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Calendar No. 353

105TH CONGRESS
2D SESSION

S. 1415

[Report No. 105-180]

A BILL

To reform and restructure the processes by which tobacco products are manufactured, marketed, and distributed, to prevent the use of tobacco products by minors, to redress the adverse health effects of tobacco use, and for other purposes.

MAY 1, 1998

Reported with an amendment in the nature of a
substitute

Calendar No. 353

105TH CONGRESS
2D SESSION**S. 1415****[Report No. 105-180]**

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IN THE SENATE OF THE UNITED STATES

NOVEMBER 7, 1998

Mr. MCCAIN (for himself, Mr. HOLLINGS, Mr. BREAU, and Mr. GORTON) introduced the following bill; which was read twice and referred to the Committee on Commerce, Science, and Transportation

MAY 1, 1998

Reported by Mr. MCCAIN, with an amendment in the nature of a substitute

[Strike all after the enacting clause and insert the part printed in *italie*]

A BILL

To reform and restructure the processes by which tobacco products are manufactured, marketed, and distributed, to prevent the use of tobacco products by minors, to redress the adverse health effects of tobacco use, and for other purposes.

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

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

2 (a) ~~SHORT TITLE.~~—This Act may be cited as the

3 ~~“Universal Tobacco Settlement Act”.~~

4 (b) ~~TABLE OF CONTENTS.~~—The table of contents of

5 this Act is as follows:

Sec. 1. Short title; table of contents.

Sec. 2. Findings.

Sec. 3. Purposes.

TITLE I—REGULATION OF THE TOBACCO INDUSTRY

Sec. 100. Definitions.

Subtitle A—Restriction on Marketing and Advertising

Sec. 101. Prohibitions on advertising.

Sec. 102. General restrictions.

Sec. 103. Format and content requirements for labeling and advertising.

Sec. 104. Statement of intended use.

Sec. 105. Ban on nontobacco items and services, contests and games of chance,
and sponsorship of events.

Sec. 106. Use of product descriptors.

Subtitle B—Warnings, Labeling and Packaging

Sec. 111. Cigarette warnings.

Sec. 112. Smokeless tobacco warnings.

Sec. 113. Ingredients.

Sec. 114. Enforcement, regulations, and construction.

Sec. 115. Preemption.

Sec. 116. Reports.

Sec. 117. Exports.

Sec. 118. Repeals.

Subtitle C—Restriction on Access to Tobacco Products

Sec. 121. Requirements relating to retailers.

Sec. 122. Manufacture, sale, and distribution.

Subtitle D—Licensing of Retail Tobacco Sellers

Sec. 131. Establishment of program.

Sec. 132. Requirements.

Sec. 133. Penalties, revocations and suspensions.

Sec. 134. Federal licensing of military and other entities.

Subtitle E—Regulation of Tobacco Product Development and Manufacturing

Sec. 141. Reference.

Sec. 142. Treatment of tobacco products as drugs.

Sec. 143. Health and safety regulation of tobacco products.

Subtitle F—Compliance Plans and Corporate Culture

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

2 (a) *SHORT TITLE*.—*This Act may be cited as the “Na-*
 3 *tional Tobacco Policy and Youth Smoking Reduction Act”.*

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

Sec. 1. Short title; table of contents.

Sec. 2. Findings.

Sec. 3. Purpose.

Sec. 4. Scope and effect.

Sec. 5. Non-preemption of more restrictive laws.

Sec. 6. Definitions.

*Sec. 7. Notification if youthful cigarette smoking restrictions increase youthful
 pipe and cigar smoking.*

*Sec. 8. Liability limitations disappear if manufacturers challenge advertising lim-
 its.*

Sec. 9. FTC jurisdiction not affected.

Sec. 10. Congressional review provisions.

TITLE I—REGULATION OF THE TOBACCO INDUSTRY

Subtitle A—Jurisdiction, Etc., of Food and Drug Administration

Sec. 101. Amendment of Federal Food, Drug, and Cosmetic Act of 1938.

“CHAPTER IX—TOBACCO PRODUCTS

“Sec. 901. FDA authority over tobacco products

“Sec. 902. Adulterated tobacco products.

“Sec. 903. Misbranded tobacco products.

“Sec. 904. Submission of health information to the Secretary.

“Sec. 905. Registration.

“Sec. 906. General provisions respecting control of tobacco products.

“Sec. 907. Performance standards.

“Sec. 908. Notification and other remedies

“Sec. 909. Records and reports on tobacco products.

“Sec. 910. Premarket review of certain tobacco products.

“Sec. 911. Judicial review.

“Sec. 912. Postmarket surveillance

“Sec. 913. Reduced risk tobacco products.

“Sec. 914. Preservation of State and local authority.

“Sec. 915. Tobacco Products Scientific Advisory Committee.

“Sec. 916. Equal treatment of retail outlets.

Sec. 102. Conforming and other amendments to general provisions.

Subtitle B—Advertising

Sec. 121. Advertising provisions in protocol.

Sec. 122. Tobacco product labeling and advertising .

Sec. 123. Point-of-sale restrictions.

TITLE II—REDUCTIONS IN UNDERAGE TOBACCO USE

Subtitle A—Underage Use

- Sec. 201. Goals for reducing underage tobacco use.*
- Sec. 202. Look-back assessment.*
- Sec. 203. Substantial non-attainment of required reductions.*
- Sec. 204. Definitions.*

Subtitle B—State Enforcement Incentives

- Sec. 211. Compliance bonus fund.*
- Sec. 212. Block grants.*
- Sec. 213. State enforcement incentives.*
- Sec. 214. Conforming change.*

Subtitle C—Other Programs

- Sec. 221. National smoking cessation program.*
- Sec. 222. National tobacco-free public education program.*
- Sec. 223. National community action program.*
- Sec. 224. State retail licensing program.*

TITLE III—TOBACCO PRODUCT WARNINGS AND SMOKE CONSTITUENT DISCLOSURE

Subtitle A—Product Warnings, Labeling and Packaging

- Sec. 301. Cigarette label and advertising warnings.*
 - “Sec. 4. Labeling.*
- Sec. 302. Authority to revise cigarette warning label statements.*
- Sec. 303. Smokeless tobacco labels and advertising warnings.*
 - “Sec. 3. Smokeless tobacco warning.*
- Sec. 304. Authority to revise smokeless tobacco product warning label statements.*
- Sec. 305. Tar, nicotine, and other smoke constituent disclosure to the public.*

Subtitle B—Testing and Reporting of Tobacco Product Smoke Constituents

- Sec. 311. Regulation requirement.*

TITLE IV—NATIONAL TOBACCO SETTLEMENT TRUST FUND

Subtitle A—General Payment Provisions

- Sec. 401. Establishment of trust fund.*
- Sec. 402. State litigation settlement account.*
- Sec. 403. Payments by industry*
- Sec. 404. Adjustments.*
- Sec. 405. Tax treatment of payments.*
- Sec. 406. Enforcement for nonpayment.*
- Sec. 407. Administrative provisions.*

Subtitle B—General Spending Provisions

- Sec. 411. Implementing and enforcement funds.*
- Sec. 412. Improving child care and early childhood development.*

TITLE V—STANDARDS TO REDUCE INVOLUNTARY EXPOSURE TO
TOBACCO SMOKE

- Sec. 501. Definitions.*
- Sec. 502. Smoke-free environment policy.*
- Sec. 503. Citizen actions.*
- Sec. 504. Preemption.*
- Sec. 505. Regulations.*
- Sec. 506. Effective date.*
- Sec. 507. State choice.*

TITLE VI—APPLICATION TO INDIAN TRIBES

- Sec. 601. Short title.*
- Sec. 602. Findings and purposes.*
- Sec. 603. Application of tobacco-related provisions to native Americans.*
- Sec. 604. State tobacco excise tax compliance.*

TITLE VII—CIVIL LIABILITY OF MANUFACTURERS OF TOBACCO
PRODUCTS

- Sec. 701. Definitions.*
- Sec. 702. Application.*
- Sec. 703. Preemption and relationship to other law.*
- Sec. 704. Governmental claims and Castano civil actions.*
- Sec. 705. Concurrent jurisdiction; Federal cause of action; actions; damages; liability.*
- Sec. 706. Payment of tobacco claim settlements and judgments.*
- Sec. 707. Attorney's fees and expenses.*
- Sec. 708. Non-participating manufacturers.*
- Sec. 709. Conforming amendments.*

TITLE VIII—TOBACCO INDUSTRY COMPLIANCE AND EMPLOYEE
PROTECTION FROM REPRISALS

- Sec. 801. Tobacco industry compliance accountability requirements.*
- Sec. 802. Tobacco product manufacturer employee protection.*

TITLE IX—PUBLIC DISCLOSURE OF TOBACCO INDUSTRY
DOCUMENTS

- Sec. 901. Findings.*
- Sec. 902. Applicability.*
- Sec. 903. National Tobacco Document Depository.*
- Sec. 904. Privilege and trade secret claims.*
- Sec. 905. Disclosure by the depository.*
- Sec. 906. National Tobacco Documents Review Board.*
- Sec. 907. Resolution of disputed privilege and trade secret claims.*
- Sec. 908. Appeal of board decision.*
- Sec. 909. Miscellaneous.*
- Sec. 910. Penalties.*
- Sec. 911. Definitions.*

TITLE X—LONG-TERM ECONOMIC ASSISTANCE FOR FARMERS

- Sec. 1001. Short title.*
- Sec. 1002. Definitions.*

*Subtitle A—Tobacco Community Revitalization Trust Fund**Sec. 1011. Establishment of trust fund.**Sec. 1012. Contributions by tobacco product manufacturers and importers.**Subtitle B—Tobacco Market Transition Assistance**Sec. 1021. Payments for lost tobacco quota.**Sec. 1022. Industry payments for all department costs associated with tobacco production.**Sec. 1023. Tobacco community economic development grants.**Sec. 1024. Flue-cured tobacco production permits.**“Sec. 317a. Flue-cured tobacco production permits.**Sec. 1025. Modifications in federal tobacco programs.**Subtitle C—Farmer and Worker Transition Assistance**Sec. 1031. Tobacco worker transition program.**Sec. 1032. Farmer opportunity grants.**“Subpart 9—Farmer Opportunity Grants**“Sec. 420d. Statement of purpose.**“Sec. 420e. Program authority; amount and determinations; applications.**“Sec. 420f. Student eligibility.**Subtitle D—Immunity**Sec. 1041. General immunity for tobacco producers and tobacco warehouse owners.**TITLE XI—MISCELLANEOUS**Subtitle A—Prohibitions Relating to Tobacco Products and Children**Sec. 1101. Short title.**Sec. 1102. Prohibitions relating to tobacco products and children.**“Sec. 804. Prohibition on sale or distribution of tobacco products to children.**“Sec. 805. Labeling.**Sec. 1103. Enforcement.**Sec. 1104. Reward.**Sec. 1105. Definitions.**Sec. 1106. Amendments to Public Health Service Act.**“TITLE XXVIII—NATIONAL EFFORTS TO REDUCE YOUTH SMOKING**“Subtitle E—Reducing Youth Smoking and Tobacco-Related Diseases Through Research**“Sec. 2801. Study by the Institute of Medicine.**“Sec. 2802. National tobacco task force.**“Sec. 2803. Research activities of the Centers for Disease Control and Prevention.**“Sec. 2804. Research activities of the National Institutes of Health.**Sec. 1107. Ban on distribution of tobacco products produced by child labor.**Subtitle B—Federal Licensing of Tobacco Product Distribution**Sec. 1121. Licensing of Tobacco Product Distribution.*

Subtitle C—International Provisions

- Sec. 1131. International tobacco control trust fund.*
Sec. 1132. American center on global health and tobacco.
Sec. 1133. Prohibition on use of funds to facilitate the exportation or promotion of tobacco.
Sec. 1134. Harmonization with United States international commitments and obligations.

Subtitle D—Prevention of Tobacco Smuggling

- Sec. 1141. Definitions.*
Sec. 1142. Tobacco product labeling requirements.
Sec. 1143. Requirements for the tracking of tobacco products.
Sec. 1144. Tobacco product permits.
Sec. 1145. Prohibitions.
Sec. 1146. Pricing and labeling of products sold on military installations or by native Americans.
Sec. 1147. Prohibition against sale of tobacco products in or to duty-free shops or forwarding through or manufacture in trade zones.
Sec. 1148. Jurisdiction; penalties; compromise of liability.
Sec. 1149. Amendments to the Contraband Cigarette Trafficking Act.
Sec. 1150. Authorization of appropriations.

Subtitle E—Antitrust Exemption

- Sec. 1161. Limited Antitrust Exemption.*

Subtitle F—Special Provisions Concerning Programs for Women, Minorities, and Others

- Sec. 1171. Research related to patterns of smoking by women and minorities.*
Sec. 1172. Counter-advertising programs.
Sec. 1173. Prevention activities of community and migrant health centers.

Subtitle G—Sense of the Senate

- Sec. 1181. Sense of the Senate.*

Subtitle H—Ban On Sale Of Tobacco Products Through The Use Of Vending Machines

- Sec. 1191. Ban of sale of tobacco products through the use of vending machines.*

TITLE XII—TOBACCO ASBESTOS TRUST FUND

- Sec. 1201. Definitions.*
Sec. 1202. Tobacco Asbestos Trust Fund.
Sec. 1203. Payments from fund I.
Sec. 1204. Payments from fund II.
Sec. 1205. Transfers from National Tobacco Settlement Trust Fund.
Sec. 1206. Rules for claims against asbestos trusts, asbestos defendants, and tobacco companies.

TITLE XIII—VETERANS' BENEFITS

- Sec. 1301. Recovery by secretary of veterans affairs.*

“PART VII—RECOVERY OF COMPENSATION COSTS FOR TOBACCO-RELATED
DISABILITY OR DEATH

“CHAPTER 91—TORT LIABILITY FOR DISABILITY OR DEATH DUE
TO TOBACCO USE

“§ 9101. *Recovery by Secretary of Veterans Affairs*

“§ 9102. *Regulations*

“§ 9103. *Limitation or repeal of other provisions for recovery of compensation*

“§ 9104. *Exemption from annual limitation on damages*

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 epic and worsening*
5 *proportions that results in new generations of to-*
6 *bacco-dependent 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 contrib-*
16 *ute significantly to the use of nicotine-containing to-*
17 *bacco 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-*

1 *sive restrictions on the sale, promotion, and distribu-*
2 *tion of such products are needed.*

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

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

12 *(9) Under Article I, Section 8 of the Constitu-*
13 *tion, the Congress is vested with the responsibility for*
14 *regulating interstate commerce and commerce with*
15 *Indian tribes.*

16 *(10) The sale, distribution, marketing, advertis-*
17 *ing, and use of tobacco products are activities in and*
18 *substantially affecting interstate commerce. Such*
19 *products are sold, marketed, advertised, and distrib-*
20 *uted in interstate commerce on a nationwide basis,*
21 *and have a substantial effect on the Nation's economy.*

22 *(11) The sale, distribution, marketing, advertis-*
23 *ing, and use of such products substantially affect*
24 *interstate commerce through the health care and other*
25 *costs attributable to the use of tobacco products.*

1 (12) *Civil actions against tobacco product manu-*
2 *facturers and others are pending in Federal and State*
3 *courts arising from the use, marketing, and sale of to-*
4 *bacco products. Among these actions are cases brought*
5 *by the attorneys general of more than 40 States, cer-*
6 *tain cities and counties, and the Commonwealth of*
7 *Puerto Rico, and other parties, including Indian*
8 *tribes, and class actions brought by private claimants*
9 *(such as in the Castano Civil Actions), seeking to re-*
10 *cover monies expended to treat tobacco-related dis-*
11 *eases and for the protection of minors and consumers,*
12 *as well as penalties and other relief for violations of*
13 *antitrust, health, consumer protection, and other*
14 *laws.*

15 (13) *Civil actions have been filed throughout the*
16 *United States against tobacco product manufacturers*
17 *and their distributors, trade associations, law firms,*
18 *and consultants on behalf of individuals or classes of*
19 *individuals claiming to be dependent upon and in-*
20 *jured by tobacco products.*

21 (14) *These civil actions are complex, time-con-*
22 *suming, expensive, and burdensome for both the liti-*
23 *gants and Federal and State courts. To date, these*
24 *civil actions have not resulted in sufficient redress for*
25 *smokers or non-governmental third-party payers. To*

1 *the extent that governmental entities have been or*
2 *may in the future be compensated for tobacco-related*
3 *claims they have brought, it is not now possible to*
4 *identify what portions of such past or future recover-*
5 *ies can be attributed to their various antitrust, health,*
6 *consumer protection, or other causes of action.*

7 *(15) It is in the public interest for Congress to*
8 *adopt comprehensive public health legislation because*
9 *of tobacco's unique position in the Nation's history*
10 *and economy; the need to prevent the sale, distribu-*
11 *tion, marketing and advertising of tobacco products to*
12 *persons under the minimum legal age to purchase*
13 *such products; and the need to educate the public, es-*
14 *pecially young people, regarding the health effects of*
15 *using tobacco products.*

16 *(16) The public interest requires a timely, fair,*
17 *equitable, and consistent result that will serve the*
18 *public interest by (A) providing that a portion of the*
19 *costs of treatment for diseases and adverse health ef-*
20 *fects associated with the use of tobacco products is*
21 *borne by the manufacturers of these products, and (B)*
22 *restricting throughout the Nation the sale, distribu-*
23 *tion, marketing, and advertising of tobacco products*
24 *only to persons of legal age to purchase such products.*

1 (17) *Public health authorities estimate that the*
2 *benefits to the Nation of enacting Federal legislation*
3 *to accomplish these goals would be significant in*
4 *human and economic terms.*

5 (18) *Reducing the use of tobacco by minors by*
6 *50 percent would prevent well over 60,000 early*
7 *deaths each year and save up to \$43 billion each year*
8 *in reduced medical costs, improved productivity, and*
9 *the avoidance of premature deaths.*

10 (19) *Advertising, marketing, and promotion of*
11 *tobacco products have been especially directed to at-*
12 *tract young persons to use tobacco products and these*
13 *efforts have resulted in increased use of such products*
14 *by youth. Past efforts to oversee these activities have*
15 *not been successful in adequately preventing such in-*
16 *creased use.*

17 (20) *In 1995, the tobacco industry spent close to*
18 *\$4,900,000,000 to attract new users, retain current*
19 *users, increase current consumption, and generate fa-*
20 *vorable long-term attitudes toward smoking and to-*
21 *bacco use.*

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

1 (22) Tobacco product advertising is regularly
2 seen by persons under the age of 18, and persons
3 under the age of 18 are regularly exposed to tobacco
4 product promotional efforts.

5 (23) Through advertisements during and spon-
6 sorship of sporting events, tobacco has become strongly
7 associated with sports and has become portrayed as
8 an integral part of sports and the healthy lifestyle as-
9 sociated with rigorous sporting activity.

10 (24) Children are exposed to substantial and un-
11 avoidable tobacco advertising that leads to favorable
12 beliefs about tobacco use, plays a role in leading
13 young people to overestimate the prevalence of tobacco
14 use, and increases the number of young people who
15 begin to use tobacco.

16 (25) Tobacco advertising increases the size of the
17 tobacco market by increasing consumption of tobacco
18 products including increasing tobacco use by young
19 people.

20 (26) Children are more influenced by tobacco ad-
21 vertising than adults, they smoke the most advertised
22 brands, and children as young as 3 to 6 years old can
23 recognize a character associated with smoking at the
24 same rate as they recognize cartoons and fast food
25 characters.

1 (27) Tobacco company documents indicate that
2 young people are an important and often crucial seg-
3 ment of the tobacco market.

4 (28) Comprehensive advertising restrictions will
5 have a positive effect on the smoking rates of young
6 people.

7 (29) Restrictions on advertising are necessary to
8 prevent unrestricted tobacco advertising from under-
9 mining legislation prohibiting access to young people
10 and providing for education about tobacco use.

11 (30) International experience shows that adver-
12 tising regulations that are stringent and comprehen-
13 sive have a greater impact on overall tobacco use and
14 young people's use than weaker or less comprehensive
15 ones. Text-only requirements, while not as stringent
16 as a ban, will help reduce underage use of tobacco
17 products while preserving the informational function
18 of advertising.

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

22 (32) If, as a direct or indirect result of this Act,
23 the consumption of tobacco products in the United
24 States is reduced significantly, then tobacco farmers,
25 their families, and their communities may suffer eco-

1 *conomic hardship and displacement, notwithstanding*
2 *their lack of involvement in the manufacturing and*
3 *marketing of tobacco products.*

4 **SEC. 3. PURPOSE.**

5 *The purposes of this Act are—*

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

13 *(2) to require the tobacco industry to fund both*
14 *Federal and State oversight of the tobacco industry*
15 *from on-going payments by tobacco product manufac-*
16 *turers;*

17 *(3) to require tobacco product manufacturers to*
18 *provide ongoing funding to be used for an aggressive*
19 *Federal, State, and local enforcement program and*
20 *for a nationwide retail licensing system to prevent*
21 *minors from obtaining tobacco products, while ex-*
22 *pressly permitting the States to adopt additional*
23 *measures that further restrict or eliminate the prod-*
24 *ucts' use;*

1 (4) *to ensure that the Food and Drug Adminis-*
2 *tration and the States may continue to address issues*
3 *of particular concern to public health officials, espe-*
4 *cially the use of tobacco by young people and depend-*
5 *ence on tobacco;*

6 (5) *to impose severe financial surcharges on to-*
7 *bacco product manufacturers if they do not substan-*
8 *tially reduce tobacco use by young people during the*
9 *next decade;*

10 (6) *to authorize appropriate agencies of the Fed-*
11 *eral government to set national standards controlling*
12 *the manufacture of tobacco products and the identity,*
13 *public disclosure, and amount of ingredients used in*
14 *such products;*

15 (7) *to provide new and flexible enforcement au-*
16 *thority to ensure that the tobacco industry makes ef-*
17 *forts to develop and introduce less harmful tobacco*
18 *products;*

19 (8) *to confirm the Food and Drug Administra-*
20 *tion's authority to regulate the levels of tar, nicotine,*
21 *and other harmful components of tobacco products;*

22 (9) *in order to ensure that adults are better in-*
23 *formed, to require tobacco product manufacturers to*
24 *disclose all research which has not previously been*
25 *made available, as well as research generated in the*

1 *future, relating to the health and dependency effects*
2 *or safety of tobacco products;*

3 *(10) to impose on tobacco product manufacturers*
4 *the obligation to provide funding for a variety of pub-*
5 *lic health initiatives;*

6 *(11) to establish a minimum Federal standard*
7 *for stringent restrictions on smoking in public places,*
8 *with funding to enforce such standard derived from*
9 *payments made by tobacco product manufacturers,*
10 *while also to permit State, Tribal, and local govern-*
11 *ments to enact additional and more stringent stand-*
12 *ards or elect not to be covered by the Federal stand-*
13 *ard;*

14 *(12) to authorize and fund from payments by to-*
15 *bacco product manufacturers a continuing national*
16 *counter-advertising and tobacco control campaign*
17 *which seeks to educate consumers and discourage chil-*
18 *dren and adolescents from beginning to use tobacco*
19 *products, and which encourages current users of to-*
20 *bacco products to discontinue using such products;*

21 *(13) to establish a mechanism to compensate the*
22 *States in settlement of their various claims against*
23 *tobacco product manufacturers;*

24 *(14) to authorize and to fund from payments by*
25 *tobacco product manufacturers a nationwide program*

1 *of smoking cessation administered through State and*
2 *Tribal governments and the private sector;*

3 *(15) to establish and fund from payments by to-*
4 *bacco product manufacturers a National Tobacco Set-*
5 *tlement Fund;*

6 *(16) to affirm the rights of individuals to access*
7 *to the courts, to civil trial by jury, and to damages*
8 *to compensate them for harm caused by tobacco prod-*
9 *ucts;*

10 *(17) to continue to permit the sale of tobacco*
11 *products to adults in conjunction with measures to*
12 *ensure that they are not sold or accessible to underage*
13 *purchasers;*

14 *(18) to impose appropriate regulatory controls*
15 *on the tobacco industry; and*

16 *(19) to protect tobacco farmers and their commu-*
17 *nities from the economic impact of this Act by pro-*
18 *viding full funding for and the continuation of the*
19 *Federal tobacco program and by providing funds for*
20 *farmers and communities to develop new opportuni-*
21 *ties in tobacco-dependent communities.*

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

23 *(a) INTENDED EFFECT.—This Act is not intended to—*

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

4 (2) *express any position of the Congress with re-*
5 *gard to the imposition of punitive damages in general*
6 *or as applied to any specific industry, case, con-*
7 *troversy, or product other than as provided in this*
8 *Act;*

9 (3) *provide any authority regarding the imposi-*
10 *tion of, or the appropriateness of imposing, punitive*
11 *damages; or*

12 (4) *except as provided in this Act, affect any ac-*
13 *tion pending in State, Tribal, or Federal court, or*
14 *any agreement, consent decree, or contract of any*
15 *kind.*

16 (b) *TAXATION.*—*Notwithstanding any other provision*
17 *of law, this Act and the amendments made by this Act shall*
18 *not affect any authority of the Secretary of the Treasury*
19 *(including any authority assigned to the Bureau of Alcohol,*
20 *Tobacco and Firearms) or of State or local governments*
21 *with regard to taxation for tobacco or tobacco products.*

22 (c) *AGRICULTURAL ACTIVITIES.*—*The provisions of*
23 *this Act which authorize the Secretary to take certain ac-*
24 *tions with regard to tobacco and tobacco products shall not*
25 *be construed to affect any authority of the Secretary of Agri-*

1 culture under existing law regarding the growing, cultiva-
2 tion, or curing of raw tobacco.

3 **SEC. 5. NON-PREEMPTION OF MORE RESTRICTIVE LAWS.**

4 (a) *AGE RESTRICTIONS.*—*Nothing in this Act or the*
5 *Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et*
6 *seq.), as amended by this Act, shall prevent a Federal agen-*
7 *cy (including the Armed Forces), a State or its political*
8 *subdivisions, or the government of an Indian tribe from*
9 *adopting and enforcing additional measures that further re-*
10 *strict or prohibit tobacco product sale to, use by, and acces-*
11 *sibility to persons under the legal age of purchase estab-*
12 *lished by such agency, State, subdivision, or government of*
13 *an Indian tribe.*

14 (b) *ADDITIONAL MEASURES.*—*Except as otherwise ex-*
15 *pressly provided in this Act, nothing in this Act, the Fed-*
16 *eral Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.),*
17 *or rules promulgated under such Acts, shall limit the au-*
18 *thority of a Federal agency (including the Armed Forces),*
19 *a State or its political subdivisions, or the government of*
20 *an Indian tribe to enact, adopt, promulgate, and enforce*
21 *any law, rule, regulation, or other measure with respect to*
22 *tobacco products, including laws, rules, regulations, or other*
23 *measures relating to or prohibiting the sale, distribution,*
24 *possession, exposure to, or use of tobacco products by per-*
25 *sons of any age that are in addition to the provisions of*

1 *this Act and the amendments made by this Act. No provi-*
2 *sion of this Act or amendment made by this Act shall limit*
3 *or otherwise affect any State, Tribal, or local taxation of*
4 *tobacco products.*

5 (c) *STATE LAW NOT AFFECTED.—Except as otherwise*
6 *expressly provided in this Act, nothing in this Act, the Fed-*
7 *eral Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.),*
8 *or rules promulgated under such Acts, shall supersede the*
9 *authority of the States, pursuant to State law, to expend*
10 *funds provided by this Act.*

11 **SEC. 6. DEFINITIONS.**

12 *In this Act:*

13 (1) *BRAND.—The term “brand” means a variety*
14 *of tobacco product distinguished by the tobacco used,*
15 *tar content, nicotine content, flavoring used, size, fil-*
16 *tration, or packaging, logo, registered trademark or*
17 *brand name, identifiable pattern of colors, or any*
18 *combination of such attributes.*

19 (2) *CIGARETTE.—The term “cigarette” has the*
20 *meaning given that term by section 3(1) of the Fed-*
21 *eral Cigarette Labeling and Advertising Act (15*
22 *U.S.C. 1332(1)), but also includes tobacco, in any*
23 *form, that is functional in the product, which, because*
24 *of its appearance, the type of tobacco used in the*
25 *filler, or its packaging and labeling, is likely to be of-*

1 ferred to, or purchased by, consumers as a cigarette or
2 as roll-your-own tobacco.

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

8 (4) *COMMERCE.*—The term “commerce” has the
9 meaning given that term by section 3(2) of the Fed-
10 eral Cigarette Labeling and Advertising Act (15
11 U.S.C. 1332(2)).

12 (5) *CONSENT DECREE.*—The term “consent de-
13 cree” means a consent decree among participating to-
14 bacco product manufacturers whose substantive terms
15 are substantially equivalent to the form consent decree
16 published for purposes of this paragraph in the Con-
17 gressional Record.

18 (6) *DISTRIBUTOR.*—The term “distributor” as
19 regards a tobacco product means any person who fur-
20 thers the distribution of cigarette or smokeless tobacco,
21 whether domestic or imported, at any point from the
22 original place of manufacture to the person who sells
23 or distributes the product to individuals for personal
24 consumption. Common carriers are not considered
25 distributors for purposes of this Act.

1 (7) *INDIAN COUNTRY; INDIAN LANDS.*—*The terms*
2 *“Indian country” and “Indian lands” have the mean-*
3 *ing given the term “Indian country” by section 1151*
4 *of title 18, United States Code, and includes lands*
5 *under the jurisdiction of an Indian tribe or tribal or-*
6 *ganization.*

7 (8) *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 (25 U.S.C. 450b(e)).*

11 (9) *LITTLE CIGAR.*—*The term “little cigar” has*
12 *the meaning given that term by section 3(7) of the*
13 *Federal Cigarette Labeling and Advertising Act (15*
14 *U.S.C. 1332(7)).*

15 (10) *TOBACCO PRODUCT MANUFACTURER.*—*Ex-*
16 *cept in title VII, the term “tobacco product manufac-*
17 *turer” means any person, including any repacker or*
18 *relabeler, who manufactures, fabricates, assembles,*
19 *processes, or labels a finished cigarette or smokeless*
20 *tobacco product.*

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

1 (12) *PACKAGE*.—The term “package” means a
2 pack, box, carton, or container of any kind or, if no
3 other container, any wrapping (including cellophane),
4 in which cigarettes or smokeless tobacco are offered for
5 sale, sold, or otherwise distributed to consumers.

6 (13) *POINT-OF-SALE*.—The term “point-of-sale”
7 means any location at which a consumer can pur-
8 chase or otherwise obtain cigarettes or smokeless to-
9 bacco for personal consumption.

10 (14) *RETAILER*.—The term “retailer” means any
11 person who sells cigarettes or smokeless tobacco to in-
12 dividuals for personal consumption, or who operates
13 a facility where self-service displays of tobacco prod-
14 ucts are permitted.

15 (15) *ROLL-YOUR-OWN TOBACCO*.—The term “roll-
16 your-own tobacco” means any tobacco which, because
17 of its appearance, type, packaging, or labeling, is
18 suitable for use and likely to be offered to, or pur-
19 chased by, consumers as tobacco for making cigarettes.

20 (16) *SECRETARY*.—Except in title VII and where
21 the context otherwise requires, the term “Secretary”
22 means the Secretary of Health and Human Services.

23 (17) *SMOKELESS TOBACCO*.—The term “smoke-
24 less tobacco” means any product that consists of cut,
25 ground, powdered, or leaf tobacco that contains nico-

1 *tine and that is intended to be placed in the oral cav-*
2 *ity.*

3 (18) *STATE.*—*The term “State” means any*
4 *State of the United States and, for purposes of this*
5 *Act, includes 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 (19) *TOBACCO PRODUCT.*—*The term “tobacco*
12 *product” means cigarettes, cigarette tobacco, smokeless*
13 *tobacco, little cigars, roll-your-own tobacco, and fine*
14 *cut products.*

15 (20) *UNITED STATES.*—*The term “United*
16 *States” means the 50 States of the United States of*
17 *America and the District of Columbia, the Common-*
18 *wealth of Puerto Rico, Guam, the Virgin Islands,*
19 *American Samoa, Wake Island, Midway Islands,*
20 *Kingman Reef, Johnston Atoll, the Northern Mariana*
21 *Islands, and any other trust territory or possession of*
22 *the United States.*

23 (21) *MASTER SETTLEMENT AGREEMENT.*— *The*
24 *term “Master Settlement Agreement” means the*
25 *agreement either previously entered or to be entered*

1 *into by the States, the participating tobacco product*
 2 *manufacturers, and the Trade Associations imple-*
 3 *menting the June 20, 1997, Proposed Resolution, and*
 4 *published in the Congressional Record for purposes of*
 5 *this Act.*

6 (22) *PARTICIPATING TOBACCO PRODUCT MANU-*
 7 *FACTURER.— The term “participating tobacco prod-*
 8 *uct manufacturer” means—*

9 (A) *a tobacco product manufacturer that,*
 10 *within 45 days after the date of enactment of*
 11 *this Act (or within 45 days after the date on*
 12 *which such manufacturer first manufactures to-*
 13 *bacco products for sale or distribution in the*
 14 *United States, if such date is after the date of*
 15 *enactment of this Act)—*

16 (i) *becomes a signatory to the Master*
 17 *Settlement Agreement; and*

18 (ii) *enters into consent decrees with*
 19 *each State that made a request within the*
 20 *time period described in section 704(b); or*

21 (B) *a surviving entity established by a par-*
 22 *ticipating tobacco product manufacturer.*

23 (23) *NON-PARTICIPATING TOBACCO PRODUCT*
 24 *MANUFACTURER.— The term “non-participating to-*
 25 *bacco product manufacturer” means a tobacco prod-*

1 *uct manufacturer that is not a participating tobacco*
 2 *product manufacturer.*

3 (24) *PROTOCOL.— The term “Protocol” means*
 4 *the agreement to be entered into by the Secretary of*
 5 *Health and Human Services with the participating*
 6 *tobacco product manufacturers under this Act.*

7 **SEC. 7. NOTIFICATION IF YOUTHFUL CIGARETTE SMOKING**
 8 **RESTRICTIONS INCREASE YOUTHFUL PIPE**
 9 **AND CIGAR SMOKING.**

10 *The Secretary shall notify the Congress if the Secretary*
 11 *determines that a decrease in underage use of tobacco prod-*
 12 *ucts resulting from the enactment of this Act has produced*
 13 *an increase in underage use of pipe tobacco and cigars.*

14 **SEC. 8. LIABILITY LIMITATIONS DISAPPEAR IF TOBACCO**
 15 **PRODUCT MANUFACTURER CHALLENGES AD-**
 16 **VERTISING LIMITS.**

17 *If a tobacco product manufacturer, or any party act-*
 18 *ing on behalf of, in collusion with, or at the request of, a*
 19 *tobacco product manufacturer brings an action to have the*
 20 *advertising restrictions imposed on tobacco products under*
 21 *this Act, or the amendments made by this Act, or the appli-*
 22 *cation of those regulations to any person or circumstance*
 23 *held to be unconstitutional or otherwise invalid under the*
 24 *laws of the United States then the provisions of title VII*
 25 *relating to limitations on liability shall not apply to that*

1 *manufacturer, beginning on the date on which the action*
2 *is filed in a court of competent jurisdiction, and continuing*
3 *until such time as the action is withdrawn or dismissed.*

4 **SEC. 9. FTC JURISDICTION NOT AFFECTED.**

5 (a) *IN GENERAL.*—*Except where expressly provided in*
6 *this Act, nothing in this Act shall be construed as limiting*
7 *or diminishing the authority of the Federal Trade Commis-*
8 *sion to enforce the laws under its jurisdiction with respect*
9 *to the advertising, sale, or distribution of tobacco products.*

10 (b) *ENFORCEMENT BY FTC.*—*Any advertising that*
11 *violates this Act, part 897 of title 21, Code of Federal Regu-*
12 *lations, or the Protocol is an unfair or deceptive act or*
13 *practice under section 5(a) of the Federal Trade Commis-*
14 *sion Act (15 U.S.C. 45(a)) and shall be considered a viola-*
15 *tion of a rule promulgated under section 18 of that Act (15*
16 *U.S.C. 57a).*

17 **SEC. 10. CONGRESSIONAL REVIEW PROVISIONS.**

18 *In accordance with section 801 of title 5, United States*
19 *Code, the Congress shall review, and may disapprove, any*
20 *rule under this Act that is subject to section 801. This sec-*
21 *tion does not apply to the rule set forth in part 897 of title*
22 *21, Code of Federal Regulations.*

**TITLE I—REGULATION OF THE
TOBACCO INDUSTRY**

**Subtitle A—Jurisdiction, etc., of
Food and Drug Administration**

**SEC. 101. AMENDMENT OF FEDERAL FOOD, DRUG, AND COS-
METIC ACT OF 1938.**

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

“(kk) The term ‘tobacco product’ means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).”.

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

(1) by redesignating chapter IX as chapter X;

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

(3) by inserting after section 803 the following:

1 **“CHAPTER IX—TOBACCO PRODUCTS**

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

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

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

10 “(2) a health claim is made for such products
11 under section 201(g)(1)(C) or 201(h)(3).

12 “(b) *APPLICABILITY.*—This chapter shall apply to all
13 tobacco products subject to the provisions of part 897 of title
14 21, Code of Federal Regulations, and to any other tobacco
15 products that the Secretary by regulation deems to be sub-
16 ject to this chapter.

17 “(c) *FDA RULE IN EFFECT.*—The provisions of part
18 897 of title 21, Code of Federal Regulations, shall be deemed
19 to be lawful and to have been lawfully promulgated under
20 the authority of this chapter. The provisions of such part
21 that are not in effect on the date of enactment of this chap-
22 ter shall take effect as in such part or upon such later date
23 as determined by the Secretary by order.

24 “(d) *SCOPE.*—

1 “(1) Nothing in this chapter shall be construed
2 to affect the regulation of drugs and devices under
3 chapter V that are not tobacco products by the Sec-
4 retary under the Federal Food, Drug and Cosmetic
5 Act.

6 “(2) The provisions of this chapter shall not
7 apply to tobacco leaf that is not in the possession of
8 the manufacturer, or to the producers of tobacco leaf,
9 including tobacco growers, tobacco warehouses, and
10 tobacco grower cooperatives, nor shall any employee of
11 the Food and Drug Administration have any author-
12 ity whatsoever to enter onto a farm owned by a pro-
13 ducer of tobacco leaf without the written consent of
14 such producer. Notwithstanding any other provision
15 of this subparagraph, if a producer of tobacco leaf is
16 also a tobacco product manufacturer or controlled by
17 a tobacco product manufacturer, the producer shall be
18 subject to this chapter in the producer’s capacity as
19 a manufacturer. Nothing in this chapter shall be con-
20 strued to grant the Secretary authority to promulgate
21 regulations on any matter that involves the produc-
22 tion of tobacco leaf or a producer thereof, other than
23 activities by a manufacturer affecting production. For
24 purposes of the preceding sentence, the term ‘con-
25 trolled by’ means a member of the same controlled

1 *group of corporations as that term is used in section*
2 *52(a) of the Internal Revenue Code of 1986, or under*
3 *common control within the meaning of the regulations*
4 *promulgated under section 52(b) of such Code.*

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

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

8 *“(1) it consists in whole or in part of any filthy,*
9 *putrid, or decomposed substance, or is otherwise con-*
10 *taminated by any poisonous or deleterious substance*
11 *that may render the product injurious to health;*

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

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

19 *“(4) it is, or purports to be or is represented as,*
20 *a tobacco product which is subject to a performance*
21 *standard established under section 907 unless such to-*
22 *bacco product is in all respects in conformity with*
23 *such standard;*

1 “(5) it is required by section 910(a) to have pre-
2 market approval, is not exempt under section 906(f),
3 and does not have an approved application in effect;

4 “(6) the methods used in, or the facilities or con-
5 trols used for, its manufacture, packing or storage are
6 not in conformity with applicable requirements under
7 section 906(e)(1) or an applicable condition pre-
8 scribed by an order under section 906(e)(2); or

9 “(7) it is a tobacco product for which an exemp-
10 tion has been granted under section 906(f) for inves-
11 tigational use and the person who was granted such
12 exemption or any investigator who uses such tobacco
13 product under such exemption fails to comply with a
14 requirement prescribed by or under such section.

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

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

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

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

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

1 “(B) an accurate statement of the quantity
2 of the contents in terms of weight, measure, or
3 numerical count,
4 except that under subparagraph (B) of this para-
5 graph reasonable variations shall be permitted, and
6 exemptions as to small packages shall be established,
7 by regulations prescribed by the Secretary;

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

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

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

1 “(6) if it was manufactured, prepared, propa-
2 gated, compounded, or processed in any State in an
3 establishment not duly registered under section
4 905(b), if it was not included in a list required by
5 section 905(i), if a notice or other information re-
6 specting it was not provided as required by such sec-
7 tion or section 905(j), or if it does not bear such sym-
8 bols from the uniform system for identification of to-
9 bacco products prescribed under section 905(e) as the
10 Secretary by regulation requires;

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

13 “(A) its advertising is false or misleading
14 in any particular; or

15 “(B) it is sold, distributed, or used in viola-
16 tion of regulations prescribed under section
17 906(d);

18 “(8) unless, in the case of any tobacco product
19 distributed or offered for sale in any State, the manu-
20 facturer, packer, or distributor thereof includes in all
21 advertisements and other descriptive printed matter
22 issued or caused to be issued by the manufacturer,
23 packer, or distributor with respect to that tobacco
24 product—

1 “(A) a true statement of the tobacco prod-
2 uct’s established name as defined in paragraph
3 (4) of this subsection, printed prominently; and

4 “(B) a brief statement of—

5 “(i) the uses of the tobacco product and
6 relevant warnings, precautions, side effects,
7 and contraindications; and

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

19 “(9) if it is a tobacco product subject to a per-
20 formance standard established under section 907, un-
21 less it bears such labeling as may be prescribed in
22 such performance standard; or

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

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

1 “(B) to furnish any material or informa-
2 tion required by or under section 909; or

3 “(C) to comply with a requirement under
4 section 912.

5 “(b) *PRIOR APPROVAL OF STATEMENTS ON LABEL.*—
6 *The Secretary may, by regulation, require prior approval*
7 *of statements made on the label of a tobacco product. No*
8 *regulation issued under this subsection may require prior*
9 *approval by the Secretary of the content of any advertise-*
10 *ment and no advertisement of a tobacco product, published*
11 *after the date of enactment of the National Tobacco Policy*
12 *and Youth Smoking Reduction Act shall, with respect to*
13 *the matters specified in this section or covered by regula-*
14 *tions issued hereunder, be subject to the provisions of sec-*
15 *tions 12 through 15 of the Federal Trade Commission Act*
16 *(15 U.S.C. 52 through 55). This subsection does not apply*
17 *to any printed matter which the Secretary determines to*
18 *be labeling as defined in section 201(m).*

19 **“SEC. 904. SUBMISSION OF HEALTH INFORMATION TO THE**
20 **SECRETARY.**

21 “(a) *REQUIREMENT.*—*Not later than 6 months after*
22 *the date of enactment of the National Tobacco Policy and*
23 *Youth Smoking Reduction Act, each tobacco product manu-*
24 *facturer or importer of tobacco products, or agents thereof,*
25 *shall submit to the Secretary the following information:*

1 “(1) *A listing of all tobacco ingredients, sub-*
2 *stances and compounds that are, on such date, added*
3 *by the manufacturer to the tobacco, paper, filter, or*
4 *other component of each tobacco product by brand*
5 *and by quantity in each brand and subbrand.*

6 “(2) *A description of the content, delivery, and*
7 *form of nicotine in each tobacco product measured in*
8 *milligrams of nicotine.*

9 “(3) *All documents (including underlying sci-*
10 *entific information) relating to research activities,*
11 *and research findings, conducted, supported, or pos-*
12 *sessed by the manufacturer (or agents thereof) on the*
13 *health, behavioral, or physiologic effects of tobacco*
14 *products, their constituents, ingredients, and compo-*
15 *nents, and tobacco additives, described in paragraph*
16 *(1).*

17 “(4) *All documents (including underlying sci-*
18 *entific information) relating to research activities,*
19 *and research findings, conducted, supported, or pos-*
20 *essed by the manufacturer that relate to the issue of*
21 *whether a reduction in risk to health from tobacco*
22 *products can occur upon the employment of tech-*
23 *nology available or known to the manufacturer.*

1 “(5) *All documents (including underlying sci-*
2 *entific information) relating to marketing research*
3 *involving the use of tobacco products.*

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

7 “(b) *ANNUAL SUBMISSION.—A tobacco product manu-*
8 *facturer or importer that is required to submit information*
9 *under subsection (a) shall update such information on an*
10 *annual basis under a schedule determined by the Secretary.*

11 “(c) *TIME FOR SUBMISSION.—*

12 “(1) *NEW PRODUCTS.—At least 90 days prior to*
13 *the delivery for introduction into interstate commerce*
14 *of a tobacco product not on the market on the date*
15 *of enactment of this chapter, the manufacturer of such*
16 *product shall provide the information required under*
17 *subsection (a) and such product shall be subject to the*
18 *annual submission under subsection (b).*

19 “(2) *MODIFICATION OF EXISTING PRODUCTS.—If*
20 *at any time a tobacco product manufacturer adds to*
21 *its tobacco products a new tobacco additive, increases*
22 *or decreases the quantity of an existing tobacco addi-*
23 *tive or the nicotine content, delivery, or form, or*
24 *eliminates a tobacco additive from any tobacco prod-*
25 *uct, the manufacturer shall within 60 days of such*

1 *action so advise the Secretary in writing and ref-*
2 *erence such modification in submissions made under*
3 *subsection (b).*

4 **“SEC. 905. ANNUAL REGISTRATION.**

5 *“(a) DEFINITIONS.—As used in this section—*

6 *“(1) the term ‘manufacture, preparation,*
7 *compounding, or processing’ shall include repackag-*
8 *ing or otherwise changing the container, wrapper, or*
9 *labeling of any tobacco product package in further-*
10 *ance of the distribution of the tobacco product from*
11 *the original place of manufacture to the person who*
12 *makes final delivery or sale to the ultimate consumer*
13 *or user; and*

14 *“(2) the term ‘name’ shall include in the case of*
15 *a partnership the name of each partner and, in the*
16 *case of a corporation, the name of each corporate offi-*
17 *cer and director, and the State of incorporation.*

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

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

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

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

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

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

12 “(h) *FOREIGN ESTABLISHMENTS MAY REGISTER.*—
13 *Any establishment within any foreign country engaged in*
14 *the manufacture, preparation, compounding, or processing*
15 *of a tobacco product or tobacco products, may register under*
16 *this section under regulations promulgated by the Sec-*
17 *retary. Such regulations shall require such establishment to*
18 *provide the information required by subsection (i) of this*
19 *section and shall include provisions for registration of any*
20 *such establishment upon condition that adequate and effec-*
21 *tive means are available, by arrangement with the govern-*
22 *ment of such foreign country or otherwise, to enable the Sec-*
23 *retary to determine from time to time whether tobacco prod-*
24 *ucts manufactured, prepared, compounded, or processed in*
25 *such establishment, if imported or offered for import into*

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

3 *“(i) REGISTRATION INFORMATION.—*

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

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

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

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

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

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

21 *“(A) A list of each tobacco product intro-*
22 *duced by the registrant for commercial distribu-*
23 *tion which has not been included in any list pre-*
24 *viously filed by that person with the Secretary*
25 *under this subparagraph or paragraph (1) of*

1 *this subsection. A list under this subparagraph*
2 *shall list a tobacco product by its established*
3 *name and shall be accompanied by the other in-*
4 *formation required by paragraph (1).*

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

14 *“(C) If since the date the registrant reported*
15 *under subparagraph (B) a notice of discontinu-*
16 *ance that person has resumed the manufacture,*
17 *preparation, compounding, or processing for*
18 *commercial distribution of the tobacco product*
19 *with respect to which such notice of discontinu-*
20 *ance was reported, notice of such resumption, the*
21 *date of such resumption, the identity of such to-*
22 *bacco product by established name, and other in-*
23 *formation required by paragraph (1), unless the*
24 *registrant has previously reported such resump-*
25 *tion to the Secretary under this subparagraph.*

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

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

7 “(1) *IN GENERAL.—Each person who is required*
8 *to register under this section and who proposes to*
9 *begin the introduction or delivery for introduction*
10 *into interstate commerce for commercial distribution*
11 *of a tobacco product intended for human use that was*
12 *not commercially marketed (other than for test mar-*
13 *keting) in the United States as of August 11, 1995,*
14 *as defined by the Secretary by regulation shall, at*
15 *least 90 days before making such introduction or de-*
16 *livery, report to the Secretary (in such form and*
17 *manner as the Secretary shall by regulation pre-*
18 *scribe)—*

19 “(A) *the basis for such person’s determina-*
20 *tion that the tobacco product is substantially*
21 *equivalent, within the meaning of section 910, to*
22 *a tobacco product commercially marketed (other*
23 *than for test marketing) in the United States as*
24 *of August 11, 1995, that is in compliance with*
25 *the requirements of this Act; and*

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

4 “(2) APPLICATION TO CERTAIN POST-AUGUST
5 11TH PRODUCTS.—A report under this subsection for
6 a tobacco product that was first introduced or deliv-
7 ered for introduction into interstate commerce for
8 commercial distribution in the United States after
9 August 11, 1995, and before the date of enactment of
10 the National Tobacco Policy and Youth Smoking Re-
11 duction Act shall be submitted to the Secretary within
12 6 months after the date of enactment of that Act.

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

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

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

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

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

19 “(c) *LIMITED CONFIDENTIALITY OF INFORMATION.—*
20 *Any information reported to or otherwise obtained by the*
21 *Secretary or the Secretary’s representative under section*
22 *904, 907, 908, 909, or 910 or 704, or under subsection (e)*
23 *or (f) of this section, which is exempt from disclosure under*
24 *subsection (a) of section 552 of title 5, United States Code,*
25 *by reason of subsection (b)(4) of that section shall be consid-*

1 *ered confidential and shall not be disclosed, except that the*
2 *information may be disclosed to other officers or employees*
3 *concerned with carrying out this chapter, or when relevant*
4 *in any proceeding under this chapter.*

5 “(d) *RESTRICTIONS.*—

6 “(1) *The Secretary may by regulation require*
7 *that a tobacco product be restricted to sale, distribu-*
8 *tion, or use upon such conditions, including restric-*
9 *tions on the access to, and the advertising and pro-*
10 *motion of, the tobacco product, as the Secretary may*
11 *prescribe in such regulation if, because of its poten-*
12 *tiality for harmful effect or the collateral measures*
13 *necessary to its use, the Secretary determines that*
14 *such regulation would be appropriate for the protec-*
15 *tion of the public health. The finding as to whether*
16 *such regulation would be appropriate for the protec-*
17 *tion of the public health shall be determined with re-*
18 *spect to the risks and benefits to the population as a*
19 *whole, including users and non-users of the tobacco*
20 *product, and taking into account—*

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

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

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

8 “(2) The label of a tobacco product shall bear
9 such appropriate statements of the restrictions re-
10 quired by a regulation under subsection (a) as the
11 Secretary may in such regulation prescribe.

12 “(3) Because of the importance of any decision
13 by the Secretary to restrict the sale of any class of to-
14 bacco products on the market on the date of enact-
15 ment of the National Tobacco Policy and Youth
16 Smoking Reduction Act to specified categories of re-
17 tail outlets, it is appropriate for the Congress to have
18 the opportunity to review such a decision. Therefore,
19 any such restriction may not take effect before the
20 date that is 2 years after the President notifies the
21 Congress that a final regulation imposing the restric-
22 tion has been issued.

23 “(e) GOOD MANUFACTURING PRACTICE REQUIRE-
24 MENTS.—

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

3 “(A) *The Secretary may, in accordance*
4 *with subparagraph (B), prescribe regulations re-*
5 *quiring that the methods used in, and the facili-*
6 *ties and controls used for, the manufacture, pre-*
7 *production design validation (including a proc-*
8 *ess to assess the performance of a tobacco prod-*
9 *uct), packing and storage of a tobacco product,*
10 *conform to current good manufacturing practice,*
11 *as prescribed in such regulations, to assure that*
12 *the public health is protected and that the to-*
13 *bacco product is in compliance with this chapter.*

14 “(B) *The Secretary shall—*

15 “(i) *before promulgating any regula-*
16 *tion under subparagraph (A), afford the To-*
17 *bacco Products Scientific Advisory Commit-*
18 *tee established under section 915 an oppor-*
19 *tunity to submit recommendations with re-*
20 *spect to the regulation proposed to be pro-*
21 *mulgated;*

22 “(ii) *before promulgating any regula-*
23 *tion under subparagraph (A), afford oppor-*
24 *tunity for an oral hearing;*

1 “(iii) provide the advisory committee a
2 reasonable time to make its recommendation
3 with respect to proposed regulations under
4 subparagraph (A); and

5 “(iv) in establishing the effective date
6 of a regulation promulgated under this sub-
7 section, take into account the differences in
8 the manner in which the different types of
9 tobacco products have historically been pro-
10 duced, the financial resources of the dif-
11 ferent tobacco product manufacturers, and
12 the state of their existing manufacturing fa-
13 cilities; and shall provide for a reasonable
14 period of time for such manufacturers to
15 conform to good manufacturing practices.

16 “(2) *EXEMPTIONS; VARIANCES.*—

17 “(A) Any person subject to any requirement
18 prescribed under paragraph (1) may petition the
19 Secretary for a permanent or temporary exemp-
20 tion or variance from such requirement. Such a
21 petition shall be submitted to the Secretary in
22 such form and manner as the Secretary shall
23 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 *cilities 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) *The Secretary may refer to the To-*
16 *bacco Products Scientific Advisory Committee es-*
17 *tablished under section 915 any petition submit-*
18 *ted under subparagraph (A). The advisory com-*
19 *mittee shall report its recommendations to the*
20 *Secretary with respect to a petition referred to it*
21 *within 60 days after the date of the petition's re-*
22 *ferral. Within 60 days after—*

23 “(i) *the date the petition was submit-*
24 *ted to the Secretary under subparagraph*
25 *(A); or*

1 “(ii) the day after the petition was re-
2 ferred to an advisory committee,
3 whichever occurs later, the Secretary shall by
4 order either deny the petition or approve it.

5 “(C) The Secretary may approve—

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

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

22 “(D) An order of the Secretary approving a
23 petition for a variance shall prescribe such con-
24 ditions respecting the methods used in, and the
25 facilities and controls used for, the manufacture,

1 *packing, and storage of the tobacco product to be*
2 *granted the variance under the petition as may*
3 *be necessary to assure that the tobacco product*
4 *will be in compliance with this chapter.*

5 “(E) *After the issuance of an order under*
6 *subparagraph (B) respecting a petition, the peti-*
7 *tioner shall have an opportunity for an informal*
8 *hearing on such order.*

9 “(3) *Compliance with requirements under this*
10 *subsection shall not be required before the period end-*
11 *ing 3 years after the date of enactment of the Na-*
12 *tional Tobacco Policy and Youth Smoking Reduction*
13 *Act.*

14 “(f) *EXEMPTION FOR INVESTIGATIONAL USE.—The*
15 *Secretary may exempt tobacco products intended for inves-*
16 *tigational use from this chapter under such conditions as*
17 *the Secretary may prescribe by regulation .*

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

1 **“SEC. 907. PERFORMANCE STANDARDS.**

2 “(a) *IN GENERAL.*—

3 “(1) *FINDING REQUIRED.*—*The Secretary may*
4 *adopt performance standards for a tobacco product if*
5 *the Secretary finds that a performance standard is*
6 *appropriate for the protection of the public health.*
7 *This finding shall be determined with respect to the*
8 *risks and benefits to the population as a whole, in-*
9 *cluding users and non-users of the tobacco product,*
10 *and taking into account—*

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

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

17 “(2) *CONTENT OF PERFORMANCE STANDARDS.*—
18 *A performance standard established under this section*
19 *for a tobacco product—*

20 “(A) *shall include provisions to provide per-*
21 *formance that is appropriate for the protection*
22 *of the public health, including provisions, where*
23 *appropriate—*

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

1 “(ii) for the reduction or elimination
2 of other constituents or harmful components
3 of the product; or

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

6 “(B) shall, where necessary to be appro-
7 priate for the protection of the public health, in-
8 clude—

9 “(i) provisions respecting the construc-
10 tion, components, ingredients, and prop-
11 erties of the tobacco product;

12 “(ii) provisions for the testing (on a
13 sample basis or, if necessary, on an individ-
14 ual basis) of the tobacco product;

15 “(iii) provisions for the measurement
16 of the performance characteristics of the to-
17 bacco product;

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

1 “(v) a provision requiring that the sale
2 and distribution of the tobacco product be
3 restricted but only to the extent that the sale
4 and distribution of a tobacco product may
5 be restricted under a regulation under sec-
6 tion 906(d); and

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

10 “(3) PERIODIC RE-EVALUATION OF PERFORM-
11 ANCE STANDARDS.—The Secretary shall provide for
12 periodic evaluation of performance standards estab-
13 lished under this section to determine whether such
14 standards should be changed to reflect new medical,
15 scientific, or other technological data. The Secretary
16 may provide for testing under paragraph (2) by any
17 person.

18 “(4) INVOLVEMENT OF OTHER AGENCIES; IN-
19 FORMED PERSONS.—In carrying out duties under this
20 section, the Secretary shall, to the maximum extent
21 practicable—

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

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

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

11 “(b) *ESTABLISHMENT OF STANDARDS.*—

12 “(1) *NOTICE.*—

13 “(A) The Secretary shall publish in the Fed-
14 eral Register a notice of proposed rulemaking for
15 the establishment, amendment, or revocation of
16 any performance standard for a tobacco product.

17 “(B) A notice of proposed rulemaking for
18 the establishment or amendment of a perform-
19 ance standard for a tobacco product shall—

20 “(i) set forth a finding with supporting
21 justification that the performance standard
22 is appropriate for the protection of the pub-
23 lic health;

24 “(ii) set forth proposed findings with
25 respect to the risk of illness or injury that

1 *the performance standard is intended to re-*
2 *duce or eliminate; and*

3 “(iii) invite interested persons to sub-
4 mit an existing performance standard for
5 the tobacco product, including a draft or
6 proposed performance standard, for consid-
7 eration by the Secretary.

8 “(C) A notice of proposed rulemaking for
9 the revocation of a performance standard shall
10 set forth a finding with supporting justification
11 that the performance standard is no longer nec-
12 essary to be appropriate for the protection of the
13 public health.

14 “(D) The Secretary shall consider all infor-
15 mation submitted in connection with a proposed
16 standard, including information concerning the
17 countervailing effects of the performance stand-
18 ard on the health of adolescent tobacco users,
19 adult tobacco users, or non-tobacco users, such as
20 the creation of a significant demand for contra-
21 band or other tobacco products that do not meet
22 the requirements of this chapter and the signifi-
23 cance of such demand, and shall issue the stand-
24 ard if the Secretary determines that the standard

1 *would be appropriate for the protection of the*
2 *public health.*

3 “(E) *The Secretary shall provide for a com-*
4 *ment period of not less than 60 days.*

5 “(2) *PROMULGATION.—*

6 “(A) *After the expiration of the period for*
7 *comment on a notice of proposed rulemaking*
8 *published under paragraph (1) respecting a per-*
9 *formance standard and after consideration of*
10 *such comments and any report from the Tobacco*
11 *Products Scientific Advisory Committee under*
12 *section 915, the Secretary shall—*

13 “(i) *promulgate a regulation establish-*
14 *ing a performance standard and publish in*
15 *the Federal Register findings on the matters*
16 *referred to in paragraph (1); or*

17 “(ii) *publish a notice terminating the*
18 *proceeding for the development of the stand-*
19 *ard together with the reasons for such ter-*
20 *mination.*

21 “(B) *A regulation establishing a perform-*
22 *ance standard shall set forth the date or dates*
23 *upon which the standard shall take effect, but no*
24 *such regulation may take effect before one year*
25 *after the date of its publication unless the Sec-*

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

7 “(3) *SPECIAL RULE FOR STANDARD BANNING*
 8 *CLASS OF PRODUCT OR ELIMINATING NICOTINE CON-*
 9 *TENT.—Because of the importance of a decision of the*
 10 *Secretary to issue a regulation establishing a per-*
 11 *formance standard—*

12 “(A) *eliminating all cigarettes, all smokeless*
 13 *tobacco products, or any similar class of tobacco*
 14 *products, or*

15 “(B) *requiring the reduction of nicotine*
 16 *yields of a tobacco product to zero,*
 17 *it is appropriate for the Congress to have the oppor-*
 18 *tunity to review such a decision. Therefore, any such*
 19 *standard may not take effect before a date that is 2*
 20 *years after the President notifies the Congress that a*
 21 *final regulation imposing the restriction has been*
 22 *issued.*

23 “(4) *AMENDMENT; REVOCATION.—*

24 “(A) *The Secretary, upon the Secretary’s*
 25 *own initiative or upon petition of an interested*

1 *person may by a regulation, promulgated in ac-*
2 *cordance with the requirements of paragraphs*
3 *(1) and (2)(B) of this subsection, amend or re-*
4 *voke a performance standard.*

5 *“(B) The Secretary may declare a proposed*
6 *amendment of a performance standard to be ef-*
7 *fective on and after its publication in the Fed-*
8 *eral Register and until the effective date of any*
9 *final action taken on such amendment if the Sec-*
10 *retary determines that making it so effective is*
11 *in the public interest.*

12 *“(5) REFERENCE TO ADVISORY COMMITTEE.—*
13 *The Secretary—*

14 *“(A) may, on the Secretary’s own initiative,*
15 *refer a proposed regulation for the establishment,*
16 *amendment, or revocation of a performance*
17 *standard; or*

18 *“(B) shall, upon the request of an interested*
19 *person which demonstrates good cause for refer-*
20 *ral and which is made before the expiration of*
21 *the period for submission of comments on such*
22 *proposed regulation,*
23 *refer such proposed regulation to the Tobacco Prod-*
24 *ucts Scientific Advisory Committee established under*
25 *section 915, for a report and recommendation with*

1 *respect to any matter involved in the proposed regula-*
2 *tion which requires the exercise of scientific judgment.*
3 *If a proposed regulation is referred under this sub-*
4 *paragraph to the advisory committee, the Secretary*
5 *shall provide the advisory committee with the data*
6 *and information on which such proposed regulation is*
7 *based. The advisory committee shall, within 60 days*
8 *after the referral of a proposed regulation and after*
9 *independent study of the data and information fur-*
10 *nished to it by the Secretary and other data and in-*
11 *formation before it, submit to the Secretary a report*
12 *and recommendation respecting such regulation, to-*
13 *gether with all underlying data and information and*
14 *a statement of the reason or basis for the rec-*
15 *ommendation. A copy of such report and rec-*
16 *ommendation shall be made public by the Secretary.*

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

18 “(a) *NOTIFICATION.—If the Secretary determines*
19 *that—*

20 “(1) *a tobacco product which is introduced or de-*
21 *livered for introduction into interstate commerce for*
22 *commercial distribution presents an unreasonable risk*
23 *of substantial harm to the public health; and*

24 “(2) *notification under this subsection is nec-*
25 *essary to eliminate the unreasonable risk of such*

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

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

21 “(c) *RECALL AUTHORITY.*—

22 “(1) *IN GENERAL.*—*If the Secretary finds that*
23 *there is a reasonable probability that a tobacco prod-*
24 *uct contains a manufacturing or other defect not ordi-*
25 *narily contained in tobacco products on the market*

1 that would cause serious, adverse health consequences
2 or death, the Secretary shall issue an order requiring
3 the appropriate person (including the manufacturers,
4 importers, distributors, or retailers of the tobacco
5 product) to immediately cease distribution of such to-
6 bacco product. The order shall provide the person sub-
7 ject to the order with an opportunity for an informal
8 hearing, to be held not later than 10 days after the
9 date of the issuance of the order, on the actions re-
10 quired by the order and on whether the order should
11 be amended to require a recall of such tobacco prod-
12 uct. If, after providing an opportunity for such a
13 hearing, the Secretary determines that inadequate
14 grounds exist to support the actions required by the
15 order, the Secretary shall vacate the order.

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

18 “(A) If, after providing an opportunity for
19 an informal hearing under paragraph (1), the
20 Secretary determines that the order should be
21 amended to include a recall of the tobacco prod-
22 uct with respect to which the order was issued,
23 the Secretary shall, except as provided in sub-
24 paragraph (B), amend the order to require a re-
25 call. The Secretary shall specify a timetable in

1 *which the tobacco product recall will occur and*
 2 *shall require periodic reports to the Secretary de-*
 3 *scribing the progress of the recall.*

4 “(B) *An amended order under subpara-*
 5 *graph (A)—*

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

8 “(ii) *shall provide for notice to persons*
 9 *subject to the risks associated with the use*
 10 *of such tobacco product.*

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

17 “(3) *REMEDY NOT EXCLUSIVE.—The remedy pro-*
 18 *vided by this subsection shall be in addition to rem-*
 19 *edies provided by subsection (a) of this section.*

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

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

1 *by regulation reasonably require to assure that such tobacco*
2 *product is not adulterated or misbranded and to otherwise*
3 *protect public health. Regulations prescribed under the pre-*
4 *ceding sentence—*

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

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

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

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

1 *sion of a report or information to the Secretary state*
2 *the reason or purpose for such request and identify to*
3 *the fullest extent practicable such report or informa-*
4 *tion;*

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

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

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

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

(1) *Except as provided in paragraph (3), the Secretary shall by regulation require a tobacco product manufacturer or importer of a tobacco product to report promptly to the Secretary any corrective action taken or removal from the market of a tobacco product undertaken by such manufacturer or importer if the removal or correction was undertaken—*

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

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

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

“(2) No report of the corrective action or removal of a tobacco product may be required under paragraph (1) if a report of the corrective action or removal is required and has been submitted under subsection (a) of this section.

“SEC. 910. PREMARKET REVIEW OF CERTAIN TOBACCO PRODUCTS.

“(a) IN GENERAL.—

1 “(1) *PREMARKET APPROVAL REQUIRED.*—

2 “(A) *NEW PRODUCTS.*—Approval under this
3 *section of an application for premarket approval*
4 *for any tobacco product that is not commercially*
5 *marketed (other than for test marketing) in the*
6 *United States as of August 11, 1995, is required*
7 *unless the manufacturer has submitted a report*
8 *under section 905(j), and the Secretary has*
9 *issued an order that the tobacco product is sub-*
10 *stantially equivalent to a tobacco product com-*
11 *mercially marketed (other than for test market-*
12 *ing) in the United States as of August 11, 1995,*
13 *that is in compliance with the requirements of*
14 *this Act.*

15 “(B) *PRODUCTS INTRODUCED BETWEEN AU-*
16 *GUST 11, 1995, AND ENACTMENT OF THIS CHAP-*
17 *TER.*—Subparagraph (A) does not apply to a to-
18 *bacco product that—*

19 “(i) *was first introduced or delivered*
20 *for introduction into interstate commerce*
21 *for commerce for commercial distribution in*
22 *the United States after August 11, 1995,*
23 *and before the date of enactment of the Na-*
24 *tional Tobacco Policy and Youth Smoking*
25 *Reduction Act; and*

1 “(ii) for which a report was submitted
2 under section 905(j) within 6 months after
3 such date,
4 until the Secretary issues an order that the to-
5 bacco product is substantially equivalent for pur-
6 poses of this section or requires premarket ap-
7 proval.

8 “(2) SUBSTANTIALLY EQUIVALENT DEFINED.—

9 “(A) For purposes of this section and sec-
10 tion 905(j), the term ‘substantially equivalent’ or
11 ‘substantial equivalence’ mean, 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) For purposes of subparagraph (A), the
2 term ‘characteristics’ means the materials, ingre-
3 dients, design, composition, heating source, or
4 other features of a tobacco product.

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

11 “(3) HEALTH INFORMATION.—

12 “(A) As part of a submission under section
13 905(j) respecting a tobacco product, the person
14 required to file a premarket notification under
15 such section shall provide an adequate summary
16 of any health information related to the tobacco
17 product or state that such information will be
18 made available upon request by any person.

19 “(B) Any summary under subparagraph
20 (A) respecting a tobacco product shall contain
21 detailed information regarding data concerning
22 adverse health effects and shall be made available
23 to the public by the Secretary within 30 days of
24 the issuance of a determination that such tobacco

1 *product is substantially equivalent to another to-*
2 *bacco product.*

3 “(b) *APPLICATION.*—

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

6 “(A) *full reports of all information, pub-*
7 *lished or known to or which should reasonably be*
8 *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, and properties, and of the principle or*
15 *principles of operation, of such tobacco product;*

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

21 “(D) *an identifying reference to any per-*
22 *formance standard under section 907 which*
23 *would be applicable to any aspect of such tobacco*
24 *product, and either adequate information to*
25 *show that such aspect of such tobacco product*

1 *fully meets such performance standard or ade-*
2 *quate information to justify any deviation from*
3 *such standard;*

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

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

9 *“(G) such other information relevant to the*
10 *subject matter of the application as the Secretary*
11 *may require.*

12 *“(2) REFERENCE TO ADVISORY COMMITTEE.—*
13 *Upon receipt of an application meeting the require-*
14 *ments set forth in paragraph (1), the Secretary—*

15 *“(A) may, on the Secretary’s own initiative;*
16 *or*

17 *“(B) shall, upon the request of an appli-*
18 *cant,*

19 *refer such application to the Tobacco Products Sci-*
20 *entific Advisory Committee established under section*
21 *915 and for submission (within such period as the*
22 *Secretary may establish) of a report and rec-*
23 *ommendation respecting approval of the application,*
24 *together with all underlying data and the reasons or*
25 *basis for the recommendation.*

1 “(c) *ACTION ON APPLICATION.*—

2 “(1) *DEADLINE.*—

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

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

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

20 “(B) *An order approving an application for*
21 *a tobacco product may require as a condition to*
22 *such approval that the sale and distribution of*
23 *the tobacco product be restricted but only to the*
24 *extent that the sale and distribution of a tobacco*

1 *product may be restricted under a regulation*
2 *under section 906(d).*

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

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

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

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

20 “(D) *such tobacco product is not shown to*
21 *conform in all respects to a performance stand-*
22 *ard in effect under section 907, compliance with*
23 *which is a condition to approval of the applica-*
24 *tion, and there is a lack of adequate information*
25 *to justify the deviation from such standard.*

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

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

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

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

22 “(5) *BASIS FOR ACTION.*—

23 “(A) For purposes of paragraph (2)(A),
24 whether permitting a tobacco product to be mar-
25 keted would be appropriate for the protection of

1 *the public health shall, when appropriate, be de-*
2 *termined on the basis of well-controlled inves-*
3 *tigations, which may include one or more clini-*
4 *cal investigations by experts qualified by train-*
5 *ing and experience to evaluate the tobacco prod-*
6 *uct.*

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

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

15 “(1) *IN GENERAL.—The Secretary shall, upon*
16 *obtaining, where appropriate, advice on scientific*
17 *matters from the Tobacco Products Scientific Advi-*
18 *sory Committee established under section 915, and*
19 *after due notice and opportunity for informal hearing*
20 *to the holder of an approved application for a tobacco*
21 *product, issue an order withdrawing approval of the*
22 *application if the Secretary finds—*

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

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

4 “(C) that the applicant—

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

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

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

15 “(D) on the basis of new information before
16 the Secretary with respect to such tobacco prod-
17 uct, evaluated together with the evidence before
18 the Secretary when the application was ap-
19 proved, that the methods used in, or the facilities
20 and controls used for, the manufacture, process-
21 ing, packing, or installation of such tobacco
22 product do not conform with the requirements of
23 section 906(e) and were not brought into con-
24 formity with such requirements within a reason-

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

3 “(E) *on the basis of new information before*
4 *the Secretary, evaluated together with the evi-*
5 *dence before the Secretary when the application*
6 *was approved, that the labeling of such tobacco*
7 *product, based on a fair evaluation of all mate-*
8 *rial facts, is false or misleading in any particu-*
9 *lar and was not corrected within a reasonable*
10 *time after receipt of written notice from the Sec-*
11 *retary of such fact; or*

12 “(F) *on the basis of new information before*
13 *the Secretary, evaluated together with the evi-*
14 *dence before the Secretary when the application*
15 *was approved, that such tobacco product is not*
16 *shown to conform in all respects to a perform-*
17 *ance standard which is in effect under section*
18 *907, compliance with which was a condition to*
19 *approval of the application, and that there is a*
20 *lack of adequate information to justify the devi-*
21 *ation from such standard.*

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

1 *which he receives notice of such withdrawal, obtain*
2 *review thereof in accordance with subsection (e) of*
3 *this section.*

4 “(3) *TEMPORARY SUSPENSION.*—*If, after provid-*
5 *ing an opportunity for an informal hearing, the Sec-*
6 *retary determines there is reasonable probability that*
7 *the continuation of distribution of a tobacco product*
8 *under an approved application would cause serious,*
9 *adverse health consequences or death, that is greater*
10 *than ordinarily caused by tobacco products on the*
11 *market, the Secretary shall by order temporarily sus-*
12 *pend the approval of the application approved under*
13 *this section. If the Secretary issues such an order, the*
14 *Secretary shall proceed expeditiously under para-*
15 *graph (1) to withdraw such application.*

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

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

20 “(2) *by mailing the order by registered mail or*
21 *certified mail addressed to the applicant at the appli-*
22 *cant’s last known address in the records of the Sec-*
23 *retary.*

24 **“SEC. 911. JUDICIAL REVIEW.**

25 “(a) *IN GENERAL.*—*Not later than 30 days after—*

1 “(1) the promulgation of a regulation under sec-
2 tion 907 establishing, amending, or revoking a per-
3 formance standard for a tobacco product; or
4 “(2) a denial of an application for approval
5 under section 910(c);
6 any person adversely affected by such regulation or order
7 may file a petition with the United States Court of Appeals
8 for the District of Columbia or for the circuit wherein such
9 person resides or has his principal place of business for ju-
10 dicial review of such regulation or order. A copy of the peti-
11 tion shall be transmitted by the clerk of the court to the
12 Secretary or other officer designated by the Secretary for
13 that purpose. The Secretary shall file in the court the record
14 of the proceedings on which the Secretary based the Sec-
15 retary’s regulation or order and each record or order shall
16 contain a statement of the reasons for its issuance and the
17 basis, on the record, for its issuance. For purposes of this
18 section, the term ‘record’ means all notices and other matter
19 published in the Federal Register with respect to the regula-
20 tion or order reviewed, all information submitted to the Sec-
21 retary with respect to such regulation or order, proceedings
22 of any panel or advisory committee with respect to such
23 regulation or order, any hearing held with respect to such
24 regulation or order, and any other information identified
25 by the Secretary, in the administrative proceeding held

1 *with respect to such regulation or order, as being relevant*
2 *to such regulation or order.*

3 “(b) *COURT MAY ORDER THE SECRETARY TO MAKE*
4 *ADDITIONAL FINDINGS.—If the petitioner applies to the*
5 *court for leave to adduce additional data, views, or argu-*
6 *ments respecting the regulation or order being reviewed and*
7 *shows to the satisfaction of the court that such additional*
8 *data, views, or arguments are material and that there were*
9 *reasonable grounds for the petitioner’s failure to adduce*
10 *such data, views, or arguments in the proceedings before*
11 *the Secretary, the court may order the Secretary to provide*
12 *additional opportunity for the oral presentation of data,*
13 *views, or arguments and for written submissions. The Sec-*
14 *retary may modify the Secretary’s findings, or make new*
15 *findings by reason of the additional data, views, or argu-*
16 *ments so taken and shall file with the court such modified*
17 *or new findings, and the Secretary’s recommendation, if*
18 *any, for the modification or setting aside of the regulation*
19 *or order being reviewed, with the return of such additional*
20 *data, views, or arguments.*

21 “(c) *STANDARD OF REVIEW.—Upon the filing of the*
22 *petition under subsection (a) of this section for judicial re-*
23 *view of a regulation or order, the court shall have jurisdic-*
24 *tion to review the regulation or order in accordance with*
25 *chapter 7 of title 5, United States Code, and to grant appro-*

1 priate relief, including interim relief, as provided in such
2 chapter. A regulation or order described in paragraph (1)
3 or (2) of subsection (a) of this section shall not be affirmed
4 if it is found to be unsupported by substantial evidence on
5 the record taken as a whole.

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

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

15 “(f) *REGULATIONS AND ORDERS MUST RECITE BASIS*
16 *IN RECORD.*—To facilitate judicial review under this sec-
17 tion or under any other provision of law of a regulation
18 or order issued under section 906, 907, 908, 909, 910, or
19 914, each such regulation or order shall contain a statement
20 of the reasons for its issuance and the basis, in the record
21 of the proceedings held in connection with its issuance, for
22 its issuance.

23 **“SEC. 912. POSTMARKET SURVEILLANCE.**

24 “(a) *DISCRETIONARY SURVEILLANCE.*—The Secretary
25 may require a tobacco product manufacturer to conduct

1 *postmarket surveillance for a tobacco product of the manu-*
 2 *facturer if the Secretary determines that postmarket surveil-*
 3 *lance of the tobacco product is necessary to protect the pub-*
 4 *lic health or is necessary to provide information regarding*
 5 *the health risks and other safety issues involving the tobacco*
 6 *product.*

7 “(b) *SURVEILLANCE APPROVAL.*—Each tobacco prod-
 8 *uct manufacturer required to conduct a surveillance of a*
 9 *tobacco product under subsection (a) of this section shall,*
 10 *within 30 days after receiving notice that the manufacturer*
 11 *is required to conduct such surveillance, submit, for the ap-*
 12 *proval of the Secretary, a protocol for the required surveil-*
 13 *lance. The Secretary, within 60 days of the receipt of such*
 14 *protocol, shall determine if the principal investigator pro-*
 15 *posed to be used in the surveillance has sufficient qualifica-*
 16 *tions and experience to conduct such surveillance and if*
 17 *such protocol will result in collection of useful data or other*
 18 *information necessary to protect the public health. The Sec-*
 19 *retary may not approve such a protocol until it has been*
 20 *reviewed by an appropriately qualified scientific and tech-*
 21 *nical review committee established by the Secretary.*

22 **“SEC. 913. REDUCED RISK TOBACCO PRODUCTS.**

23 “(a) *REQUIREMENTS.*—

24 “(1) *IN GENERAL.*—For purposes of this section,
 25 the term ‘reduced risk tobacco product’ means a to-

1 *bacco product designated by the Secretary under*
2 *paragraph (2).*

3 “(2) *DESIGNATION.*—

4 “(A) *IN GENERAL.*—A product may be des-
5 *ignated by the Secretary as a reduced risk to-*
6 *bacco product if the Secretary finds that the*
7 *product will significantly reduce harm to indi-*
8 *viduals caused by a tobacco product and is oth-*
9 *erwise appropriate to protect public health, based*
10 *on an application submitted by the manufac-*
11 *turer of the product (or other responsible person)*
12 *that—*

13 “(i) *demonstrates through testing on*
14 *animals and short-term human testing that*
15 *use of such product results in ingestion or*
16 *inhalation of a substantially lower yield of*
17 *toxic substances than use of conventional to-*
18 *bacco products in the same category as the*
19 *proposed reduced risk product; and*

20 “(ii) *if required by the Secretary, in-*
21 *cludes studies of the long-term health effects*
22 *of the product.*

23 *If such studies are required, the manufacturer*
24 *may consult with the Secretary regarding proto-*
25 *cols for conducting the studies.*

1 “(B) *BASIS FOR FINDING.*—*In making the*
2 *finding under subparagraph (A), the Secretary*
3 *shall take into account—*

4 “(i) *the risks and benefits to the popu-*
5 *lation as a whole, including both users of*
6 *tobacco products and non-users of tobacco*
7 *products;*

8 “(ii) *the increased or decreased likeli-*
9 *hood that existing users of tobacco products*
10 *will stop using such products including re-*
11 *duced risk tobacco products;*

12 “(iii) *the increased or decreased likeli-*
13 *hood that those who do not use tobacco*
14 *products will start to use such products, in-*
15 *cluding reduced risk tobacco products; and*

16 “(iii) *the risks and benefits to consum-*
17 *ers from the use of a reduced risk tobacco*
18 *product as compared to the use of products*
19 *approved under chapter V to reduce expo-*
20 *sure to tobacco.*

21 “(3) *MARKETING REQUIREMENTS.*—*A tobacco*
22 *product may be marketed and labeled as a reduced*
23 *risk tobacco product if it—*

1 “(A) has been designated as a reduced risk
2 tobacco product by the Secretary under para-
3 graph (2);

4 “(B) bears a label prescribed by the Sec-
5 retary concerning the product’s contribution to
6 reducing harm to health; and

7 “(C) complies with requirements prescribed
8 by the Secretary relating to marketing and ad-
9 vertising of the product, and other provisions of
10 this chapter as prescribed by the Secretary.

11 “(b) *REVOCATION OF DESIGNATION.*—At any time
12 after the date on which a tobacco product is designated as
13 a reduced risk tobacco product under this section the Sec-
14 retary may, after providing an opportunity for an informal
15 hearing, revoke such designation if the Secretary deter-
16 mines, based on information not available at the time of
17 the designation, that—

18 “(1) the finding made under subsection (a)(2) is
19 no longer valid; or

20 “(2) the product is being marketed in violation
21 of subsection (a)(3).

22 “(c) *LIMITATION.*—A tobacco product that is des-
23 igned as a reduced risk tobacco product that is in compli-
24 ance with subsection (a) shall not be regulated as a drug
25 or device.

1 “(d) *DEVELOPMENT OF REDUCED RISK TOBACCO*
 2 *PRODUCT TECHNOLOGY.*—*A tobacco product manufacturer*
 3 *shall provide written notice to the Secretary upon the devel-*
 4 *opment or acquisition by the manufacturer of any tech-*
 5 *nology that would reduce the risk of a tobacco product to*
 6 *the health of the user for which the manufacturer is not*
 7 *seeking designation as a ‘reduced risk tobacco product’*
 8 *under subsection (a).*

9 **“SEC. 914. PRESERVATION OF STATE AND LOCAL AUTHOR-**
 10 **ITY.**

11 “(a) *ADDITIONAL REQUIREMENTS.*—

12 “(1) *IN GENERAL.*—*Except as provided in para-*
 13 *graph (2), nothing in this Act shall be construed as*
 14 *prohibiting a State or political subdivision thereof*
 15 *from adopting or enforcing a requirement applicable*
 16 *to a tobacco product that is in addition to, or more*
 17 *stringent than, requirements established under this*
 18 *chapter.*

19 “(2) *PREEMPTION OF CERTAIN STATE AND LOCAL*
 20 *REQUIREMENTS.*—

21 “(A) *Except as provided in subparagraph*
 22 *(B), no State or political subdivision of a State*
 23 *may establish or continue in effect with respect*
 24 *to a tobacco product any requirement which is*
 25 *different from, or in addition to, any require-*

ment applicable under the provisions of this chapter relating to performance standards, pre-market approval, adulteration, misbranding, registration, reporting, good manufacturing standards, or reduced risk products.

“(B) Subparagraph (A) does not apply to requirements relating to the sale, use, or distribution of a tobacco product including requirements related to the access to, and the advertising and promotion of, a tobacco product.

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

“(c) *WAIVERS.*—Upon the application of a State or political subdivision thereof, the Secretary may, by regulation promulgated after notice and an opportunity for an oral hearing, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a tobacco product if—

“(1) the requirement is more stringent than a requirement applicable under the provisions described in subsection (a)(3) which would be applicable to the

1 tobacco product if an exemption were not in effect
2 under this subsection; or

3 “(2) the requirement—

4 “(A) is required by compelling local condi-
5 tions; and

6 “(B) compliance with the requirement
7 would not cause the tobacco product to be in vio-
8 lation of any applicable requirement of this
9 chapter.

10 **“SEC. 915. TOBACCO PRODUCTS SCIENTIFIC ADVISORY**
11 **COMMITTEE.**

12 “(a) *ESTABLISHMENT.*—Not later than 1 year after the
13 date of enactment of the National Tobacco Policy and Youth
14 Smoking Reduction Act, the Secretary shall establish a 9-
15 member advisory committee, to be known as the ‘Tobacco
16 Products Scientific Advisory Committee’.

17 “(b) *MEMBERSHIP.*—

18 “(1) *IN GENERAL.*—The Secretary shall appoint
19 as members of the Tobacco Products Scientific Advi-
20 sory Committee individuals who are technically
21 qualified by training and experience in the medicine,
22 medical ethics, science, or technology involving the
23 manufacture, evaluation, or use of tobacco products,
24 who are of appropriately diversified professional
25 backgrounds. The committee shall be composed of—

1 “(A) 3 individuals who are officers or em-
2 ployees of a State or local government, or of the
3 Federal government;

4 “(B) 2 individuals as representatives of in-
5 terests of the tobacco manufacturing industry;

6 “(C) 2 individuals as representatives of in-
7 terests of physicians and other healthcare profes-
8 sionals; and

9 “(D) 2 individuals as representatives of the
10 general public.

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 of the Advisory Committee to
19 serve as chairperson.

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

23 “(1) as provided in this chapter;

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

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

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

7 “(d) COMPENSATION; SUPPORT; FACa.—

8 “(1) COMPENSATION AND TRAVEL.—Members of
9 the Advisory Committee who are not officers or em-
10 ployees of the United States, while attending con-
11 ferences or meetings of the committee or otherwise en-
12 gaged in its business, shall be entitled to receive com-
13 pensation at rates to be fixed by the Secretary, which
14 may not exceed the daily equivalent of the rate in ef-
15 fect for level 4 of the Senior Executive Schedule under
16 section 5382 of title 5, United States Code, for each
17 day (including travel time) they are so engaged; and
18 while so serving away from their homes or regular
19 places of business each member may be allowed travel
20 expenses, including per diem in lieu of subsistence, as
21 authorized by section 5703 of title 5, United States
22 Code, for persons in the Government service employed
23 intermittently.

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

4 “(3) *NONAPPLICATION OF FACA.*—*Section 14 of*
 5 *the Federal Advisory Committee Act (5 U.S.C.*
 6 *App.) does not apply 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 commit-*
 10 *tee. Each such panel and committee shall delete from any*
 11 *transcript made under this subsection information which*
 12 *is exempt from disclosure under section 552(b) of title 5,*
 13 *United States Code.*

14 **“SEC. 916. EQUAL TREATMENT OF RETAIL OUTLETS.**

15 *“The Secretary shall issue regulations to require that*
 16 *retail establishments for which the predominant business is*
 17 *the sale of tobacco products comply with any advertising*
 18 *restrictions applicable to retail establishments accessible to*
 19 *individuals under the age of 18.”.*

20 **SEC. 102. CONFORMING AND OTHER AMENDMENTS TO GEN-**
 21 **ERAL PROVISIONS.**

22 “(a) *AMENDMENT OF FEDERAL FOOD, DRUG, AND COS-*
 23 *METIC ACT.*—*Except as otherwise expressly provided, when-*
 24 *ever in this section an amendment is expressed in terms*
 25 *of an amendment to, or repeal of, a section or other provi-*

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

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

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

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

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

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

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

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

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

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

23 (9) by striking subsection (p) and inserting the
24 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(J)(2).”;*

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

8 “(q)(1) *The failure or refusal—*

9 “(A) *to comply with any requirement prescribed*
 10 *under section 518, 520(g), 906(f), or 908;*

11 “(B) *to furnish any notification or other mate-*
 12 *rial or information required by or under section 519,*
 13 *520(g), 904, 906(f), or 909; or*

14 “(C) *to comply with a requirement under section*
 15 *522 or 912.”;*

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

18 (12) *by inserting “or tobacco product” in sub-*
 19 *section (r) after “device” each time that it appears.*

20 (c) *SECTION 303.—Section 303(f)(1)(A) (21 U.S.C.*
 21 *333(f)(1)(A)) is amended by inserting “or tobacco products”*
 22 *after “devices”.*

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

1 (1) by striking “and” before “(D)” in subsection
2 (a)(2);

3 (2) by striking “device.” in subsection (a)(2) and
4 inserting a comma and “(E) Any adulterated or mis-
5 branded tobacco product.”;

6 (3) by inserting “tobacco product,” in subsection
7 (d)(1) after “device,”;

8 (4) by inserting “or tobacco product” in sub-
9 section (g)(1) after “device” each place it appears;
10 and

11 (5) by inserting “or tobacco product” in sub-
12 section (g)(2)(A) after “device” each place it appears.

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

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

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

17 “(2) For a tobacco product, to the extent feasible, the
18 Secretary shall contract with the States in accordance with
19 paragraph (1) to carry out inspections of retailers in con-
20 nection with the enforcement of this Act.”.

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

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

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

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

5 (1) by inserting “tobacco products,” in sub-
6 section (a)(1)(A) after “devices,” each place it ap-
7 pears;

8 (2) by inserting “or tobacco products” in sub-
9 section (a)(1)(B) after “restricted devices” each place
10 it appears; and

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

13 (h) SECTION 705.—Section 705(b) (21 U.S.C. 375(b))
14 is amended by inserting “tobacco products,” after “de-
15 vices,”.

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

18 (j) SECTION 801.—Section 801 (21 U.S.C. 381) is
19 amended—

20 (1) by inserting “tobacco products,” after “de-
21 vices,” in subsection (a) the first time it appears;

22 (2) by inserting “or subsection (j) of section 905”
23 in subsection (a) after “section 510”; and

1 (3) *by striking “drugs or devices” each time it*
2 *appears in subsection (a) and inserting “drugs, de-*
3 *vices, or tobacco products”;*

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

6 (2) *by redesignating paragraph (4) of subsection*
7 *(e) as paragraph (5) and inserting after paragraph*
8 *(3), the following:*

9 *“(4) Paragraph (1) does not apply to any to-*
10 *bacco product—*

11 *“(A) which does not comply with an appli-*
12 *cable requirement of section 907 or 910; or*

13 *“(B) which under section 906(f) is exempt*
14 *from either such section.*

15 *This paragraph does not apply if the Secretary has*
16 *determined that the exportation of the tobacco product*
17 *is not contrary to the public health and safety and*
18 *has the approval of the country to which it is in-*
19 *tended for export or the tobacco product is eligible for*
20 *export under section 802.”.*

21 (k) *SECTION 802.—Section 802 (21 U.S.C. 382) is*
22 *amended—*

23 (1) *by striking “device—” in subsection (a) and*
24 *inserting “device or tobacco product—”;*

1 (2) by striking “and” after the semicolon in sub-
2 section (a)(1)(C);

3 (3) by striking subparagraph (C) of subsection
4 (a)(2) and all that follows in that subsection and in-
5 serting the following:

6 “(C) is a banned device under section 516;

7 or

8 “(3) which, in the case of a tobacco product—

9 “(A) does not comply with an applicable re-
10 quirement of section 907 or 910; or

11 “(B) under section 906(f) is exempt from ei-
12 ther such section,

13 is adulterated, misbranded, and in violation of such
14 sections or Act unless the export of the drug, device,
15 or tobacco product is, except as provided in subsection
16 (f), authorized under subsection (b), (c), (d), or (e) of
17 this section or section 801(e)(2) or 801(e)(4). If a
18 drug, device, or tobacco product described in para-
19 graph (1), (2), or (3) may be exported under sub-
20 section (b) and if an application for such drug or de-
21 vice under section 505, 515, or 910 of this Act or sec-
22 tion 351 of the Public Health Service Act (42 U.S.C.
23 262) was disapproved, the Secretary shall notify the
24 appropriate public health official of the country to

1 *which such drug, device, or tobacco product will be ex-*
 2 *ported of such disapproval.”;*

3 (4) *by inserting “or tobacco product” in sub-*
 4 *section (b)(1)(A) after “device” each time it appears;*

5 (5) *by inserting “or tobacco product” in sub-*
 6 *section (c) after “device” and inserting “or section*
 7 *906(f)” after “520(g).”;*

8 (6) *by inserting “or tobacco product” in sub-*
 9 *section (f) after “device” each time it appears; and*

10 (7) *by inserting “or tobacco product” in sub-*
 11 *section (g) after “device” each time it appears.*

12 (1) *SECTION 1003.—Section 1003(d)(2)(C) (as redesign-*
 13 *ated by section 101(a)) is amended—*

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

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

17 ***Subtitle B—Advertising***

18 ***SEC. 121. ADVERTISING PROVISIONS IN PROTOCOL.***

19 *The Protocol shall contain provisions enforceable at*
 20 *law under which tobacco product manufacturers commit to*
 21 *observe limitations on advertising that meet the require-*
 22 *ments set forth in this subtitle.*

1 **SEC. 122. TOBACCO PRODUCT LABELING AND ADVERTIS-**
2 **ING.**

3 (a) *IN GENERAL.*—*The Protocol shall require that no*
4 *tobacco product will be sold or distributed in the United*
5 *States—*

6 (1) *unless its advertising and labeling (including*
7 *the package)—*

8 (A) *contain no human image, animal*
9 *image, or cartoon character;*

10 (B) *are not outdoor advertising, including*
11 *advertising in enclosed stadia and advertising*
12 *from within a retail establishment that is di-*
13 *rected toward or visible from the outside of the*
14 *establishment;*

15 (C) *are accompanied by a disclaimer in the*
16 *advertising that words such as “light” or “low*
17 *tar” describing the product do not render the*
18 *product less hazardous than any other tobacco*
19 *product, in addition to such other requirements*
20 *as the Secretary may impose;*

21 (D) *at the time the advertising or labeling*
22 *is first used are submitted to the Secretary so*
23 *that the Secretary may conduct regular review of*
24 *the advertising and labeling;*

25 (E) *comply with any applicable require-*
26 *ment of the Federal Food, Drug, and Cosmetic*

1 *Act, the Federal Cigarette Labeling and Adver-*
2 *tising Act, and any regulation promulgated*
3 *under either of those Acts;*

4 *(F) do not appear on the international com-*
5 *puter network of both Federal and non-Federal*
6 *interoperable packet switches data networks (the*
7 *“Internet”), unless such advertising is designed*
8 *to be inaccessible in or from the United States*
9 *to all individuals under the age of 18 years;*

10 *(G) use only black text on white back-*
11 *ground, other than—*

12 *(i) those locations where self-service*
13 *displays are permitted under subsection*
14 *123, if the advertising is not visible from*
15 *outside the establishment and is affixed to a*
16 *wall or fixture in the establishment; and*

17 *(ii) advertisements appearing in any*
18 *publication which the tobacco product man-*
19 *ufacturer, distributor, or retailer dem-*
20 *onstrates to the Secretary is a newspaper,*
21 *magazine, periodical, or other publication*
22 *whose readers under the age of 18 years*
23 *constitute 15 percent or less of the total*
24 *readership as measured by competent and*
25 *reliable survey evidence, and that is read by*

1 *less than 2 million persons under the age*
2 *of 18 years as measured by competent and*
3 *reliable survey evidence;*

4 *(H) for video formats, use only static black*
5 *text on a white background, and any accom-*
6 *panying audio uses only words without music or*
7 *sound effects; and*

8 *(I) for audio formats, use only words with-*
9 *out music or sound effects;*

10 *(2) if a logo, symbol, motto, selling message, rec-*
11 *ognizable color or pattern of colors, or any other indi-*
12 *cia of product identification of the tobacco product is*
13 *contained in a movie, program, or video game for*
14 *which a direct or indirect payment has been made to*
15 *ensure its placement;*

16 *(3) if a direct or indirect payment has been*
17 *made by any tobacco product manufacturer, distribu-*
18 *tor, or retailer to any entity for the purpose of pro-*
19 *moting the image or use of the tobacco product*
20 *through print or film media that appeals to individ-*
21 *uals under the age of 18 years or through a live per-*
22 *formance by an entertainment artist that appeals to*
23 *such individuals;*

24 *(4) if a logo, symbol, motto, selling message, rec-*
25 *ognizable color or pattern of colors, or any other indi-*

1 *cia or product identification identical to, similar to,*
2 *or identifiable with the tobacco product is used for*
3 *any item (other than a tobacco product) or service*
4 *marketed, licensed, distributed or sold or caused to be*
5 *marketed, licensed, distributed, or sold by the tobacco*
6 *product manufacturer or distributor of the tobacco*
7 *product;*

8 (5) *unless its package label and advertising bear*
9 *the product's established name and a statement of its*
10 *intended use, as follows:*

11 (A) *"Cigarettes-A Nicotine Delivery De-*
12 *vice";*

13 (B) *"Cigarette Tobacco-A Nicotine Delivery*
14 *Device"; or*

15 (C) *"Loose Leaf Chewing Tobacco", "Plug*
16 *Chewing Tobacco", "Twist Chewing Tobacco",*
17 *"Moist Snuff", or "Dry Snuff", whichever is ap-*
18 *propriate for the product, followed by "-A Nico-*
19 *tine Delivery Device"; and*

20 (6)(A) *except as provided in subparagraph (B),*
21 *if advertising or labeling for such product that is oth-*
22 *erwise in accordance with the requirements of this*
23 *section bears a tobacco product brand name (alone or*
24 *in conjunction with any other word) or any other in-*
25 *dicia of tobacco product identification and is dissemi-*

1 nated in a medium other than newspapers, maga-
2 zines, periodicals or other publications (whether peri-
3 odic or limited distribution), nonpoint-of-sale pro-
4 motional material (including direct mail), point-of-
5 sale promotional material, or audio or video formats
6 delivered at a point-of-sale; but

7 (B) notwithstanding subparagraph (A), advertis-
8 ing or labeling for cigarettes or smokeless tobacco may
9 be disseminated in a medium that is not specified in
10 paragraph (1) if the tobacco product manufacturer,
11 distributor, or retailer notifies the Secretary not later
12 than 30 days prior to the use of such medium, and
13 the notice describes the medium and the extent to
14 which the advertising or labeling may be seen by per-
15 sons under the age of 18 years.

16 (b) *COLOR PRINT ADS ON MAGAZINES.*—The Protocol
17 shall also provide that no tobacco product may be sold or
18 distributed in the United States if any advertising for that
19 product on the outside back cover of a magazine appears
20 in any color or combination of colors.

21 **SEC. 123. POINT-OF-SALE RESTRICTIONS.**

22 (a) *IN GENERAL.*—Except as provided in subsection
23 (b), the Protocol shall provide that no participating tobacco
24 product manufacturer, distributor, or retailer shall engage
25 in point-of-sale advertising of any tobacco product in any

1 *retail establishment (other than an establishment that sells*
2 *only tobacco products) in which an individual under 18*
3 *years of age is present, or permitted to enter, at any time.*

4 (b) *PERMITTED POS LOCATIONS.—*

5 (1) *PLACEMENT.—A retailer may place 1 point-*
6 *of-sale advertisement in or at each retail establish-*
7 *ment for its brand or the contracted house retailer or*
8 *private label brand of its wholesaler.*

9 (2) *SIZE.—The display area of any such point-*
10 *of-sale advertisement (either individually or in the*
11 *aggregate) shall not be larger than 576 square inches*
12 *and shall consist of black letters on white background*
13 *or another recognized typography.*

14 (3) *PROXIMITY TO CANDY.—Any such point-of-*
15 *sale advertisement shall not be attached to or located*
16 *within 2 feet of any display fixture on which candy*
17 *is displayed for sale.*

18 (c) *AUDIO OR VIDEO.—Any audio or video format per-*
19 *mitted under regulations promulgated by the Secretary may*
20 *be distributed at the time of sale of a tobacco product to*
21 *individuals over the age of 18 years, but no such format*
22 *may be played or shown in or at any location where tobacco*
23 *products are offered for sale.*

24 (d) *NO RESTRICTIVE COVENANTS.—No participating*
25 *tobacco product manufacturer or distributor of tobacco*

1 products may enter into any arrangement with a retailer
 2 that limits the retailer's ability to display any form of ad-
 3 vertising or promotional material originating with another
 4 supplier and permitted by law to be displayed in a retail
 5 establishment.

6 (e) *DEFINITIONS.*—As used in this section, the terms
 7 “point-of-sale advertisement” and “point-of-sale advertis-
 8 ing” mean all printed or graphical materials bearing the
 9 brand name (alone or in conjunction with any other word),
 10 logo, symbol, motto, selling message, or any other indicia
 11 of product identification identical or similar to, or identifi-
 12 able with, those used for any brand of cigarettes or smokeless
 13 tobacco, which, when used for its intended purpose, can rea-
 14 sonably be anticipated to be seen by customers at a location
 15 where tobacco products are offered for sale.

16 **TITLE II—REDUCTIONS IN** 17 **UNDERAGE TOBACCO USE**

18 **Subtitle A—Underage Use**

19 **SEC. 201. GOALS FOR REDUCING UNDERAGE TOBACCO USE.**

20 (a) *GOALS.*—As part of a comprehensive national to-
 21 bacco control policy, the Secretary, working in cooperation
 22 with State, Tribal, and local governments and the private
 23 sector, shall take all actions under this Act necessary to en-
 24 sure that the required percentage reductions in underage
 25 use of tobacco products set forth in this title are achieved.

1 (b) *REQUIRED REDUCTIONS FOR CIGARETTES.*—With
 2 respect to cigarettes, the required percentage reduction in
 3 underage use, as set forth in section 202, means—

<i>Calendar Year After Date of Enactment</i>	<i>Required Percentage Reduction as a Percent- age of Base Incidence Percentage in Underage Cigarette Use</i>
<i>Years 3 and 4</i>	<i>15 percent</i>
<i>Years 5 and 6</i>	<i>30 percent</i>
<i>Years 7, 8, and 9</i>	<i>50 percent</i>
<i>Year 10 and thereafter</i>	<i>60 percent</i>

4 (c) *REQUIRED REDUCTIONS FOR SMOKELESS TO-*
 5 *BACCO.*—With respect to smokeless tobacco products, the re-
 6 quired percentage reduction in underage use, as set forth
 7 in section 202, means—

<i>Calendar Year After Date of Enactment</i>	<i>Required Percentage Reduction as a Percent- age of Base Incidence Percentage in Underage Smokeless Tobacco Use</i>
<i>Years 3 and 4</i>	<i>12.5 percent</i>
<i>Years 5 and 6</i>	<i>25 percent</i>
<i>Years 7, 8, and 9</i>	<i>35 percent</i>
<i>Year 10 and thereafter</i>	<i>45 percent</i>

8 **SEC. 202. LOOK-BACK ASSESSMENT.**

9 (a) *DETERMINATION OF UNDERAGE USE.*—Upon the
 10 conclusion of the third calendar year after the date of enact-
 11 ment of this Act, and annually thereafter, the Secretary
 12 shall determine the percent incidence of underage use of
 13 cigarettes and of smokeless tobacco by calculating the aver-
 14 age, weighted by relative population of such age groups in
 15 1995 as determined by the Bureau of the Census, of the per-
 16 centages of individuals in grade 12 (ages 16 and 17), in
 17 grade 10 (ages 14 and 15), and in grade 8 (age 13) who

1 *used cigarettes or smokeless tobacco, as appropriate, on a*
2 *daily basis during the preceding calendar year. The per-*
3 *centages used in this calculation are to be those measured*
4 *by (1) the University of Michigan Survey, or (2) such com-*
5 *parable index using identical methodology as is chosen by*
6 *the Secretary after notice and the opportunity for comment*
7 *in accordance with section 553 of title 5, United States*
8 *Code. If the methodology employed by the University of*
9 *Michigan Survey is changed in a material manner from*
10 *that employed from 1986 through 1996 (including changes*
11 *in the States or regions on which the University of Michi-*
12 *gan Survey is based), or is (in the opinion of the Secretary)*
13 *no longer the best available data, the Secretary shall use*
14 *the percentages measured by an index chosen by the Sec-*
15 *retary, after notice and the opportunity for comment in ac-*
16 *cordance with section 553 of title 5, United States Code,*
17 *that has a methodology identical to that employed by the*
18 *University of Michigan Survey from 1986 through 1996.*
19 *The Secretary shall make the data on which the results of*
20 *the University of Michigan Survey or such other com-*
21 *parable index are based available to the public upon re-*
22 *quest.*

23 (b) *CALCULATION OF NON-ATTAINMENT PENALTIES.—*

24 (1) *SECRETARY TO DETERMINE NON-ATTAINMENT*
25 *PERCENTAGE.—The Secretary shall determine the*

1 *non-attainment percentage for cigarettes and for*
 2 *smokeless tobacco for each calendar year.*

3 (2) *NON-ATTAINMENT PENALTY FOR CIGA-*
 4 *RETTES.—For each calendar year in which the per-*
 5 *centage reduction in underage use required by section*
 6 *201(b) is not attained, the Secretary shall assess a*
 7 *penalty on cigarette manufacturers as follows:*

<i>If the non-attainment per- centage is:</i>	<i>The penalty is:</i>
<i>Not more than 5 percent</i>	<i>\$80,000,000 multiplied by the non-attainment percentage</i>
<i>More than 5% but not more than 10%</i>	<i>\$400,000,000, plus \$160,000,000 multiplied by the non-attainment percentage in excess of 5% but not in excess of 10%</i>
<i>More than 10% but not more than 20%</i>	<i>\$1,200,000,000, plus \$240,000,000 multiplied by the non-attainment percentage in excess of 10% but not in excess of 20%</i>
<i>More than 20%</i>	<i>\$3,500,000,000</i>

8 (3) *NON-ATTAINMENT PENALTY FOR SMOKELESS*
 9 *TOBACCO.—For each year in which the percentage re-*
 10 *duction in underage use required by section 201(c) is*
 11 *not attained, the Secretary shall assess a penalty on*
 12 *smokeless tobacco product manufacturers as follows:*

<i>If the non-attainment percentage is:</i>	<i>The penalty is:</i>
<i>Not more than 5 percent</i>	<i>\$8,000,000 multiplied by the non-attainment percentage</i>
<i>More than 5% but not more than 10%</i>	<i>\$40,000,000, plus \$16,000,000 multiplied by the non-attainment percentage in excess of 5% but not in excess of 10%</i>
<i>More than 10% but not more than 20%</i>	<i>\$120,000,000, plus \$24,000,000 multiplied by the non-attainment percentage in excess of 10% but not in excess of 20%</i>
<i>More than 20%</i>	<i>\$350,000,000</i>

1 (4) *PENALTIES TO BE ADJUSTED FOR INFLA-*
2 *TION.—*

3 (A) *IN GENERAL.—Beginning with the*
4 *fourth calendar year after the date of enactment*
5 *of this Act, each dollar amount in the tables in*
6 *paragraphs (2) and (3) shall be increased by the*
7 *inflation adjustment.*

8 (B) *INFLATION ADJUSTMENT.—For pur-*
9 *poses of subparagraph (A), the inflation adjust-*
10 *ment for any calendar year is the percentage (if*
11 *any) by which—*

12 (i) *the CPI for the preceding calendar*
13 *year, exceeds*

14 (ii) *the CPI for the calendar year*
15 *1998.*

16 (C) *CPI.—For purposes of subparagraph*
17 *(B), the CPI for any calendar year is the aver-*
18 *age of the Consumer Price Index for all-urban*

1 consumers published by the Department of
2 Labor.

3 (D) *ROUNDING.*—If any increase deter-
4 mined under subparagraph (A) is not a multiple
5 of \$1,000, the increase shall be rounded to the
6 nearest multiple of \$1,000.

7 (c) *JOINT, SEVERAL, AND STRICT OBLIGATION FOR*
8 *PENALTIES.*—

9 (1) *CIGARETTE MANUFACTURERS.*—Any penalty
10 due and payable by cigarette manufacturers shall be
11 the joint, several, and strict obligation of such manu-
12 facturers.

13 (2) *SMOKELESS TOBACCO.*—Any penalty payable
14 by smokeless tobacco product manufacturers shall be
15 the joint, several, and strict obligation of such manu-
16 facturers.

17 (d) *EXEMPTIONS FOR SMALL MANUFACTURERS.*—

18 (1) *ALLOCATION BY MARKET SHARE.*—The Sec-
19 retary shall make such allocations according to each
20 manufacturer's share of the domestic cigarette or do-
21 mestic smokeless tobacco market, as appropriate, in
22 the year for which the penalty is being assessed, based
23 on actual Federal excise tax payments.

24 (2) *EXEMPTION.*—In any year in which a pen-
25 alty is being assessed, the Secretary shall exempt from

1 *payment any tobacco product manufacturer with less*
2 *than 1 percent of the domestic market share for a spe-*
3 *cific category of tobacco product unless the Secretary*
4 *finds that the manufacturer's brands used by under-*
5 *age individuals at a rate equal to or greater than the*
6 *manufacturer's total market share for the type of to-*
7 *bacco product.*

8 (e) *METHOD OF PENALTY ASSESSMENT.—The Sec-*
9 *retary shall assess a penalty for a specific calendar year*
10 *on or before May 1 of the subsequent calendar year. Penalty*
11 *payments shall be paid on or before July 1 of the year in*
12 *which they are assessed. The Secretary may establish, by*
13 *regulation, interest at a rate up to 3 times the prevailing*
14 *prime rate at the time the penalty is assessed, and addi-*
15 *tional charges in an amount up to 3 times the penalty,*
16 *for late payment of the penalty.*

17 (f) *BUSINESS EXPENSE DEDUCTION.—Any penalty*
18 *paid by a tobacco product manufacturer under this section*
19 *shall not be deductible as an ordinary and necessary busi-*
20 *ness expense or otherwise under the Internal Revenue Code*
21 *of 1986.*

22 (g) *PENALTY LIABILITY AMONG MANUFACTURERS.—*

23 (1) *IN GENERAL.—The District Courts of the*
24 *United States shall have jurisdiction to adjudicate*
25 *any claim brought under this section by a tobacco*

1 product manufacturer against one or more other to-
2 bacco product manufacturers—

3 (A) to recover a portion of the penalty paid
4 by the plaintiff manufacturer; or

5 (B) for a reallocation of the penalty among
6 tobacco product manufacturers.

7 (2) CONTRIBUTION OR REIMBURSEMENT LIABIL-
8 ITY.—A tobacco product manufacturer shall be liable
9 under this subsection to one or more other manufac-
10 turers if the plaintiff tobacco product manufacturer
11 establishes by a preponderance of the evidence that the
12 defendant tobacco product manufacturer, through its
13 acts or omissions, was responsible for a disproportion-
14 ate share of the non-attainment penalty as compared
15 to the responsibility of the plaintiff manufacturer, as
16 contemplated in subsection (c)(3).

17 (3) RESPONSIBILITY FOR AGENTS, ETC.—In any
18 action brought under this subsection, a tobacco prod-
19 uct manufacturer shall be held responsible for any act
20 or omission of its attorneys, advertising agencies, or
21 other agents that contributed to that manufacturer's
22 responsibility for the penalty assessed under this sec-
23 tion.

1 **SEC. 203. SUBSTANTIAL NON-ATTAINMENT OF REQUIRED**
2 **REDUCTIONS.**

3 (a) *ACTION BY SECRETARY.—*

4 (1) *IN GENERAL.—If the Secretary determines*
5 *that the non-attainment percentage for any year is*
6 *greater than 20 percentage points for cigarettes or*
7 *smokeless tobacco, then the Secretary shall determine,*
8 *on a brand-by-brand basis, using data that reflects a*
9 *1999 baseline, which tobacco product manufacturers*
10 *are responsible within the 2 categories of tobacco*
11 *products for the excess. The Secretary may commence*
12 *an action under this section against the tobacco prod-*
13 *uct manufacturer or manufacturers of the brand or*
14 *brands of cigarettes or smokeless tobacco products for*
15 *which the non-attainment percentage exceeded 20 per-*
16 *centage points.*

17 (2) *DETERMINATION.—The Secretary shall use*
18 *research methodology that is similar to, or the same*
19 *as, that used in the University of Michigan Survey,*
20 *except—*

21 (A) *the methodology shall be adapted to de-*
22 *termining underage usage by brand; and*

23 (B) *the base period shall be calendar year*
24 *1999.*

25 (b) *PROCEDURES.—Any action under this section shall*
26 *be commenced by the Secretary in the United States Dis-*

1 strict Court for the District of Columbia within 90 days
2 after publication in the Federal Register of the determina-
3 tion that the non-attainment percentage for the tobacco
4 product in question is greater than 20 percentage points.
5 Any such action shall be heard and determined by a 3-judge
6 court under section 2284 of title 28, United States Code.

7 (c) DETERMINATION BY COURT.—In any action under
8 this section, the court shall determine whether the prepon-
9 derance of the evidence shows that a tobacco product manu-
10 facturer—

11 (1) has failed to comply substantially with the
12 provisions of this Act regarding underage tobacco use,
13 of any rules or regulations promulgated thereunder,
14 or of any Federal or State laws regarding underage
15 tobacco use;

16 (2) has taken any material action to undermine
17 the achievement of the required percentage reduction
18 for the tobacco product in question; or

19 (3) has failed to comply with all recommenda-
20 tions of the Tobacco Agreement Accountability Panel
21 established under section 801.

22 (d) REMOVAL OF ANNUAL AGGREGATE PAYMENT LIM-
23 ITATION.—Except as provided in subsections (e) and (g), if
24 the court determines that the preponderance of the evidence
25 shows that a tobacco product manufacturer engaged in con-

1 duct described in subsection (c) then section 706(c) of this
2 Act does not apply to the enforcement against, or the pay-
3 ment by, such tobacco product manufacturer of any judg-
4 ment or settlement that becomes final after that determina-
5 tion is made. The liability apportionment agreement de-
6 scribed in section 706(e) of this Act shall not require that
7 other tobacco product manufacturers pay an increased
8 amount in any year over the amount they would have had
9 to pay but for this section.

10 (e) *DEFENSE*.—An action under this section shall be
11 dismissed, and subsection (d) shall not apply, if the court
12 finds that the Secretary's determination under subsection
13 (a) was unlawful under subparagraph (A), (B), (C), or (D)
14 of section 706(2) of title 5, United States Code. Any judg-
15 ments paid under section 706(c) of this Act and section
16 (1)(d)(3) of the Protocol prior to a final judgment determin-
17 ing that the Secretary's determination was erroneous shall
18 be fully credited, with interest, under section 707(e) of this
19 Act and section (1)(d)(3) of the Protocol.

20 (f) *REVIEW*.—Decisions of the court under this section
21 are reviewable only by the Supreme Court by writ of certio-
22 rari granted upon the petition of any party. The applicabil-
23 ity of subsection (d) shall be stayed during the pendency
24 of any such petition or review.

1 (g) *CONTINUING EFFECT.*—Subsection (d) shall cease
 2 to apply to a tobacco product manufacturer found to have
 3 engaged in conduct described in subsection (c) upon the
 4 later of—

5 (1) a determination by the Secretary under sec-
 6 tion 201 after the commencement of action under sub-
 7 section (a) that the non-attainment percentage for the
 8 tobacco product in question is 20 or fewer percentage
 9 points; or

10 (2) a finding by the court in an action filed
 11 against the Secretary by the manufacturer, not earlier
 12 than 2 years after the determination described in sub-
 13 section (c) becomes final, that the preponderance of
 14 the evidence shows that, in the period since that deter-
 15 mination, the manufacturer—

16 (A) has complied with the provisions of this
 17 Act regarding underage tobacco use, of any rules
 18 or regulations promulgated thereunder, and of
 19 any other applicable Federal, State, or local
 20 laws, rules, or regulations;

21 (B) has not taken any action to undermine
 22 the achievement of the required percentage reduc-
 23 tion for the tobacco product in question; and

24 (C) has pursued substantial additional
 25 measures reasonably calculated to attain the re-

1 *quired percentage reduction for the tobacco prod-*
2 *uct in question.*

3 *A judgment or settlement against the tobacco product man-*
4 *ufacturer that becomes final after a determination or find-*
5 *ing described in paragraph (1) or (2) of this subsection is*
6 *not subject to subsection (d). An action under paragraph*
7 *(2) of this subsection shall be commenced in the United*
8 *States District Court for the District of Columbia, and shall*
9 *be heard and determined by a 3-judge court under section*
10 *2284 of title 28, United States Code. A decision by the court*
11 *under paragraph (2) of this subsection is reviewable only*
12 *by the Supreme Court by writ of certiorari granted upon*
13 *the petition of any party, and the decision shall be stayed*
14 *during the pendency of the petition or review. A determina-*
15 *tion or finding described in paragraph (1) or (2) of this*
16 *subsection does not limit the Secretary's authority to bring*
17 *a subsequent action under this section against any tobacco*
18 *product manufacturer or the applicability of subsection (d)*
19 *with respect to any such subsequent action.*

20 (h) *DEFINITIONS.—The definitions set forth in section*
21 *701 of this Act apply to terms used in this section. A judg-*
22 *ment or settlement becomes final within the meaning of this*
23 *section when it would qualify as a final judgment or final*
24 *settlement under section 701.*

1 **SEC. 204. DEFINITIONS.**

2 *As used in this subtitle—*

3 (1) The term “base incidence percentage”
4 means—

5 (A) in the case of cigarettes, the average,
6 weighted by relative population of the following
7 age groups in 1995 as determined by the Bureau
8 of the Census, of (i) the average of the percent-
9 ages of individuals in grade 12 (ages 16 and 17)
10 from 1986 to 1996 who used cigarettes on a
11 daily basis; (ii) the average of the percentages of
12 individuals in grade 10 (ages 14 and 15) from
13 1991 to 1996 who used cigarettes on a daily
14 basis; and (iii) the average of the percentages of
15 individuals in grade 8 (age 13) from 1991 to
16 1996 who used cigarettes on a daily basis; and

17 (B) in the case of smokeless tobacco prod-
18 ucts, the average, weighted by relative population
19 of the following age groups in 1995 as deter-
20 mined by the Bureau of the Census, of the per-
21 centage of individuals in grade 12 (ages 16 and
22 17), individuals in grade 10 (ages 14 and 15),
23 and individuals in grade 8 (age 13) who used
24 smokeless tobacco products on a daily basis in
25 1996.