graphics to accompany the text, increase the*
21 *required label area from 30 percent up to 50 percent of the*
22 *front and rear panels of the package, or establish the format,*
23 *type size, and text of any other disclosures required under*
24 *the Federal Food, Drug, and Cosmetic Act, if the Secretary*
25 *finds that such a change would promote greater public un-*

1 *derstanding of the risks associated with the use of smokeless*
2 *tobacco products.”.*

3 **(b) PREEMPTION.**—*Section 7(a) of the Comprehensive*
4 *Smokeless Tobacco Health Education Act of 1986 (15*
5 *U.S.C. 4406(a)) is amended by striking “No” and inserting*
6 *“Except as provided in the Family Smoking Prevention*
7 *and Tobacco Control Act (and the amendments made by*
8 *that Act), no”.*

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

11 *Section 4 of the Federal Cigarette Labeling and Adver-*
12 *tising Act (15 U.S.C. 1333), as amended by sections 201*
13 *and 202, is further amended by adding at the end the fol-*
14 *lowing:*

15 **“(e) TAR, NICOTINE, AND OTHER SMOKE CON-**
16 **STITUENT DISCLOSURE.**—

17 **“(1) IN GENERAL.**—*The Secretary shall, by a*
18 *rulemaking conducted under section 553 of title 5,*
19 *United States Code, determine (in the Secretary’s sole*
20 *discretion) whether cigarette and other tobacco prod-*
21 *uct manufacturers shall be required to include in the*
22 *area of each cigarette advertisement specified by sub-*
23 *section (b) of this section, or on the package label, or*
24 *both, the tar and nicotine yields of the advertised or*
25 *packaged brand. Any such disclosure shall be in ac-*

1 *cordance with the methodology established under such*
2 *regulations, shall conform to the type size require-*
3 *ments of subsection (b) of this section, and shall ap-*
4 *pear within the area specified in subsection (b) of this*
5 *section.*

6 “(2) *RESOLUTION OF DIFFERENCES.*—*Any dif-*
7 *ferences between the requirements established by the*
8 *Secretary under paragraph (1) and tar and nicotine*
9 *yield reporting requirements established by the Fed-*
10 *eral Trade Commission shall be resolved by a memo-*
11 *randum of understanding between the Secretary and*
12 *the Federal Trade Commission.*

13 “(3) *CIGARETTE AND OTHER TOBACCO PRODUCT*
14 *CONSTITUENTS.*—*In addition to the disclosures re-*
15 *quired by paragraph (1), the Secretary may, under a*
16 *rulemaking conducted under section 553 of title 5,*
17 *United States Code, prescribe disclosure requirements*
18 *regarding the level of any cigarette or other tobacco*
19 *product constituent including any smoke constituent.*
20 *Any such disclosure may be required if the Secretary*
21 *determines that disclosure would be of benefit to the*
22 *public health, or otherwise would increase consumer*
23 *awareness of the health consequences of the use of to-*
24 *bacco products, except that no such prescribed disclo-*
25 *sure shall be required on the face of any cigarette*

1 *package or advertisement. Nothing in this section*
 2 *shall prohibit the Secretary from requiring such pre-*
 3 *scribed disclosure through a cigarette or other tobacco*
 4 *product package or advertisement insert, or by any*
 5 *other means under the Federal Food, Drug, and Cos-*
 6 *metic Act.*

7 “(4) *RETAILERS.*—*This subsection applies to a*
 8 *retailer only if that retailer is responsible for or di-*
 9 *rects the label statements required under this sec-*
 10 *tion.*”.

11 ***TITLE III—PREVENTION OF IL-***
 12 ***LICIT TRADE IN TOBACCO***
 13 ***PRODUCTS***

14 ***SEC. 301. LABELING, RECORDKEEPING, RECORDS INSPEC-***
 15 ***TION.***

16 *Chapter IX of the Federal Food, Drug, and Cosmetic*
 17 *Act, as added by section 101, is further amended by adding*
 18 *at the end the following:*

19 ***“SEC. 920. LABELING, RECORDKEEPING, RECORDS INSPEC-***
 20 ***TION.***

21 “(a) *ORIGIN LABELING.*—*Beginning 1 year after the*
 22 *date of enactment of the Family Smoking Prevention and*
 23 *Tobacco Control Act, the label, packaging, and shipping*
 24 *containers of tobacco products for introduction or delivery*
 25 *for introduction into interstate commerce in the United*

1 *States shall bear the statement ‘sale only allowed in the*
2 *United States’.*

3 “(b) *REGULATIONS CONCERNING RECORDKEEPING*
4 *FOR TRACKING AND TRACING.*—

5 “(1) *IN GENERAL.*—*The Secretary shall promul-*
6 *gate regulations regarding the establishment and*
7 *maintenance of records by any person who manufac-*
8 *tures, processes, transports, distributes, receives, pack-*
9 *ages, holds, exports, or imports tobacco products.*

10 “(2) *INSPECTION.*—*In promulgating the regula-*
11 *tions described in paragraph (1), the Secretary shall*
12 *consider which records are needed for inspection to*
13 *monitor the movement of tobacco products from the*
14 *point of manufacture through distribution to retail*
15 *outlets to assist in investigating potential illicit*
16 *trade, smuggling, or counterfeiting of tobacco prod-*
17 *ucts.*

18 “(3) *CODES.*—*The Secretary may require codes*
19 *on the labels of tobacco products or other designs or*
20 *devices for the purpose of tracking or tracing the to-*
21 *bacco product through the distribution system.*

22 “(4) *SIZE OF BUSINESS.*—*The Secretary shall*
23 *take into account the size of a business in promul-*
24 *gating regulations under this section.*

1 “(5) *RECORDKEEPING BY RETAILERS.*—*The Sec-*
2 *retary shall not require any retailer to maintain*
3 *records relating to individual purchasers of tobacco*
4 *products for personal consumption.*

5 “(c) *RECORDS INSPECTION.*—*If the Secretary has a*
6 *reasonable belief that a tobacco product is part of an illicit*
7 *trade or smuggling or is a counterfeit product, each person*
8 *who manufactures, processes, transports, distributes, re-*
9 *ceives, holds, packages, exports, or imports tobacco products*
10 *shall, at the request of an officer or employee duly des-*
11 *ignated by the Secretary, permit such officer or employee,*
12 *at reasonable times and within reasonable limits and in*
13 *a reasonable manner, upon the presentation of appropriate*
14 *credentials and a written notice to such person, to have ac-*
15 *cess to and copy all records (including financial records)*
16 *relating to such article that are needed to assist the Sec-*
17 *retary in investigating potential illicit trade, smuggling, or*
18 *counterfeiting of tobacco products.*

19 “(d) *KNOWLEDGE OF ILLEGAL TRANSACTION.*—

20 “(1) *NOTIFICATION.*—*If the manufacturer or dis-*
21 *tributor of a tobacco product has knowledge which*
22 *reasonably supports the conclusion that a tobacco*
23 *product manufactured or distributed by such manu-*
24 *facturer or distributor that has left the control of such*
25 *person may be or has been—*

1 “(A) imported, exported, distributed, or of-
2 ferred for sale in interstate commerce by a person
3 without paying duties or taxes required by law;
4 or

5 “(B) imported, exported, distributed, or di-
6 verted for possible illicit marketing,
7 the manufacturer or distributor shall promptly notify
8 the Attorney General and the Secretary of the Treas-
9 ury of such knowledge.

10 “(2) *KNOWLEDGE DEFINED.*—For purposes of
11 this subsection, the term ‘knowledge’ as applied to a
12 manufacturer or distributor means—

13 “(A) the actual knowledge that the manu-
14 facturer or distributor had; or

15 “(B) the knowledge which a reasonable per-
16 son would have had under like circumstances or
17 which would have been obtained upon the exer-
18 cise of due care.”.

19 **SEC. 302. STUDY AND REPORT.**

20 (a) *STUDY.*—The Comptroller General of the United
21 States shall conduct a study of cross-border trade in tobacco
22 products to—

23 (1) collect data on cross-border trade in tobacco
24 products, including illicit trade and trade of counter-

1 *feit tobacco products and make recommendations on*
2 *the monitoring of such trade;*

3 (2) *collect data on cross-border advertising (any*
4 *advertising intended to be broadcast, transmitted, or*
5 *distributed from the United States to another coun-*
6 *try) of tobacco products and make recommendations*
7 *on how to prevent or eliminate, and what technologies*
8 *could help facilitate the elimination of, cross-border*
9 *advertising; and*

10 (3) *collect data on the health effects (particularly*
11 *with respect to individuals under 18 years of age) re-*
12 *sulting from cross-border trade in tobacco products,*
13 *including the health effects resulting from—*

14 (A) *the illicit trade of tobacco products and*
15 *the trade of counterfeit tobacco products; and*

16 (B) *the differing tax rates applicable to to-*
17 *bacco products.*

18 (b) *REPORT.—Not later than 18 months after the date*
19 *of enactment of this Act, the Comptroller General of the*
20 *United States shall submit to the Committee on Health,*
21 *Education, Labor, and Pensions of the Senate and the Com-*
22 *mittee on Energy and Commerce of the House of Represent-*
23 *atives a report on the study described in subsection (a).*

24 (c) *DEFINITION.—In this section:*

1 (1) *The term “cross-border trade” means trade*
2 *across a border of the United States, a State or Terri-*
3 *tory, or Indian country.*

4 (2) *The term “Indian country” has the meaning*
5 *given to that term in section 1151 of title 18, United*
6 *States Code.*

7 (3) *The terms “State” and “Territory” have the*
8 *meanings given to those terms in section 201 of the*
9 *Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
10 *321).*

Union Calendar No. 485

110TH CONGRESS
2^D SESSION

H. R. 1108

[Report No. 110-762]

A BILL

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

JULY 17, 2008

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed