

107TH CONGRESS
2D SESSION

H. R. 3940

To eliminate the Federal quota and price support programs for tobacco, to compensate quota holders and active producers for the loss of tobacco quota asset value, to establish a permanent advisory board to determine and describe the physical characteristics of United States farm-produced tobacco and unmanufactured imported tobacco, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 12, 2002

Mr. MCINTYRE (for himself and Mr. TOM DAVIS of Virginia) introduced the following bill; which was referred to the Committee on Agriculture, and in addition to the Committee on Energy and Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To eliminate the Federal quota and price support programs for tobacco, to compensate quota holders and active producers for the loss of tobacco quota asset value, to establish a permanent advisory board to determine and describe the physical characteristics of United States farm-produced tobacco and unmanufactured imported tobacco, 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 “Tobacco Livelihood and Economic Assistance for our
 4 Farmers Act of 2002”.

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

Sec. 1. Short title; table of contents.

Sec. 2. Severability.

TITLE I—TERMINATION OF CURRENT TOBACCO PROGRAMS

Sec. 101. Termination of marketing quota programs and repeal of related provisions.

Sec. 102. Termination of tobacco price support loan and no net cost provisions and repeal of related provisions.

Sec. 103. Geographical restrictions on expansion of tobacco production.

Sec. 104. Continued availability of Federal crop insurance.

TITLE II—PAYMENTS TO TOBACCO QUOTA HOLDERS AND PRODUCERS

Sec. 201. Definitions.

Sec. 202. Payments to tobacco quota holders.

Sec. 203. Transition payments for active producers of quota tobacco.

TITLE III—TOBACCO QUALITY BOARD

Sec. 301. Establishment of Board.

Sec. 302. Membership.

Sec. 303. Duties.

Sec. 304. Administrative provisions.

TITLE IV—TOBACCO PRODUCT MANUFACTURER AND IMPORTER USER FEES

Sec. 401. User fee.

Sec. 402. Allocation of user fees.

TITLE V—FDA REGULATION OF TOBACCO PRODUCTS

Sec. 501. Findings.

Sec. 502. Definitions.

Sec. 503. Amendment of Federal Food, Drug, and Cosmetic Act.

Sec. 504. Regulatory record.

Sec. 505. Conforming and other amendments to general provisions.

Sec. 506. Cigarette label and advertising warnings.

Sec. 507. Authority to revise cigarette warning label statements.

Sec. 508. Smokeless tobacco labels and advertising warnings.

Sec. 509. Authority to revise smokeless tobacco product warning label statements.

Sec. 510. Tar, nicotine, and other smoke constituent disclosure to the public.

Sec. 511. Regulation requirement.

Sec. 512. FTC jurisdiction not affected.

1 SEC. 2. SEVERABILITY.

2 If any provision of this Act, or an amendment made
3 by this Act, or the application of such provision to any
4 person or circumstance, is held to be invalid, the remain-
5 der of this Act, or an amendment made by this Act, or
6 the application of such provision to other persons or cir-
7 cumstances, shall not be affected.

8 TITLE I—TERMINATION OF
9 CURRENT TOBACCO PROGRAMS

10 SEC. 101. TERMINATION OF MARKETING QUOTA PROGRAMS
11 AND REPEAL OF RELATED PROVISIONS.

12 (a) TOBACCO CONTROL ACT.—The Act of April 25,
13 1936 (commonly known as the Tobacco Control Act; 7
14 U.S.C. 515–515k), is repealed.

15 (b) COMMODITY HANDLING ORDERS.—Section 8c(2)
16 of the Agricultural Adjustment Act (7 U.S.C. 608c(2)),
17 reenacted with amendments by the Agricultural Marketing
18 Agreement Act of 1937, is amended by striking “to-
19 bacco,”.

20 (c) PROCESSING TAX.—Section 9(b) of the Agricul-
21 tural Adjustment Act (7 U.S.C. 609(b)), reenacted with
22 amendments by the Agricultural Marketing Agreement
23 Act of 1937, is amended—

24 (1) in paragraph (2), by striking “tobacco,”

1 (2) in paragraph (6)(B)(i), by striking “, or, in
2 the case of tobacco, is less than the fair exchange
3 value by not more than 10 per centum,”.

4 (d) BURLEY TOBACCO IMPORT REVIEW.—Section 3
5 of Public Law 98–59 (7 U.S.C. 625) is repealed.

6 (e) DECLARATION OF POLICY.—Section 2 of the Ag-
7 ricultural Adjustment Act of 1938 (7 U.S.C. 1282) is
8 amended by striking “tobacco,”.

9 (f) DEFINITIONS.—Section 301(b) of the Agricultural
10 Adjustment Act of 1938 (7 U.S.C. 1301(b)) is amended—

11 (1) in paragraph (3)—

12 (A) by striking subparagraph (C); and

13 (B) by redesignating subparagraph (D) as
14 subparagraph (C);

15 (2) in paragraph (6)(A), by striking “tobacco,”;

16 (3) in paragraph (7), by striking the following:

17 “Tobacco (flue-cured), July 1–June 30;

18 Tobacco (other than flue-cured), October 1–Sep-
19 tember 30);”

20 (4) in paragraph (10)—

21 (A) by striking subparagraph (B); and

22 (B) by redesignating subparagraph (C) as
23 subparagraph (B);

24 (5) in paragraph (11)(B), by striking “and to-
25 bacco”;

1 (6) in paragraph (12), by striking “tobacco,”;
2 (7) in paragraph (14)—
3 (A) by striking “(A)” in subparagraph (A);
4 and
5 (B) by striking subparagraphs (B), (C),
6 and (D);
7 (8) by striking paragraph (15);
8 (9) in paragraph (16)—
9 (A) by striking subparagraph (B); and
10 (B) by redesignating subparagraph (C) as
11 subparagraph (B);
12 (10) by striking paragraph (17); and
13 (11) by redesignating paragraph (16) as para-
14 graph (15).
15 (g) PARITY PAYMENTS.—Section 303 of the Agricul-
16 tural Adjustment Act of 1938 (7 U.S.C. 1303) is amended
17 in the first sentence by striking “rice, or tobacco” and
18 inserting “or rice”.
19 (h) MARKETING QUOTAS.—Part I of subtitle B of
20 title III of the Agricultural Adjustment Act of 1938 (7
21 U.S.C. 1311 et seq.) is repealed.
22 (i) ADMINISTRATIVE PROVISIONS.—Section 361 of
23 the Agricultural Adjustment Act of 1938 (7 U.S.C. 1361)
24 is amended by striking “tobacco,”.

1 (j) ADJUSTMENT OF QUOTAS.—Section 371 of the
2 Agricultural Adjustment Act of 1938 (7 U.S.C. 1371) is
3 amended—

4 (1) in the first sentence of subsection (a) by
5 striking “peanuts, or tobacco” and inserting “or
6 peanuts”; and

7 (2) in the first sentence of subsection (b), by
8 striking “peanuts or tobacco” and inserting “or pea-
9 nuts”.

10 (k) REPORTS AND RECORDS.—Section 373 of the Ag-
11 ricultural Adjustment Act of 1938 (7 U.S.C. 1373) is
12 amended—

13 (1) by striking “peanuts, or tobacco” each place
14 it appears in subsections (a) and (b) and inserting
15 “or peanuts”; and

16 (2) in subsection (a)—

17 (A) in the first sentence by striking “all
18 persons engaged in the business of redrying,
19 prizing, or stemming tobacco for producers,”;
20 and

21 (B) in the last sentence by striking “\$500”
22 and all that follows through the period at the
23 end of the sentence and inserting “\$500.”.

24 (l) REGULATIONS.—Section 375(a) of the Agricul-
25 tural Adjustment Act of 1938 (7 U.S.C. 1375(a)) is

1 amended by striking “peanuts, or tobacco” and inserting
2 “or peanuts”.

3 (m) EMINENT DOMAIN.—Section 378 of the Agricul-
4 tural Adjustment Act of 1938 (7 U.S.C. 1378) is
5 amended—

6 (1) in the first sentence of subsection (c) by
7 striking “cotton, tobacco, and peanuts” and insert-
8 ing “cotton and peanuts”; and

9 (2) by striking subsections (d), (e), and (f).

10 (n) BURLEY TOBACCO FARM RECONSTITUTION.—
11 Section 379 of the Agricultural Adjustment Act of 1938
12 (7 U.S.C. 1379) is amended—

13 (1) in subsection (a)—

14 (A) by striking “(a)”; and

15 (B) in paragraph (6) by striking “, but
16 this clause (6) shall not be applicable in the
17 case of burley tobacco”; and

18 (2) by striking subsections (b) and (c).

19 (o) ACREAGE-POUNDAGE QUOTAS.—Section 4 of the
20 Act of April 16, 1955 (Public Law 89–12; 7 U.S.C. 1314c
21 note), is repealed.

22 (p) BURLEY TOBACCO ACREAGE ALLOTMENTS.—
23 The Act of July 12, 1952 (7 U.S.C. 1315), is repealed.

1 (q) TRANSFER OF ALLOTMENTS.—Section 703 of the
 2 Food and Agriculture Act of 1965 (7 U.S.C. 1316) is re-
 3 pealed.

4 (r) ADVANCE RECOURSE LOANS.—Section
 5 13(a)(2)(B) of the Food Security Improvements Act of
 6 1986 (7 U.S.C. 1433c–1(a)(2)(B)) is amended by striking
 7 “tobacco and”.

8 (s) TOBACCO FIELD MEASUREMENT.—Section 1112
 9 of the Omnibus Budget Reconciliation Act of 1987 (Public
 10 Law 100–203) is amended by striking subsection (c).

11 (t) LIABILITY.—The amendments made by this sec-
 12 tion shall not affect the liability of any person under any
 13 provision of law in effect before the amendments take ef-
 14 fect as provided under subsection (u).

15 (u) APPLICATION OF AMENDMENTS.—The amend-
 16 ments made by this section shall apply with respect to the
 17 2003 and subsequent tobacco crops.

18 **SEC. 102. TERMINATION OF TOBACCO PRICE SUPPORT**
 19 **LOAN AND NO NET COST PROVISIONS AND**
 20 **REPEAL OF RELATED PROVISIONS.**

21 (a) PARITY PRICE SUPPORT.—Section 101 of the Ag-
 22 ricultural Act of 1949 (7 U.S.C. 1441) is amended—

23 (1) in the first sentence of subsection (a), by
 24 striking “tobacco (except as otherwise provided here-
 25 in), corn” and inserting “corn”;

1 (2) by striking subsection (c);

2 (3) in subsection (d)(3)—

3 (A) by striking “, except tobacco,”; and

4 (B) by striking “and no price support shall
5 be made available for any crop of tobacco for
6 which marketing quotas have been disapproved
7 by producers;”; and

8 (4) by redesignating subsections (d) and (e) as
9 subsection (c) and (d), respectively.

10 (b) TERMINATION OF TOBACCO PRICE SUPPORT AND
11 NO NET COST PROVISIONS.—Sections 106, 106A, 106B,
12 and 106C of the Agricultural Act of 1949 (7 U.S.C. 1445,
13 1445–1, 1445–2, 1445–3) are repealed.

14 (c) DEFINITION OF BASIC AGRICULTURAL COM-
15 MODITY.—Section 408(c) of the Agricultural Act of 1949
16 (7 U.S.C. 1428(c)) is amended by striking “tobacco,”.

17 (d) REVIEW OF BURLEY TOBACCO IMPORTS.—Sec-
18 tion 3 of Public Law 98–59 (7 U.S.C. 625) is repealed.

19 (e) POWERS OF COMMODITY CREDIT CORPORA-
20 TION.—Section 5 of the Commodity Credit Corporation
21 Charter Act (15 U.S.C. 714c) is amended by inserting
22 “(other than tobacco)” after “agricultural commodities”
23 each place it appears.

24 (f) TRANSITION PROVISIONS.—

1 (1) PRICE SUPPORT LOAN OBLIGATIONS.—The
2 amendments made by this section shall not affect
3 any person’s obligations that arise under or with re-
4 spect to the price support loan program or loans
5 issued through such program under any provision of
6 law in effect before the amendments take effect as
7 provided under subsection (g).

8 (2) TOBACCO STOCKS AND LOANS.—The Sec-
9 retary of Agriculture shall issue regulations that
10 require—

11 (A) the orderly disposition of quota to-
12 bacco held by any producer-owned cooperative
13 marketing association that has entered into a
14 loan agreement with the Commodity Credit
15 Corporation to make price support available to
16 producers of quota tobacco;

17 (B) the repayment of all tobacco price sup-
18 port loans or surrender of collateral by such as-
19 sociations not later than one year after this sec-
20 tion becomes effective.

21 (3) SPECIAL RULES FOR TERMINATION OF NO
22 NET COST FUNDS AND ACCOUNTS.—Notwithstanding
23 any other provision of law, upon the repeal by sub-
24 section (b) of the authorities in section 106A and
25 106B of the Agricultural Act of 1949 for the estab-

1 lishment of tobacco no net cost funds and accounts,
2 respectively—

3 (A) any obligation of a tobacco producer,
4 purchaser, or importer to make payments into
5 any such fund or account also shall terminate;
6 and

7 (B) any monies in any such fund or ac-
8 count shall be disposed of in the manner pre-
9 scribed by the Secretary of Agriculture, except
10 that—

11 (i) to the extent needed, such monies
12 shall be applied or used for the purposes
13 therefor prescribed by such sections; and

14 (ii) if any monies remain, the Sec-
15 retary shall transfer such monies to the
16 Secretary of Health and Human Services
17 for use in accordance with section 402.

18 (g) APPLICATION OF AMENDMENTS.—This section
19 and the amendments made by this section shall apply with
20 respect to the 2003 and subsequent tobacco crops.

21 **SEC. 103. GEOGRAPHICAL RESTRICTIONS ON EXPANSION**
22 **OF TOBACCO PRODUCTION.**

23 (a) PURPOSE.—The purpose of this section is to pro-
24 vide an orderly economic transition away from the mar-
25 keting of tobacco based on quotas and price support while

1 also addressing the economic dislocation, and the resulting
2 impact on interstate commerce, that the termination of the
3 current tobacco program might cause in certain commu-
4 nities.

5 (b) PENALTY APPLICABLE TO TOBACCO GROWN IN
6 NONQUOTA COUNTIES AND STATES.—The marketing of
7 tobacco in the 2003 or subsequent marketing years, of a
8 kind of tobacco that was subject to a marketing quota in
9 the 2002 marketing year, shall be subject to a penalty
10 equal to 100 percent of the total amount received on the
11 marketing of the tobacco unless the tobacco was grown
12 in any county in which such kind of tobacco was grown
13 pursuant to a marketing quota in the 2002 marketing
14 year.

15 (c) DEFINITIONS.—In this section:

16 (1) The term “marketing year” means July 1
17 to June 30 for flue-cured tobacco and October 1 to
18 September 30 for all other kinds of tobacco.

19 (2) The term “marketing quota in the 2002
20 marketing year” means a quota established for that
21 year pursuant to part I of subtitle B of title III of
22 the Agricultural Adjustment Act of 1938 (7 U.S.C.
23 1311 et seq.) and related provisions, as in effect for
24 that marketing year.

1 **SEC. 104. CONTINUED AVAILABILITY OF FEDERAL CROP IN-**
2 **SURANCE.**

3 Nothing in this title shall be construed to affect the
4 eligibility of tobacco producers to obtain crop insurance
5 for their crops pursuant to the Federal Crop Insurance
6 Act (7 U.S.C. 1501 et seq.) under the terms of such Act.

7 **TITLE II—PAYMENTS TO TO-**
8 **BACCO QUOTA HOLDERS AND**
9 **PRODUCERS**

10 **SEC. 201. DEFINITIONS.**

11 In this title:

12 (1) The term “active producer of quota to-
13 bacco” means a person that was the actual pro-
14 ducer, as determined by the Secretary, of tobacco
15 marketed under a marketing quota for the 2001 to-
16 bacco marketing year.

17 (2) The term “quota tobacco” means a kind of
18 tobacco that is subject to farm marketing quotas or
19 farm acreage allotments for the 1999, 2000, 2001,
20 and 2002 tobacco marketing years under a mar-
21 keting quota or allotment program established under
22 part I of subtitle B of title III of the Agricultural
23 Adjustment Act of 1938 (7 U.S.C. 1281 et seq.).

24 (3) The term “Secretary” means the Secretary
25 of Agriculture.

1 (4) The term “tobacco quota holder” means an
2 owner of a farm on January 1, 2002, for which a
3 tobacco farm marketing quota or farm acreage allot-
4 ment for quota tobacco was established with respect
5 to the 2002 tobacco marketing year under a mar-
6 keting quota program established under part I of
7 subtitle B of title III of the Agricultural Adjustment
8 Act of 1938.

9 **SEC. 202. PAYMENTS TO TOBACCO QUOTA HOLDERS.**

10 (a) **PAYMENT REQUIRED.**—The Secretary shall make
11 payments to each eligible tobacco quota holder for the ter-
12 mination of tobacco marketing quotas and related price
13 support under title I, which shall constitute full and fair
14 compensation for any losses relating to such termination.

15 (b) **ELIGIBILITY.**—To be eligible to receive a payment
16 under this section, a person shall submit to the Secretary
17 an application containing such information as the Sec-
18 retary may require to demonstrate to the satisfaction of
19 the Secretary that the person satisfies the definition of
20 tobacco quota holder. The application shall be submitted
21 within such time, in such form, and in such manner as
22 the Secretary may require.

23 (c) **BASE QUOTA LEVEL.**—

1 (1) IN GENERAL.—The Secretary shall establish
2 a base quota level applicable to each eligible tobacco
3 quota holder, as determined under subsection (b).

4 (2) POUNDAGE QUOTAS.—For each kind of to-
5 bacco for which the marketing quota is expressed in
6 pounds, the base quota level for each tobacco quota
7 holder shall be equal to the basic tobacco marketing
8 quota under the Agriculture Adjustment Act of 1938
9 for the 1998 marketing year for quota tobacco on
10 the farm owned by the tobacco quota holder.

11 (3) MARKETING QUOTAS OTHER THAN POUND-
12 AGE QUOTAS.—For each kind of tobacco for which
13 there is marketing quota or allotment on an acreage
14 basis, the base quota level for each tobacco quota
15 holder shall be the amount equal to the product ob-
16 tained by multiplying—

17 (A) the basic tobacco farm marketing
18 quota or allotment for the 1998 marketing year
19 established by the Secretary for quota tobacco
20 on the farm owned by the tobacco quota holder;
21 by

22 (B) the average county production yield
23 per acre for the county in which the farm is lo-
24 cated for the kind of tobacco for the 1998 mar-
25 keting year.

1 (d) PAYMENT.—The Secretary shall make payments
2 to each eligible tobacco quota holder, as determined under
3 subsection (b), in a total amount equal to the product ob-
4 tained by multiplying—

5 (1) \$8 per pound; by

6 (2) the base quota level established for the
7 quota holder under subsection (c).

8 (e) TIME FOR PAYMENT.—The payments to eligible
9 tobacco quota holders required under this section shall be
10 made in five equal installments during fiscal years 2003,
11 2004, 2005, 2006, and 2007.

12 (f) RESOLUTION OF DISPUTES.—Any dispute regard-
13 ing the eligibility of a person to receive a payment under
14 this section, or the amount of the payment, shall be re-
15 solved by the county committee established under section
16 8 of the Soil Conservation and Domestic Allotment Act
17 (16 U.S.C. 590h) for the county or other area in which
18 the farm owned by the person is located.

19 (g) COMMODITY CREDIT CORPORATION.—The Sec-
20 retary shall use the funds, facilities and authorities of the
21 Commodity Credit Corporation to carry out this section.

1 **SEC. 203. TRANSITION PAYMENTS FOR ACTIVE PRODUCERS**
2 **OF QUOTA TOBACCO.**

3 (a) **TRANSITION PAYMENTS REQUIRED.**—The Sec-
4 retary shall make transition payments under this section
5 to eligible active producers of quota tobacco.

6 (b) **ELIGIBILITY.**—To be eligible to receive a transi-
7 tion payment under this section, a person shall submit to
8 the Secretary an application containing such information
9 as the Secretary may require to demonstrate to the satis-
10 faction of the Secretary that the person satisfies the defi-
11 nition of active producer of quota tobacco. The application
12 shall be submitted within such time, in such form, and
13 in such manner as the Secretary may require.

14 (c) **PRODUCTION BASE.**—The Secretary shall estab-
15 lish a production base applicable to each eligible active
16 producer of quota tobacco, as determined under subsection
17 (b). A producer's production base shall be equal to the
18 quantity, in pounds, of quota tobacco subject to the basic
19 marketing quota produced and marketed by the producer
20 under the Agriculture Adjustment Act of 1938 for the
21 2001 marketing year.

22 (d) **PAYMENT.**—The Secretary shall make payments
23 to each eligible active producer of quota tobacco, as deter-
24 mined under subsection (b), in a total amount equal to
25 the product obtained by multiplying—

26 (1) \$4 per pound; by

1 (2) the production base established for the ac-
2 tive producer under subsection (c).

3 (e) TIME FOR PAYMENT.—The payments to eligible
4 active producers of quota tobacco required under this sec-
5 tion shall be made in five equal installments during fiscal
6 years 2003, 2004, 2005, 2006, and 2007.

7 (f) RESOLUTION OF DISPUTES.—Any dispute regard-
8 ing the eligibility of a person to receive a payment under
9 this section, or the amount of the payment, shall be re-
10 solved by the county committee established under section
11 8 of the Soil Conservation and Domestic Allotment Act
12 (16 U.S.C. 590h) for the county or other area in which
13 the farming operation of the person is located.

14 (g) COMMODITY CREDIT CORPORATION.—The Sec-
15 retary shall use the funds, facilities and authorities of the
16 Commodity Credit Corporation to carry out this section.

17 **TITLE III—TOBACCO QUALITY** 18 **BOARD**

19 **SEC. 301. ESTABLISHMENT OF BOARD.**

20 The Secretary of Agriculture (in this title referred to
21 as the “Secretary”) shall establish a permanent advisory
22 board within the Department of Agriculture to be known
23 as the Tobacco Quality Board (in this title referred to as
24 the “Board”).

1 **SEC. 302. MEMBERSHIP.**

2 (a) NOMINATION AND APPOINTMENT.—The Board
3 shall consist of 11 members, of which five shall be ap-
4 pointed by the Secretary from nominations submitted by
5 representatives of United States tobacco producers, five
6 shall be appointed by the Secretary from nominations sub-
7 mitted by representatives of United States tobacco prod-
8 uct manufacturers, and one shall be an officer or employee
9 of the Department of Agriculture appointed by the Sec-
10 retary (who shall serve as Chair of the Board).

11 (b) TERMS.—

12 (1) CHAIR.—The Chair of the Board shall serve
13 at the pleasure of the Secretary.

14 (2) OTHER MEMBERS.—Other members of the
15 Board shall serve for two-year terms, except that,
16 for the first appointments to the Board, two pro-
17 ducer representatives and two manufacturer rep-
18 resentatives shall have initial terms of one year.

19 **SEC. 303. DUTIES.**

20 The Board shall be responsible for—

21 (1) determining and describing the physical
22 characteristics of United States farm-produced to-
23 bacco and unmanufactured imported tobacco;

24 (2) assembling and evaluating, in a systematic
25 manner, concerns and problems with the quality of
26 United States tobacco, expressed by domestic and

1 foreign buyers and manufacturers of tobacco prod-
2 ucts;

3 (3) reviewing data collected by Federal agencies
4 on the physical and chemical integrity of United
5 States produced and imported unmanufactured to-
6 bacco, to ensure that tobacco being used in domesti-
7 cally-manufactured tobacco products is of the high-
8 est quality and is free from prohibited physical and
9 chemical agents;

10 (4) investigating and communicating to the
11 Secretary—

12 (A) conditions with respect to the produc-
13 tion of tobacco that discourage improvements in
14 the quality of United States produced tobacco;
15 and

16 (B) recommendations for regulatory
17 changes that would address tobacco quality
18 issues; and

19 (5) such other related activities assigned to it
20 by the Secretary.

21 **SEC. 304. ADMINISTRATIVE PROVISIONS.**

22 (a) STAFF.—The Secretary shall provide the Board
23 with staff experienced in the sampling and analysis of un-
24 manufactured tobacco and capable of collecting data and
25 monitoring tobacco production information, and such

1 other resources necessary for the Board to perform its du-
2 ties under this subtitle, as determined by the Secretary.

3 (b) COMMODITY CREDIT CORPORATION.—The Sec-
4 retary shall use the funds, facilities and authorities of the
5 Commodity Credit Corporation to carry out this title.

6 **TITLE IV—TOBACCO PRODUCT**
7 **MANUFACTURER AND IM-**
8 **PORTER USER FEES**

9 **SEC. 401. USER FEE.**

10 (a) IN GENERAL.—The Secretary of Health and
11 Human Services shall assess an annual user fee, cal-
12 culated in accordance with this section, upon each tobacco
13 product manufacturer and tobacco product importer that
14 sells tobacco products in domestic commerce in the United
15 States. The assessments shall commence during calendar
16 year 2003, based on domestic sales of tobacco products
17 during fiscal year 2003.

18 (b) BASE AMOUNT OF USER FEE FOR EACH CLASS
19 OF TOBACCO PRODUCT.—

20 (1) The base amount of the user fee for ciga-
21 rette manufacturers and importers shall be
22 \$2,116,252,000.

23 (2) The base amount of the user fee for small
24 cigar manufacturers and importers shall be
25 \$1,051,000.

1 (3) The base amount of the user fee for large
2 cigar manufacturers and importers shall be
3 \$164,274,000.

4 (4) The base amount of the user fee for snuff
5 manufacturers and importers shall be \$9,920,000.

6 (5) The base amount of the user fee for chew-
7 ing tobacco manufacturers and importers shall be
8 \$2,275,000.

9 (6) The base amount of the user fee for pipe to-
10 bacco manufacturers and importers shall be
11 \$1,505,000.

12 (7) The base amount of the user fee for roll-
13 your-own tobacco manufacturers and importers shall
14 be \$3,231,000.

15 (c) DETERMINATION OF ANNUAL USER FEE FOR
16 EACH CLASS OF TOBACCO PRODUCT.—The total user fee
17 to be assessed upon, and paid by, the manufacturers and
18 importers of each class of tobacco product in each calendar
19 year, as allocated pursuant to subsection (d), shall be the
20 base amount for that class of tobacco product provided
21 in subsection (b) multiplied by a fraction—

22 (1) the numerator of which is the total volume
23 of domestic sales of that class of tobacco product in
24 the fiscal year ending on September 30 of that cal-
25 endar year; and

1 (2) the denominator of which is the total vol-
 2 ume of domestic sales of that class of tobacco prod-
 3 uct in fiscal year 2003.

4 (d) ALLOCATION OF TOTAL USER FEE AMOUNTS BY
 5 MARKET SHARE—

6 (1) FORMULA.—The user fee for each class of
 7 tobacco product to be paid by each manufacturer or
 8 importer of that class of tobacco product under sub-
 9 section (a) shall be determined in each year by
 10 multiplying—

11 (A) such manufacturer’s or importer’s
 12 market share, as calculated with respect to the
 13 current calendar year, of that class of tobacco
 14 product; by

15 (B) the total user fee amount for the cur-
 16 rent calendar year, as determined under sub-
 17 section (c), for that class of tobacco product.

18 (2) MARKET SHARE DEFINED.—In this sub-
 19 section, the term “market share” for each manufac-
 20 turer or importer of a class of tobacco product for
 21 the purpose of the assessment to be calculated in the
 22 current calendar year shall be equal to that manu-
 23 facturer’s or importer’s respective share (expressed
 24 as a decimal to the fourth place) of the total volume
 25 of domestic sales of that class of tobacco product

1 during the calendar year immediately preceding the
2 year of such assessment.

3 (e) DETERMINATION OF VOLUME OF DOMESTIC
4 SALES.— The calculation of the volume of domestic sales
5 of a class of tobacco product by a manufacturer or im-
6 porter, and by all manufacturers and importers as a
7 group, shall be made by the Secretary of Health and
8 Human Services based on certified reports submitted by
9 such manufacturers and importers pursuant to subsection
10 (f). For purposes of the Secretary's calculations under this
11 subsection and the certifications under subsection (f), the
12 volumes of domestic sales shall be measured, with respect
13 to cigarettes, in terms of the numbers of cigarettes sold,
14 or with respect to other classes of tobacco products, in
15 terms of such units as shall be specified by regulation by
16 the Secretary.

17 (f) CERTIFICATION OF VOLUME OF DOMESTIC
18 SALES.— Every manufacturer and importer of tobacco
19 products shall submit each year a certified report to the
20 Secretary of Health and Human Services setting forth for
21 each class of tobacco products the total, for the prior year,
22 of such manufacturer's or importer's domestic sales to
23 wholesalers and retailers and directly to consumers. These
24 certified reports must be submitted to the Secretary not

1 later than March 1 of the year after the year for which
2 the certified report is being made.

3 **SEC. 402. ALLOCATION OF USER FEES.**

4 (a) IN GENERAL.—The user fees collected pursuant
5 to section 401 and any funds transferred to the Secretary
6 of Health and Human Services by the Secretary of Agri-
7 culture pursuant to section 102(f)(3)(B) shall be available,
8 without further appropriation, in accordance with, and for
9 the purposes described, by this section. All such funds
10 shall remain available until expended.

11 (b) FUNDING FOR FDA REGULATION OF TOBACCO
12 PRODUCTS.—The Secretary of Health and Human Serv-
13 ices shall make 15 percent of the user fee amounts col-
14 lected pursuant to section 401 each year available to the
15 Food and Drug Administration for the regulation of to-
16 bacco products under chapter IX of the Federal Food,
17 Drug, and Cosmetic Act.

18 (c) FUNDING FOR OTHER TOBACCO-RELATED PRO-
19 GRAMS.—The Secretary of Health and Human Services
20 shall use the remaining 85 percent of the user fee amounts
21 collected each year pursuant to section 401 and any
22 amounts transferred to the Secretary by the Secretary of
23 Agriculture pursuant to section 102(f)(3)(B)—

1 (1) to reimburse the Commodity Credit Cor-
2 poration for the expenditures made by that agency
3 under title II of this Act; and

4 (2) to use the balance of such amounts, if any
5 such balance remains for any year after the reim-
6 bursement under paragraph (1), to fund any other
7 program that relates to tobacco products.

8 **TITLE V—FDA REGULATION OF**
9 **TOBACCO PRODUCTS**

10 **SEC. 501. FINDINGS.**

11 The Congress finds the following:

12 (1) The use of tobacco products by the Nation's
13 children is a pediatric disease of epic proportions
14 that results in new generations of tobacco-dependent
15 children and adults.

16 (2) A consensus exists within the scientific and
17 medical communities that tobacco products are in-
18 herently dangerous and cause cancer, heart disease,
19 and other serious adverse health effects.

20 (3) Nicotine is addictive.

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

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

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

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

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

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

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

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

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

9 (12) It is in the public interest for Congress to
10 adopt comprehensive public health legislation be-
11 cause of tobacco's unique position in the Nation's
12 history and economy and the need to prevent the
13 sale, distribution, marketing and advertising of to-
14 bacco products to persons under the minimum legal
15 age to purchase such products.

16 (13) The public interest requires a timely, fair,
17 equitable, and consistent result that will serve the
18 public interest by restricting throughout the Nation
19 the sale, distribution, marketing, and advertising of
20 tobacco products only to persons of legal age to pur-
21 chase such products.

22 (14) Public health authorities estimate that the
23 benefits to the Nation of enacting Federal legislation
24 to accomplish these goals would be significant in
25 human and economic terms.

1 (15) Reducing the use of tobacco by minors by
2 50 percent would prevent well over 60,000 early
3 deaths each year and save up to \$43 billion each
4 year in reduced medical costs, improved productivity,
5 and the avoidance of premature deaths.

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

13 (17) Tobacco advertising increases the size of
14 the tobacco market by increasing consumption of to-
15 bacco products including increasing tobacco use by
16 young people.

17 (18) Children are more influenced by tobacco
18 advertising than adults and they smoke the most ad-
19 vertised brands.

20 (19) Tobacco company documents indicate that
21 young people are an important and often crucial seg-
22 ment of the tobacco market.

23 (20) Advertising restrictions will have a positive
24 effect on the smoking rates of young people.

1 (21) Restrictions on advertising are necessary
 2 to prevent unrestricted tobacco advertising from un-
 3 dermining legislation prohibiting access to young
 4 people.

5 (22) It is in the public interest for Congress to
 6 adopt legislation to address the public health crisis
 7 created by actions of the tobacco industry.

8 **SEC. 502. DEFINITIONS.**

9 (a) **FEDERAL CIGARETTE LABELING AND ADVER-**
 10 **TISING ACT.**—Section 3(1) of the Federal Cigarette La-
 11 beling and Advertising Act is amended—

12 (1) in subparagraph (A) by striking “and”;

13 (2) in subparagraph (B) by striking the period
 14 and inserting “; and”; and

15 (3) by inserting the following new subparagraph
 16 at the end thereof:

17 “(C) any tobacco product, in any form, in-
 18 cluding bidis and kreteks, if the tobacco in the
 19 product is heated or burned and is functional in
 20 the product, and the product, because of its ap-
 21 pearance, the type of tobacco used in the filler,
 22 or its packaging and labeling, is likely to be of-
 23 fered to, or purchased by, consumers as a ciga-
 24 rette or as roll-your-own tobacco.”.

25 (b) **THIS TITLE.**—In this title:

1 (1) BRAND.—The term “brand” means a vari-
2 ety of tobacco product distinguished by the tobacco
3 used, tar content, nicotine content, flavoring used,
4 size, filtration, or packaging, logo, registered trade-
5 mark or brand name, identifiable pattern of colors,
6 or any combination of such attributes.

7 (2) CIGARETTE.—The term “cigarette” has the
8 meaning given that term by section 3(1) of the Fed-
9 eral Cigarette Labeling and Advertising Act (15
10 U.S.C. 1332(1)).

11 (3) CIGARETTE TOBACCO.—The term “cigarette
12 tobacco” means any product that consists of loose
13 tobacco that is intended for use by consumers in a
14 cigarette. Unless otherwise stated, the requirements
15 for cigarettes shall also apply to cigarette tobacco.

16 (4) COMMERCE.—The term “commerce” has
17 the meaning given that term by section 3(2) of the
18 Federal Cigarette Labeling and Advertising Act (15
19 U.S.C. 1332(2)).

20 (5) CONSTITUENT.—The term “constituent” in
21 relation to cigarettes means any element of main-
22 stream or sidestream smoke.

23 (6) DISTRIBUTOR.—The term “distributor” as
24 regards a tobacco product means any person who
25 furtheres the distribution of cigarette or smokeless to-

1 bacco, whether domestic or imported, at any point
2 from the original place of manufacture to the person
3 who sells or distributes the product to individuals for
4 personal consumption. Common carriers are not con-
5 sidered distributors for purposes of this title.

6 (7) INGREDIENT.—The term “ingredient” in
7 relation to cigarettes or smokeless tobacco products
8 means any substance, chemical, or compound (other
9 than tobacco, water, or reconstituted tobacco sheet
10 made wholly from tobacco) added, or specified for
11 addition, by the manufacturer to the tobacco, paper,
12 or filter of a cigarette, or to the tobacco of a smoke-
13 less tobacco product, including flavorants, processing
14 aids, casing sauces, preservatives, and combustion
15 modifiers.

16 (8) MANUFACTURER.—The term “manufac-
17 turer” means any person who manufactures tobacco
18 products intended to be sold in the United States.
19 The term “manufacturer” shall include an importer
20 or other first purchaser for resale in the United
21 States of tobacco products manufactured outside of
22 the United States or tobacco products manufactured
23 in the United States but not intended for sale in the
24 United States.

1 (9) NICOTINE.—The term “nicotine” means the
2 chemical substance named 3-(1-Methyl-2-
3 pyrrolidiny) pyridine or C[10]H[14]N[2], including
4 any salt or complex of nicotine.

5 (10) PACKAGE.—The term “package” means a
6 pack, box, carton, or container of any kind or, if no
7 other container, any wrapping (including cello-
8 phane), in which cigarettes or smokeless tobacco are
9 offered for sale, sold, or otherwise distributed to con-
10 sumers.

11 (11) RETAILER.—The term “retailer” means
12 any person who sells cigarettes or smokeless tobacco
13 to individuals for personal consumption, or who op-
14 erates a facility where self-service displays of tobacco
15 products are permitted.

16 (12) SECRETARY.—Except where the context
17 otherwise requires, the term “Secretary” means the
18 Secretary of Health and Human Services.

19 (13) SMOKELESS TOBACCO.—The term “smoke-
20 less tobacco” means any product that consists of
21 cut, ground, powdered, or leaf tobacco and that is
22 intended to be placed in the oral or nasal cavity.

1 **SEC. 503. AMENDMENT OF FEDERAL FOOD, DRUG, AND**
2 **COSMETIC ACT.**

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

6 “(kk) The term ‘tobacco product’ means any
7 product made or derived from tobacco that is in-
8 tended for human consumption, including any com-
9 ponent, part, or accessory of a tobacco product (ex-
10 cept for raw materials other than tobacco used in
11 manufacturing a component, part, or accessory of a
12 tobacco product).

13 “(ll) The definitions contained in section 502 of
14 the Tobacco Livelihood and Economic Assistance for
15 our Farmers Act of 2002 shall apply with respect to
16 chapter IX.”.

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

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

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

23 (3) by inserting after chapter VIII the fol-
24 lowing:

“CHAPTER IX—TOBACCO PRODUCTS

“SEC. 901. FDA AUTHORITY OVER TOBACCO PRODUCTS.

“(a) IN GENERAL.—Tobacco products shall be regulated by the Secretary under this chapter and shall not be subject to the provisions of chapter V, unless—

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

“(2) a health claim is made for such products under section 201(g)(1)(C) or 201(h)(3), unless the product is a reduced risk product pursuant to section 912.

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

“(c) SCOPE.—

“(1) Nothing in this chapter shall be construed to affect the Secretary’s authority over, or the regulation of, products under this Act that are not tobacco products under chapter V or any other chapter of this Act.

1 “(2) The provisions of this chapter shall not
2 apply to tobacco leaf that is not in the possession of
3 the manufacturer, or to the producers of tobacco
4 leaf, including tobacco growers, tobacco warehouses,
5 and tobacco grower cooperatives, nor shall any em-
6 ployee of the Food and Drug Administration have
7 any authority whatsoever to enter onto a farm
8 owned by a producer of tobacco leaf without the
9 written consent of such producer. Notwithstanding
10 any other provision of this subparagraph, if a pro-
11 ducer of tobacco leaf is also a tobacco product man-
12 ufacturer or controlled by a tobacco product manu-
13 facturer, the producer shall be subject to this chap-
14 ter in the producer’s capacity as a manufacturer.
15 Nothing in this chapter shall be construed to grant
16 the Secretary authority to promulgate regulations on
17 any matter that involves the production of tobacco
18 leaf or a producer thereof, other than activities by
19 a manufacturer affecting production. For purposes
20 of the preceding sentence, the term ‘controlled by’
21 means a member of the same controlled group of
22 corporations as that term is used in section 52(a) of
23 the Internal Revenue Code of 1986, or under com-
24 mon control within the meaning of the regulations
25 promulgated under section 52(b) of such Code.

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

2 “A tobacco product shall be deemed to be adulterated
3 if—

4 “(1) it consists in whole or in part of any filthy,
5 putrid, or decomposed substance, or is otherwise
6 contaminated by any poisonous or deleterious sub-
7 stance that may render the product more injurious
8 to health;

9 “(2) it has been prepared, packed, or held
10 under insanitary conditions whereby it may have
11 been contaminated with filth, or whereby it may
12 have been rendered more injurious to health;

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

17 “(4) it is, or purports to be or is represented
18 as, a tobacco product which is subject to a perform-
19 ance standard established under section 907 unless
20 such tobacco product is in all respects in conformity
21 with such standard;

22 “(5) it is required by section 910(a) to have
23 premarket approval, is not exempt under section
24 906(f), and does not have an approved application in
25 effect;

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

7 “(7) it is a tobacco product for which an ex-
8 emption has been granted under section 906(f) for
9 investigational use and the person who was granted
10 such exemption or any investigator who uses such
11 tobacco product under such exemption fails to com-
12 ply with a requirement prescribed by or under such
13 section.

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

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

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

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

21 “(A) the name and place of business of the
22 tobacco product manufacturer, packer, or dis-
23 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
10 to 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 print-
19 ed in type as required by the Secretary by regula-
20 tion;

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

1 its labeling conforms in all respects to such regula-
2 tions;

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

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

15 “(A) its advertising is false or misleading
16 in any particular; or

17 “(B) it is sold, distributed, advertised, or
18 promoted in violation of section 915 or regula-
19 tions prescribed under section 906(d);

20 “(8) unless, in the case of any tobacco product
21 distributed or offered for sale in any State, the man-
22 ufacturer, packer, or distributor thereof includes in
23 all advertisements and other descriptive printed mat-
24 ter issued or caused to be issued by the manufac-

1 turer, packer, or distributor with respect to that to-
2 bacco product—

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

6 “(B) a brief statement of—

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

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

21 “(9) unless, in the case of any tobacco product
22 distributed or offered for sale in any State, the man-
23 ufacturer, packer, or distributor thereof includes in
24 all advertisements the information required by sec-
25 tion 916(c);

1 “(10) if it is a tobacco product subject to a per-
2 formance standard established under section 907,
3 unless it bears such labeling as may be prescribed in
4 such performance standard; or

5 “(11) if there was a failure or refusal—

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

8 “(B) to furnish any material or informa-
9 tion required by or under section 909.

10 “(b) PRIOR APPROVAL OF STATEMENTS ON
11 LABEL.—The Secretary may, by regulation, require prior
12 approval of statements made on the label of a tobacco
13 product. No regulation issued under this subsection may
14 require prior approval by the Secretary of the content of
15 any advertisement and no advertisement of a tobacco
16 product, published after the date of enactment of this
17 chapter shall, with respect to the matters specified in this
18 section or covered by regulations issued hereunder, be sub-
19 ject to the provisions of sections 12 through 15 of the Fed-
20 eral Trade Commission Act (15 U.S.C. 52 through 55).
21 This subsection does not apply to any printed matter
22 which the Secretary determines to be labeling as defined
23 in section 201(m).

1 **“SEC. 904. SUBMISSION OF HEALTH INFORMATION TO THE**
2 **SECRETARY.**

3 “(a) REQUIREMENT.—Not later than 6 months after
4 the date of enactment of this chapter, each tobacco prod-
5 uct manufacturer or importer of tobacco products, or
6 agents thereof, shall submit to the Secretary the following
7 information:

8 “(1) A listing of all tobacco ingredients, sub-
9 stances and compounds that are, on such date,
10 added by the manufacturer to the tobacco, paper, fil-
11 ter, or other component of each tobacco product by
12 brand and by quantity in each brand and subbrand.

13 “(2) A description of the content, delivery, and
14 form of nicotine in each tobacco product measured
15 in milligrams of nicotine.

16 “(3) All documents (including underlying sci-
17 entific information) relating to research activities,
18 and research findings, conducted, supported, or pos-
19 sessed by the manufacturer (or agents thereof) on
20 the health, behavioral, or physiologic effects of to-
21 bacco products, their constituents, ingredients, and
22 components, and tobacco additives, described in
23 paragraph (1).

24 “(4) All documents (including underlying sci-
25 entific information) relating to research activities,
26 and research findings, conducted, supported, or pos-

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

6 “(5) All documents (including underlying sci-
7 entific information) relating to marketing research
8 involving the use of tobacco products.

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

12 “(b) ANNUAL SUBMISSION.—A tobacco product man-
13 ufacturer or importer that is required to submit informa-
14 tion under subsection (a) shall update such information
15 on an annual basis under a schedule determined by the
16 Secretary.

17 “(c) TIME FOR SUBMISSION.—

18 “(1) NEW PRODUCTS.—At least 90 days prior
19 to the delivery for introduction into interstate com-
20 merce of a tobacco product not on the market on the
21 date of enactment of this chapter, the manufacturer
22 of such product shall provide the information re-
23 quired under subsection (a) and such product shall
24 be subject to the annual submission under sub-
25 section (b).

1 “(2) MODIFICATION OF EXISTING PRODUCTS.—

2 If at any time a tobacco product manufacturer adds
3 to its tobacco products a new tobacco additive, in-
4 creases or decreases the quantity of an existing to-
5 bacco additive or the nicotine content, delivery, or
6 form, or eliminates a tobacco additive from any to-
7 bacco product, the manufacturer shall within 60
8 days of such action so advise the Secretary in writ-
9 ing and reference such modification in submissions
10 made under subsection (b).

11 **“SEC. 905. ANNUAL REGISTRATION.**

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

13 “(1) consistent with the provisions of section
14 901(c)(2), the term ‘manufacture, preparation,
15 compounding, or processing’ shall include repack-
16 aging or otherwise changing the container, wrapper,
17 or labeling of any tobacco product package in fur-
18 therance of the distribution of the tobacco product
19 from the original place of manufacture to the person
20 who makes final delivery or sale to the ultimate con-
21 sumer or user; and

22 “(2) the term ‘name’ shall include in the case
23 of a partnership the name of each partner and, in
24 the case of a corporation, the name of each cor-

1 porate officer and director, and the State of incorpo-
2 ration.

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

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

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

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

17 “(d) REGISTRATION OF ADDED ESTABLISHMENTS.—

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

24 “(e) UNIFORM PRODUCT IDENTIFICATION SYS-

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

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

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

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

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

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

11 “(i) REGISTRATION INFORMATION.—

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

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

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

16 “(C) if the registrant filing a list has de-
17 termined that a tobacco product contained in
18 such list is not subject to a performance stand-
19 ard established under section 907, a brief state-
20 ment of the basis upon which the registrant
21 made such determination if the Secretary re-
22 quests such a statement with respect to that
23 particular tobacco product.

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

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

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

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

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

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

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

14 “(j) REPORT PRECEDING INTRODUCTION OF CER-
15 TAIN SUBSTANTIALLY EQUIVALENT PRODUCTS INTO
16 INTERSTATE COMMERCE.—Each person who is required
17 to register under this section and who proposes to begin
18 the introduction or delivery for introduction into interstate
19 commerce for commercial distribution of a tobacco product
20 intended for human use that was not commercially mar-
21 keted (other than for test marketing) in the United States
22 as of the date of enactment of this chapter, as defined
23 by the Secretary by regulation shall, at least 90 days be-
24 fore making such introduction or delivery, report to the

1 Secretary (in such form and manner as the Secretary shall
2 by regulation prescribe)—

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

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

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

15 “(a) IN GENERAL.—Any requirement established by
16 or under section 902, 903, 905, or 909 applicable to a
17 tobacco product shall apply to such tobacco product until
18 the applicability of the requirement to the tobacco product
19 has been changed by action taken under section 907, sec-
20 tion 910, or subsection (d) of this section, and any re-
21 quirement established by or under section 902, 903, 905,
22 or 909 which is inconsistent with a requirement imposed
23 on such tobacco product under section 907, section 910,
24 or subsection (d) of this section shall not apply to such
25 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
4 notice which is published in the Federal Register with re-
5 spect to any other action taken under any such section
6 and which states the reasons for such action, and each
7 publication of findings required to be made in connection
8 with rulemaking under any such section shall set forth—

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

12 “(2) the period within which interested persons
13 may present their comments on the notice or find-
14 ings (including the need thereof) 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
17 Secretary by a notice published in the Federal Reg-
18 ister stating good cause therefor.

19 “(c) LIMITED CONFIDENTIALITY OF INFORMA-
20 TION.—Any information reported to or otherwise obtained
21 by the Secretary or the Secretary’s representative under
22 section 904, 905, 907, 908, 909, 910, 912, or 704, or
23 under subsection (e) or (f) of this section, which is exempt
24 from disclosure under subsection (a) of section 552 of title
25 5, United States Code, by reason of subsection (b)(4) of

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

6 “(d) RESTRICTIONS.—

7 “(1) The Secretary may by regulation require
8 that a tobacco product be restricted to sale or dis-
9 tribution upon such conditions, including restrictions
10 on the access to, and the advertising and promotion
11 of, the tobacco product, as the Secretary may pre-
12 scribe in such regulation if the Secretary determines
13 that such regulation would be appropriate for the
14 prevention of, or decrease in, the use of tobacco
15 products by children under the age at which tobacco
16 products may be legally purchased. No such condi-
17 tion may require that the sale or distribution of a
18 tobacco product be limited to the written or oral au-
19 thorization of a practitioner licensed by law to pre-
20 scribe medical products.

21 “(2) The label of a tobacco product shall bear
22 such appropriate statements of the restrictions re-
23 quired by a regulation under subsection (a) as the
24 Secretary may in such regulation prescribe.

1 “(3) No restriction under paragraph (1) may
2 prohibit the sale of any tobacco product in face-to-
3 face transactions by a specific category of retail out-
4 lets.

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

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

9 “(A) The Secretary may, in accordance
10 with subparagraph (B), prescribe regulations
11 requiring that the methods used in, and the fa-
12 cilities and controls used for, the manufacture,
13 pre-production design validation (including a
14 process to assess the performance of a tobacco
15 product), packing and storage of a tobacco
16 product, conform to current good manufac-
17 turing practice for an agricultural product, as
18 prescribed in such regulations, to assure that
19 the public health is protected and that the to-
20 bacco product is in compliance with this chap-
21 ter.

22 “(B) The Secretary shall—

23 “(i) before promulgating any regula-
24 tion under subparagraph (A), afford an ad-
25 visory committee an opportunity to submit

1 recommendations with respect to the regu-
2 lation proposed to be promulgated;

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

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

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

22 “(2) EXEMPTIONS; VARIANCES.—

23 “(A) Any person subject to any require-
24 ment prescribed under paragraph (1) may peti-
25 tion the Secretary for a permanent or tem-

1 porary exemption or variance from such re-
2 quirement. Such a petition shall be submitted
3 to the Secretary in such form and manner as
4 the Secretary shall prescribe and shall—

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

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

20 “(iii) contain such other information
21 as the Secretary shall prescribe.

22 “(B) The Secretary may refer to an advi-
23 sory committee any petition submitted under
24 subparagraph (A). The advisory committee
25 shall report its recommendations to the Sec-

1 retary with respect to a petition referred to it
2 within 60 days after the date of the petition's
3 referral. Within 60 days after—

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

7 “(ii) the day after the petition was re-
8 ferred to an advisory committee,
9 whichever occurs later, the Secretary shall by
10 order either deny the petition or approve it.

11 “(C) The Secretary may approve—

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

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

1 assure that the tobacco product will be in
2 compliance with this chapter.

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

12 “(E) After the issuance of an order under
13 subparagraph (B) respecting a petition, the pe-
14 titioner shall have an opportunity for an infor-
15 mal hearing on such order.

16 “(f) EXEMPTION FOR INVESTIGATIONAL USE.—The
17 Secretary may exempt tobacco products intended for in-
18 vestigational use from this chapter under such conditions
19 as the Secretary may prescribe by regulation.

20 “(g) RESEARCH AND DEVELOPMENT.—The Sec-
21 retary may enter into contracts for research, testing, and
22 demonstrations respecting tobacco products and may ob-
23 tain tobacco products for research, testing, and dem-
24 onstration purposes without regard to section 3324(a) and

1 (b) of title 31, United States Code, and section 5 of title
2 41, United States Code.

3 **“SEC. 907. PERFORMANCE STANDARDS.**

4 “(a) IN GENERAL.—

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

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

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

19 “(2) CONTENT OF PERFORMANCE STAND-
20 ARDS.—A performance standard established under
21 this section for a tobacco product—

22 “(A) shall include provisions to provide
23 performance that is appropriate for the protec-
24 tion of the public health, including provisions,
25 where appropriate—

1 “(i) for the reduction of nicotine
2 yields of the product;

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

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

8 “(B) shall, where necessary to be appro-
9 priate for the protection of the public health,
10 include—

11 “(i) provisions respecting the con-
12 struction, components, ingredients, and
13 properties of the tobacco product;

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

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

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

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

3 “(C) shall not render the tobacco product
4 unacceptable for adult consumption.

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

13 “(4) INVOLVEMENT OF OTHER AGENCIES; IN-
14 FORMED PERSONS.—In carrying out duties under
15 this section, the Secretary shall, to the maximum ex-
16 tent practicable—

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

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

24 “(C) invite appropriate participation,
25 through joint or other conferences, workshops,

1 or other means, by informed persons represent-
2 ative of scientific, professional, industry, or con-
3 sumer organizations who in the Secretary's
4 judgment can make a significant contribution.

5 “(b) ESTABLISHMENT OF STANDARDS.—

6 “(1) NOTICE.—

7 “(A) The Secretary shall publish in the
8 Federal Register a notice of proposed rule-
9 making for the establishment, amendment, or
10 revocation of any performance standard for a
11 tobacco product.

12 “(B) A notice of proposed rulemaking for
13 the establishment or amendment of a perform-
14 ance standard for a tobacco product shall—

15 “(i) set forth a finding with sup-
16 porting justification that the performance
17 standard is appropriate for the protection
18 of the public health;

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

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

1 proposed performance standard, for consid-
2 eration by the Secretary.

3 “(C) A notice of proposed rulemaking for
4 the revocation of a performance standard shall
5 set forth a finding with supporting justification
6 that the performance standard is no longer nec-
7 essary to be appropriate for the protection of
8 the public health.

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

22 “(E) The Secretary shall provide for a
23 comment period of not less than 60 days.

24 “(2) PROMULGATION.—

1 “(A) After the expiration of the period for
2 comment on a notice of proposed rulemaking
3 published under paragraph (1) respecting a per-
4 formance standard and after consideration of
5 such comments and any report from an advi-
6 sory committee, the Secretary shall—

7 “(i) promulgate a regulation estab-
8 lishing a performance standard and pub-
9 lish in the Federal Register findings on the
10 matters referred to in paragraph (1); or

11 “(ii) publish a notice terminating the
12 proceeding for the development of the
13 standard together with the reasons for
14 such termination.

15 “(B) A regulation establishing a perform-
16 ance standard shall set forth the date or dates
17 upon which the standard shall take effect, but
18 no such regulation may take effect before one
19 year after the date of its publication unless the
20 Secretary determines that an earlier effective
21 date is necessary for the protection of the pub-
22 lic health. Such date or dates shall be estab-
23 lished so as to minimize, consistent with the
24 public health, economic loss to, and disruption

1 or dislocation of, domestic and international
2 trade.

3 “(3) POWER RESERVED TO CONGRESS.—Be-
4 cause of the importance of any decision to issue a
5 regulation establishing a performance standard—

6 “(A) eliminating all cigarettes, all smoke-
7 less tobacco products, or any similar class of to-
8 bacco products, or

9 “(B) requiring the reduction of nicotine
10 yields of a tobacco product to zero,
11 Congress expressly reserves to itself the power to
12 make such a decision.

13 “(4) AMENDMENT; REVOCATION.—

14 “(A) The Secretary, upon the Secretary’s
15 own initiative or upon petition of an interested
16 person may by a regulation, promulgated in ac-
17 cordance with the requirements of paragraphs
18 (1) and (2)(B) of this subsection, amend or re-
19 voke a performance standard.

20 “(B) The Secretary may declare a pro-
21 posed amendment of a performance standard to
22 be effective on and after its publication in the
23 Federal Register and until the effective date of
24 any final action taken on such amendment if

1 the Secretary determines that making it so ef-
2 fective is in the public interest.

3 “(5) REFERENCE TO ADVISORY COMMITTEE.—

4 The Secretary—

5 “(A) may, on the Secretary’s own initia-
6 tive, refer a proposed regulation for the estab-
7 lishment, amendment, or revocation of a per-
8 formance standard; or

9 “(B) shall, upon the request of an inter-
10 ested person which demonstrates good cause for
11 referral and which is made before the expiration
12 of the period for submission of comments on
13 such proposed regulation,

14 refer such proposed regulation to an advisory com-
15 mittee, for a report and recommendation with re-
16 spect to any matter involved in the proposed regula-
17 tion which requires the exercise of scientific judg-
18 ment. If a proposed regulation is referred under this
19 subparagraph to the advisory committee, the Sec-
20 retary shall provide the advisory committee with the
21 data and information on which such proposed regu-
22 lation is based. The advisory committee shall, within
23 60 days after the referral of a proposed regulation
24 and after independent study of the data and infor-
25 mation furnished to it by the Secretary and other

1 data and information before it, submit to the Sec-
2 retary a report and recommendation respecting such
3 regulation, together with all underlying data and in-
4 formation and a statement of the reason or basis
5 for the recommendation. A copy of such report and
6 recommendation shall be made public by the Sec-
7 retary.

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

9 “(a) NOTIFICATION.—If the Secretary determines
10 that—

11 “(1) a tobacco product which is introduced or
12 delivered for introduction into interstate commerce
13 for commercial distribution presents a risk of sub-
14 stantial harm to the public health exceeding the
15 risks posed by tobacco products marketed before the
16 date of enactment of this chapter; and

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

22 the Secretary may issue such order as may be necessary
23 to assure that adequate notification is provided in an ap-
24 propriate form, by the persons and means best suited
25 under the circumstances involved, to all persons who

1 should properly receive such notification in order to elimi-
2 nate such risk. The Secretary may order notification by
3 any appropriate means, including public service announce-
4 ments. Before issuing an order under this subsection, the
5 Secretary shall consult with the persons who are to give
6 notice under the order.

7 “(b) NO EXEMPTION FROM OTHER LIABILITY.—
8 Compliance with an order issued under this section shall
9 not relieve any person from liability under Federal or
10 State law.

11 “(c) RECALL AUTHORITY.—

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

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

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

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

20 “(B) An amended order under subpara-
21 graph (A)—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

19 (1) Except as provided in paragraph (3), the
20 Secretary shall by regulation require a tobacco prod-
21 uct manufacturer or importer of a tobacco product
22 to report promptly to the Secretary any corrective
23 action taken or removal from the market of a to-
24 bacco product undertaken by such manufacturer or

1 importer if the removal or correction was
2 undertaken—

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

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

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

13 “(2) No report of the corrective action or re-
14 moval of a tobacco product may be required under
15 paragraph (1) if a report of the corrective action or
16 removal is required and has been submitted under
17 subsection (a) of this section.

18 **“SEC. 910. PREMARKET REVIEW OF CERTAIN TOBACCO**
19 **PRODUCTS.**

20 “(a) IN GENERAL.—

21 “(1) PREMARKET APPROVAL REQUIRED.—Ap-
22 proval under this section of an application for pre-
23 market approval for any tobacco product, other than
24 a reduced risk product under section 912, that is not
25 commercially marketed (other than for test mar-

1 keting) in the United States as of the date of this
2 chapter's enactment, is required unless the manufac-
3 turer has submitted a report under section 905(j),
4 and the Secretary has not suspended the distribution
5 of such product under this paragraph. Within 90
6 days of the submission of a report under section
7 905(j), the Secretary may by order suspend the dis-
8 tribution of the tobacco product that is the subject
9 of that report if the Secretary determines that there
10 is a reasonable likelihood that the tobacco product is
11 not substantially equivalent to a tobacco product
12 commercially marketed (other than for test mar-
13 keting) in the United States as of the date of this
14 chapter's enactment, that is in compliance with the
15 requirements of this Act. If the Secretary fails to
16 issue an order within this 90-day period, then the
17 tobacco product that is the subject of that report
18 shall be deemed to be substantially equivalent to a
19 predicate tobacco product. The issuance of an order
20 under this paragraph shall constitute final agency
21 action for purposes of section 702 of title 5, the
22 United States Code; provided, that the Secretary
23 may rescind or modify an order issued under this
24 paragraph at any time.

25 “(2) SUBSTANTIALLY EQUIVALENT DEFINED.—

1 “(A) For purposes of this section and sec-
2 tion 905(j), the term ‘substantially equivalent’
3 or ‘substantial equivalence’ mean, with respect
4 to the tobacco product being compared to the
5 predicate tobacco product, that the Secretary by
6 order has found that the tobacco product—

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

9 “(ii) has different characteristics and
10 the information submitted contains infor-
11 mation, including clinical data if deemed
12 necessary by the Secretary, that dem-
13 onstrates that it is not appropriate to reg-
14 ulate the product under this section be-
15 cause the product could not reasonably be
16 expected to increase the health risks to
17 consumers compared to a conventional to-
18 bacco product that is commercially mar-
19 keted in the United States and that is in
20 compliance with the requirements of this
21 Act.

22 “(B) For purposes of subparagraph (A),
23 the term ‘characteristics’ means the materials,
24 ingredients, design, composition, heating source,
25 or other features of a tobacco product.

1 “(C) A tobacco product may not be found
2 to be substantially equivalent to a predicate to-
3 bacco product that has been removed from the
4 market at the initiative of the Secretary or that
5 has been determined by a judicial order to be
6 misbranded or adulterated.

7 “(3) HEALTH INFORMATION.—

8 “(A) As part of a submission under section
9 905(j) respecting a tobacco product, the person
10 required to file a premarket notification under
11 such section shall provide an adequate summary
12 of any health information related to the tobacco
13 product or state that such information will be
14 made available upon request by any person.

15 “(B) Any summary under subparagraph
16 (A) respecting a tobacco product shall contain
17 detailed information regarding data concerning
18 adverse health effects and shall be made avail-
19 able to the public by the Secretary within 30
20 days of the issuance of a determination that
21 such tobacco product is substantially equivalent
22 to another tobacco product. The communication
23 that such product is a reduced risk product
24 may comply with requirements prescribed by
25 the Secretary relating to such communication,

1 and the Secretary may require prior approval
2 of the communication, in each case in accord-
3 ance with section 912.

4 “(b) APPLICATION.—

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

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

14 “(B) a full statement of the components,
15 ingredients, and properties, and of the principle
16 or principles of operation, of such tobacco prod-
17 uct;

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

23 “(D) an identifying reference to any per-
24 formance standard under section 907 which
25 would be applicable to any aspect of such to-

1 bacco product, and either adequate information
2 to show that such aspect of such tobacco prod-
3 uct fully meets such performance standard or
4 adequate information to justify any deviation
5 from such standard;

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

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

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

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

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

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

21 refer such application to an advisory committee and
22 for submission (within such period as the Secretary
23 may establish) of a report and recommendation re-
24 specting approval of the application, together with

1 all underlying data and the reasons or basis for the
2 recommendation.

3 “(c) ACTION ON APPLICATION.—

4 “(1) DEADLINE.—

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

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

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

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

1 the extent that the sale and distribution of a
2 tobacco product may be restricted under a regu-
3 lation under section 906(d).

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

11 “(A) there is a lack of a showing that per-
12 mitting such tobacco product to be marketed
13 would pose no greater risk to the public health
14 than currently marketed tobacco products;

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

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

23 “(D) such tobacco product is not shown to
24 conform in all respects to a performance stand-
25 ard in effect under section 907, compliance with

1 which is a condition to approval of the applica-
2 tion, and there is a lack of adequate informa-
3 tion to justify the deviation from such standard.

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

12 “(4) BASIS FOR ACTION.—

13 “(A) For purposes of paragraph (2)(A),
14 whether permitting a tobacco product to be
15 marketed would be appropriate for the protec-
16 tion of the public health shall, when appro-
17 priate, be determined on the basis of well-con-
18 trolled investigations, which may include one or
19 more clinical investigations by experts qualified
20 by training and experience to evaluate the to-
21 bacco product.

22 “(B) If the Secretary determines that
23 there exists valid scientific evidence (other than
24 evidence derived from investigations described
25 in subparagraph (A)) which is sufficient to

1 evaluate the tobacco product the Secretary may
2 authorize that the determination for purposes
3 of paragraph (2)(A) be made on the basis of
4 such evidence.

5 “(d) WITHDRAWAL AND TEMPORARY SUSPENSION.—

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

13 “(A) that the continued marketing of such
14 tobacco product poses greater risks to the pub-
15 lic health than other available products;

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

19 “(C) that the applicant—

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

1 “(ii) has refused to permit access to,
2 or copying or verification of, such records
3 as required by section 704; or

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

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

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

1 able time after receipt of written notice from
2 the Secretary of such fact; or

3 “(F) on the basis of new information be-
4 fore the Secretary, evaluated together with the
5 evidence before the Secretary when the applica-
6 tion was approved, that such tobacco product is
7 not shown to conform in all respects to a per-
8 formance standard which is in effect under sec-
9 tion 907, compliance with which was a condi-
10 tion to approval of the application, and that
11 there is a lack of adequate information to jus-
12 tify the deviation from such standard.

13 “(2) APPEAL.—The holder of an application
14 subject to an order issued under paragraph (1) with-
15 drawing approval of the application may, by petition
16 filed on or before the thirtieth day after the date
17 upon which he receives notice of such withdrawal,
18 obtain review thereof in accordance with subsection
19 (e) of this section.

20 “(3) TEMPORARY SUSPENSION.—If, after pro-
21 viding an opportunity for an informal hearing, the
22 Secretary determines there is reasonable probability
23 that the continuation of distribution of a tobacco
24 product under an approved application would cause
25 serious, adverse health consequences or death, that

1 is greater than ordinarily caused by tobacco prod-
2 ucts on the market, the Secretary shall by order
3 temporarily suspend the approval of the application
4 approved under this section. If the Secretary issues
5 such an order, the Secretary shall proceed expedi-
6 tiously under paragraph (1) to withdraw such appli-
7 cation.

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

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

12 “(2) by mailing the order by registered mail or
13 certified mail addressed to the applicant at the ap-
14 plicant’s last known address in the records of the
15 Secretary.

16 **“SEC. 911. JUDICIAL REVIEW.**

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

18 “(1) the promulgation of a regulation under
19 section 907 establishing, amending, or revoking a
20 performance standard for a tobacco product; or

21 “(2) a denial of an application for approval
22 under section 910(c),

23 any person adversely affected by such regulation or order
24 may file a petition with the United States Court of Ap-
25 peals for the District of Columbia or for the circuit where-

1 in such person resides or has his principal place of busi-
2 ness for judicial review of such regulation or order. A copy
3 of the petition shall be transmitted by the clerk of the
4 court to the Secretary or other officer designated by the
5 Secretary for that purpose. The Secretary shall file in the
6 court the record of the proceedings on which the Secretary
7 based the Secretary's regulation or order and each record
8 or order shall contain a statement of the reasons for its
9 issuance and the basis, on the record, for its issuance. For
10 purposes of this section, the term 'record' means all no-
11 tices and other matter published in the Federal Register
12 with respect to the regulation or order reviewed, all infor-
13 mation submitted to the Secretary with respect to such
14 regulation or order, proceedings of any panel or advisory
15 committee with respect to such regulation or order, any
16 hearing held with respect to such regulation or order, and
17 any other information identified by the Secretary, in the
18 administrative proceeding held with respect to such regu-
19 lation or order, as being relevant to such regulation or
20 order.

21 “(b) COURT MAY ORDER SECRETARY TO MAKE AD-
22 DITIONAL FINDINGS.—If the petitioner applies to the
23 court for leave to adduce additional data, views, or argu-
24 ments respecting the regulation or order being reviewed
25 and shows to the satisfaction of the court that such addi-

1 tional data, views, or arguments are material and that
2 there were reasonable grounds for the petitioner's failure
3 to adduce such data, views, or arguments in the pro-
4 ceedings before the Secretary, the court may order the
5 Secretary to provide additional opportunity for the oral
6 presentation of data, views, or arguments and for written
7 submissions. The Secretary may modify the Secretary's
8 findings, or make new findings by reason of the additional
9 data, views, or arguments so taken and shall file with the
10 court such modified or new findings, and the Secretary's
11 recommendation, if any, for the modification or setting
12 aside of the regulation or order being reviewed, with the
13 return of such additional data, views, or arguments.

14 “(c) STANDARD OF REVIEW.—Upon the filing of the
15 petition under subsection (a) of this section for judicial
16 review of a regulation or order, the court shall have juris-
17 diction to review the regulation or order in accordance
18 with chapter 7 of title 5, United States Code, and to grant
19 appropriate relief, including interim relief, as provided in
20 such chapter. A regulation or order described in paragraph
21 (1) or (2) of subsection (a) of this section shall not be
22 affirmed if it is found to be unsupported by substantial
23 evidence on the record taken as a whole.

24 “(d) FINALITY OF JUDGMENT.—The judgment of the
25 court affirming or setting aside, in whole or in part, any

1 regulation or order shall be final, subject to review by the
2 Supreme Court of the United States upon certiorari or
3 certification, as provided in section 1254 of title 28,
4 United States Code.

5 “(e) OTHER REMEDIES.—The remedies provided for
6 in this section shall be in addition to and not in lieu of
7 any other remedies provided by law.

8 “(f) REGULATIONS AND ORDERS MUST RECITE
9 BASIS IN RECORD.—To facilitate judicial review under
10 this section or under any other provision of law of a regu-
11 lation or order issued under section 906, 907, 908, 909,
12 910, or 913, each such regulation or order shall contain
13 a statement of the reasons for its issuance and the basis,
14 in the record of the proceedings held in connection with
15 its issuance, for its issuance.

16 **“SEC. 912. REDUCED RISK TOBACCO PRODUCTS.**

17 “(a) REQUIREMENTS.—

18 “(1) IN GENERAL.—For purposes of this sec-
19 tion, the term ‘reduced risk tobacco product’ means
20 a tobacco product designated by the Secretary under
21 paragraph (2).

22 “(2) DESIGNATION.—

23 “(A) IN GENERAL.—A product may be
24 designated by the Secretary as a reduced risk
25 tobacco product if the Secretary finds that the

1 product is demonstrated to significantly reduce
2 harm to individuals caused by a tobacco prod-
3 uct and is otherwise appropriate to protect pub-
4 lic health, based on an application submitted by
5 the manufacturer of the product (or other re-
6 sponsible person) that—

7 “(i)(I) demonstrates through testing
8 on animals and short-term human testing
9 that use of such product results in inges-
10 tion or inhalation of a substantially lower
11 yield of toxic substances than use of an-
12 other tobacco product in the same or dif-
13 ferent category as the proposed reduced
14 risk product; or

15 “(II) contains scientific evidence
16 showing that use of such product results in
17 a substantially lower potential risk to
18 health in one or more specific respects
19 than use of another tobacco product in the
20 same or different category as the proposed
21 reduced risk product; and

22 “(ii) if required by the Secretary, in-
23 cludes studies of the long-term health ef-
24 fects of the product.

1 If such studies are required, the manufacturer
2 may consult with the Secretary regarding proto-
3 cols for conducting the studies.

4 “(B) BASIS FOR FINDING.—In making the
5 finding under subparagraph (A), the Secretary
6 shall take into account—

7 “(i) the risks and benefits to the pop-
8 ulation as a whole, including both users of
9 tobacco products and non-users of tobacco
10 products;

11 “(ii) the increased or decreased likeli-
12 hood that existing users of tobacco prod-
13 ucts will stop using such products includ-
14 ing reduced risk tobacco products;

15 “(iii) the increased or decreased likeli-
16 hood that those who do not use tobacco
17 products will start to use such products,
18 including reduced risk tobacco products;
19 and

20 “(iv) the risks and benefits to con-
21 sumers from the use of a reduced risk to-
22 bacco product as compared to the use of
23 products approved under chapter V to re-
24 duce exposure to tobacco.

1 “(3) MARKETING REQUIREMENTS.—A tobacco
2 product may be marketed and labeled as a reduced
3 risk tobacco product if it—

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

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

10 “(C) complies with requirements prescribed
11 by the Secretary relating to marketing and ad-
12 vertising of the product, and other provisions of
13 this chapter as prescribed by the Secretary, al-
14 though in no event shall such requirements pro-
15 hibit the communication that such product is a
16 reduced risk product. The communication that
17 such product is a reduced risk product may
18 comply with requirements prescribed by the
19 Secretary relating to such communication, and
20 the Secretary may require prior approval of the
21 communication.

22 “(b) REVOCATION OF DESIGNATION.—At any time
23 after the date on which a tobacco product is designated
24 as a reduced risk tobacco product under this section the
25 Secretary may, after providing an opportunity for an in-

1 formal hearing, revoke such designation if the Secretary
2 determines, based on information not available at the time
3 of the designation, that—

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

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

8 “(c) LIMITATION.—A tobacco product that is des-
9 ignated as a reduced risk tobacco product that is in com-
10 pliance with subsection (a) shall not be regulated as a
11 drug or device.

12 “(d) DEVELOPMENT OF REDUCED RISK TOBACCO
13 PRODUCT TECHNOLOGY.—A tobacco product manufac-
14 turer shall provide written notice to the Secretary upon
15 the development or acquisition by the manufacturer of any
16 technology that would reduce the risk of a tobacco product
17 to the health of the user for which the manufacturer is
18 not seeking designation as a ‘reduced risk tobacco product’
19 under subsection (a).

20 “(e) POSTMARKET SURVEILLANCE.—

21 “(1) DISCRETIONARY SURVEILLANCE.—The
22 Secretary may require a tobacco product manufac-
23 turer to conduct postmarket surveillance for reduced
24 risk a tobacco product of the manufacturer if the
25 Secretary determines that postmarket surveillance of

1 the tobacco product is necessary to protect the pub-
2 lic health or is necessary to provide information re-
3 garding the health risks and other safety issues in-
4 volving the tobacco product.

5 “(2) SURVEILLANCE APPROVAL.—Each tobacco
6 product manufacturer required to conduct a surveil-
7 lance of a reduced risk tobacco product under para-
8 graph (1) shall, within 30 days after receiving notice
9 that the manufacturer is required to conduct such
10 surveillance, submit, for the approval of the Sec-
11 retary, a protocol for the required surveillance. The
12 Secretary, within 60 days of the receipt of such pro-
13 tocol, shall determine if the principal investigator
14 proposed to be used in the surveillance has sufficient
15 qualifications and experience to conduct such sur-
16 veillance and if such protocol will result in collection
17 of useful data or other information necessary to pro-
18 tect the public health. The Secretary may not ap-
19 prove such a protocol until it has been reviewed by
20 an appropriately qualified scientific and technical re-
21 view committee established by the Secretary.

22 **“SEC. 913. PRESERVATION OF STATE AND LOCAL AUTHOR-**
23 **ITY.**

24 “(a) ADDITIONAL REQUIREMENTS.—

1 “(1) IN GENERAL.—Except as provided in para-
2 graph (2), nothing in this Act shall be construed as
3 prohibiting a State or political subdivision thereof
4 from adopting or enforcing a requirement applicable
5 to a tobacco product that is in addition to, or more
6 stringent than, requirements established under this
7 chapter.

8 “(2) PREEMPTION OF CERTAIN STATE AND
9 LOCAL REQUIREMENTS.—

10 “(A) Except as provided in subparagraph
11 (B), no State or political subdivision of a State
12 may establish or continue in effect with respect
13 to a tobacco product any requirement which is
14 different from, or in addition to, any require-
15 ment applicable under the provisions of this
16 chapter relating to performance standards, pre-
17 market approval, adulteration, misbranding,
18 registration, labeling, good manufacturing
19 standards, or reduced risk products.

20 “(B) Subparagraph (A) does not apply to
21 requirements relating to the sale, use, or dis-
22 tribution of a tobacco product including require-
23 ments related to the access to, and the adver-
24 tising and promotion of, a tobacco product.

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

6 **“SEC. 914. EQUAL TREATMENT OF RETAIL OUTLETS.**

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

12 **“SEC. 915. ACCESS AND MARKETING RESTRICTIONS.**

13 “(a) DEFINITIONS.—For purposes of this section, the
 14 following definitions apply:

15 “(1) ADULT.—The term ‘adult’ means any per-
 16 son who is older than the minimum age at which it
 17 is legal to purchase or possess (whichever minimum
 18 age is older) tobacco products.

19 “(2) ADULT-ONLY FACILITY.—The term ‘adult-
 20 only facility’ means a facility or restricted area
 21 (whether open-air or enclosed) where the operator
 22 ensures or has a reasonable basis to believe (such as
 23 by checking identification as required under state
 24 law, or by checking the identification of any person
 25 appearing to be under the age of 27) that only

1 adults are present. A facility or restricted area need
2 not be permanently restricted to adults in order to
3 constitute an adult-only facility, provided that the
4 operator ensures or has a reasonable basis to believe
5 that only adults are present during the event or time
6 period in question.

7 “(3) BRAND NAME.—The term ‘brand name’
8 means a brand name (alone or in conjunction with
9 any other word), trademark, logo, symbol, motto,
10 selling message, recognizable pattern of colors, or
11 any other indicia of product identification identical
12 or similar to, or identifiable with, those used for any
13 domestic brand of tobacco products. The term
14 ‘brand name’ shall not include the corporate name
15 of any tobacco product manufacturer that does not
16 after the date of the enactment of this chapter sell
17 a brand of tobacco products in the United States
18 that includes such corporate name.

19 “(b) CIGARETTE AND SMOKELESS TOBACCO PROD-
20 UCT REQUIREMENTS.—

21 “(1) MINIMUM SALES AGE.—No retailer may
22 sell a tobacco product to any person younger than
23 18 years of age.

24 “(2) PROOF OF AGE.—

1 “(A) Except as otherwise provided in sub-
2 paragraph (B), each retailer shall verify by
3 means of photographic identification containing
4 the bearer’s date of birth that no person pur-
5 chasing the product is younger than 18 years of
6 age.

7 “(B) No such verification is required for
8 any person over the age of 26.

9 “(3) ENFORCEMENT BY THE STATES.—The
10 Secretary may enter into an agreement with any
11 State which has in effect a State law that is at least
12 as restrictive as this subsection, whereby such State
13 agrees to enforce such State law in a manner rea-
14 sonably designed to prevent its violation and the
15 Secretary provides a grant to such State for the pur-
16 pose of enforcing such State law. No action taken by
17 the Secretary pursuant to this paragraph shall be
18 construed to limit the authority of the Secretary
19 under this subsection.

20 “(4) MAIL ORDER SALES.—After two years
21 from the date of enactment of this chapter, the Sec-
22 retary shall transmit to Congress a report describing
23 the extent, if any, to which individuals younger than
24 18 years of age are obtaining tobacco products
25 through the mail.

1 “(c) MINIMUM PACKAGE SIZE REQUIREMENTS.—

2 “(1) No manufacturer, distributor, or retailer
3 may sell or cause to be sold, or distribute or cause
4 to be distributed, any cigarette package that con-
5 tains fewer than 20 cigarettes.

6 “(2) No retailer may break or otherwise open
7 any tobacco product package to sell or distribute in-
8 dividual cigarettes or a number of unpackaged ciga-
9 rettes that is smaller than the quantity in the min-
10 imum cigarette package size provided in paragraph
11 (1), or any quantity of another tobacco product that
12 is smaller than the smallest package distributed by
13 the manufacturer for individual consumer use.

14 “(d) BAN ON YOUTH ACCESS TO FREE SAMPLES.—

15 “(1) No manufacturer, distributor, or retailer
16 may distribute or cause to be distributed any free
17 samples of tobacco products, except in an adult-only
18 facility.

19 “(2) For purposes of this subsection, a ‘free
20 sample’ does not include a tobacco product that is
21 provided to an adult in connection with—

22 “(A) the purchase, exchange or redemption
23 for proof of purchase of any tobacco products
24 (including, but not limited to, a free offer in

1 connection with the purchase of tobacco prod-
2 ucts, such as a ‘two-for-one’ offer), or

3 “(B) the conducting of consumer testing or
4 evaluation of tobacco products with persons who
5 certify that they are adults.

6 “(e) VENDING MACHINES, SELF-SERVICE DISPLAYS,
7 MAIL-ORDER SALES, AND OTHER ‘IMPERSONAL’ MODES
8 OF SALE.—

9 “(1) Except as otherwise provided in paragraph
10 (2), a retailer may sell a tobacco product only in a
11 direct, face-to-face exchange between the retailer and
12 the consumer. Examples of methods of sale that are
13 not permitted include vending machines and self-
14 service displays.

15 “(2) The following methods of sale are per-
16 mitted under this subsection:

17 “(A) Mail-order sales, excluding mail-order
18 redemption of coupons and distribution of free
19 samples through the mail.

20 “(B) Vending machines that are located in
21 an adult-only facility.

22 “(3) For purposes of this section, a ‘self-serv-
23 ice’ display means any display where the customer
24 has access to the tobacco products without the aid
25 of a sales clerk.

1 “(f) PROHIBITION ON YOUTH TARGETING.—No
2 manufacturer, distributor, or retailer may take any action,
3 directly or indirectly, to target youth in the advertising,
4 promotion, or marketing of tobacco products, or take any
5 action the primary purpose of which is to initiate, main-
6 tain, or increase the incidence of youth smoking. For pur-
7 poses of this subsection, the term ‘youth’ means any per-
8 son or persons under 18 years of age.

9 “(g) BAN ON USE OF CARTOONS.—

10 “(1) No manufacturer, distributor, or retailer
11 may use or cause to be used any cartoon in the ad-
12 vertising, promoting, packaging, or labeling of to-
13 bacco products.

14 “(2) For purposes of this subsection, the term
15 ‘cartoon’ means any drawing or other depiction of
16 an object, person, animal, creature, or any similar
17 caricature that satisfies any of the following criteria:

18 “(A) The use of comically exaggerated fea-
19 tures;

20 “(B) The attribution of human character-
21 istics to animals, plants, or other objects, or the
22 similar use of anthropomorphic technique.

23 “(C) The attribution of unnatural or
24 extrahuman abilities, such as imperviousness to

1 pain or injury, X-ray vision, tunneling at very
2 high speeds, or transformation.

3 “(3) The term ‘cartoon’ includes ‘Joe Camel,’
4 but does not include any drawing or other depiction
5 that, on July 1, 1998, was in use in the United
6 States in any manufacturer’s corporate logo or in
7 any manufacturer’s tobacco product packaging.

8 “(h) ELIMINATION OF OUTDOOR ADVERTISING.—

9 “(1) No manufacturer, distributor, or retailer
10 may place or cause to be placed any outdoor adver-
11 tising advertising tobacco products.

12 “(2) For purposes of this subsection, the term
13 ‘outdoor advertising’ means—

14 “(A) billboards;

15 “(B) signs and placards in arenas, sta-
16 diums, shopping malls, and video game arcades
17 (whether any of the foregoing are open air or
18 enclosed); and

19 “(C) any other advertisements placed—

20 “(i) outdoors, or

21 “(ii) on the inside surface of a window
22 facing outward.

23 “(D) The term ‘outdoor advertising’ does
24 not mean—

1 “(i) an advertisement on the outside
2 of a tobacco product manufacturing facil-
3 ity;

4 “(ii) an individual advertisement that
5 does not occupy an area larger than 14
6 square feet (and that neither is placed in
7 such proximity to any other such advertise-
8 ment so as to create a single ‘mosaic’-type
9 advertisement larger than 14 square feet,
10 nor functions solely as a segment of a larg-
11 er advertising unit or series), and that is
12 placed on the outside of any retail estab-
13 lishment that sells tobacco products (other
14 than solely through a vending machine), on
15 the outside (but on the property of) any
16 such establishment, or on the inside sur-
17 face of a window facing outward in any
18 such establishment; or

19 “(iii) an advertisement inside a retail
20 establishment that sells tobacco products
21 (other than solely through a vending ma-
22 chine) that is not placed on the inside sur-
23 face of a window facing outward.

24 “(3) For purposes of this subsection, the term
25 ‘video game arcade’ means an entertainment estab-

1 lishment primarily consisting of video games (other
2 than video games intended primarily for use by per-
3 sons 18 years of age or older) and/or pinball ma-
4 chines.

5 “(i) ELIMINATION OF TRANSIT ADVERTISEMENTS.—

6 “(1) No manufacturer, distributor, or retailer
7 may place or cause to be placed any transit adver-
8 tisements advertising tobacco products.

9 “(2) For purposes of this subsection, the term
10 ‘transit advertisements’ means advertising on or
11 within private or public vehicles and all advertise-
12 ments placed at, on or within any bus stop, taxi
13 stand, transportation waiting area, train station, air-
14 port, or any similar location.

15 “(3) The term ‘transit advertisements’ does not
16 include any advertisement placed in, on, or outside
17 the premises of any retail establishment that sells
18 tobacco products (other than solely through a vend-
19 ing machine), except if such individual
20 advertisement—

21 “(A) occupies an area larger than 14
22 square feet;

23 “(B) is placed in such proximity to any
24 other such advertisement so as to create a sin-

1 gle ‘mosaic’-type advertisement larger than 14
2 square feet; or

3 “(C) functions solely as a segment of a
4 larger advertising unit or series).

5 “(j) BAR ON ADVERTISING IN ANY YOUTH-ORI-
6 ENTED PUBLICATION.—

7 “(1) No manufacturer, distributor, or retailer
8 shall advertise a tobacco product in any youth-ori-
9 ented publication (whether periodic or limited dis-
10 tribution).

11 “(2) For purposes of this subsection, a ‘youth
12 oriented publication’ is a newspaper, magazine, peri-
13 odical, or other publication—

14 “(A) whose readers younger than 18 years
15 of age constitute more than 15 percent of the
16 total readership as measured by competent and
17 reliable survey evidence; or

18 “(B) that is read by 2,000,000 or more
19 persons younger than 18 years of age as meas-
20 ured by competent and reliable survey evidence.

21 “(k) BAN ON TOBACCO PRODUCT BRAND NAME
22 SPONSORSHIPS.—

23 “(1) No manufacturer, distributor, or retailer
24 may sponsor or cause to be sponsored any athletic,
25 musical, artistic, or other social or cultural event, or

1 any entry or team in any event, in the brand name
2 (alone or in conjunction with any other word), logo,
3 symbol, motto, selling message, recognizable color or
4 pattern of colors, or any other indicia of product
5 identification identical or similar to, or identifiable
6 with, those used for any brand of cigarettes or
7 smokeless tobacco.

8 “(2) Nothing in this subsection shall be con-
9 strued to prevent a manufacturer, distributor, or re-
10 tailer from sponsoring or causing to be sponsored
11 any athletic, musical, artistic, or other social or cul-
12 tural event, or team or entry, in the name of the
13 corporation which manufactures the tobacco product,
14 provided that both the corporate name and the cor-
15 poration were registered and in use in the United
16 States prior to January 1, 2001, and that the cor-
17 porate name does not include any brand name (alone
18 or in conjunction with any other word), logo, symbol,
19 motto, selling message, recognizable color or pattern
20 of colors, or any other indicia of product identifica-
21 tion identical or similar to, or identifiable with, those
22 used for any brand of cigarettes or smokeless to-
23 bacco.

24 “(3) This subsection shall not apply to any
25 event sponsored in an adult-only facility.

1 “(l) BAN ON TOBACCO BRAND NAME MERCHAN-
2 DISE.—

3 “(1) No manufacturer may market, distribute,
4 offer, sell, license or cause to be marketed, distrib-
5 uted, offered, sold, or licensed (including, without
6 limitation, by catalogue or direct mail), any apparel
7 or other merchandise (other than tobacco products,
8 items the sole function of which is to advertise to-
9 bacco products, or written or electronic publications)
10 which bears a brand name.

11 “(2) Nothing in this subsection shall—

12 “(A) prohibit the distribution to any man-
13 ufacturer’s employee who is an adult of any
14 item described above that is intended for the
15 personal use of such an employee;

16 “(B) require any manufacturer to retrieve,
17 collect or otherwise recover any item that prior
18 to the enactment of this chapter was marketed,
19 distributed, offered, sold, licensed, or caused to
20 be marketed, distributed, offered, sold, or li-
21 censed by such manufacturer;

22 “(C) apply to coupons or other items used
23 by adults solely in connection with the purchase
24 of tobacco products; or

1 “(D) apply to apparel or other merchan-
2 dise used within an adult-only facility that is
3 not distributed (by sale or otherwise) to any
4 member of the general public.

5 “(m) BAN ON GIFTS TO UNDERAGE PERSONS BASED
6 ON PROOFS OF PURCHASE.—

7 “(1) No manufacturer, distributor, or retailer
8 may provide or cause to be provided to any person,
9 without sufficient proof that such person is an adult,
10 any item in exchange for the purchase of tobacco
11 products, or the furnishing of credits, proofs-of-pur-
12 chase, or coupons with respect to such a purchase.

13 “(2)(A) For purposes of paragraph (1), a driv-
14 er’s license or other government-issued identification
15 (or legible photocopy thereof), the validity of which
16 is certified by the person to whom the item is pro-
17 vided, shall by itself be deemed to be a sufficient
18 form of proof of age; and

19 “(B) In the case of items provided (or to be re-
20 deemed) at retail establishments, a manufacturer
21 shall be entitled to rely on verification of proof of
22 age by the retailer, where such retailer is required
23 to obtain verification under applicable Federal, State
24 or local law.

1 “(n) BAN ON NON-TOBACCO PRODUCT BRAND
2 NAMES.—

3 “(1) Except as provided in paragraph (2), no
4 manufacturer may, pursuant to any agreement re-
5 quiring the payment of money or other valuable con-
6 sideration, use or cause to be used as a brand name
7 of any tobacco product any nationally recognized or
8 nationally established brand name or trade name of
9 any non-tobacco item or service or any nationally
10 recognized or nationally established sports team, en-
11 tertainment group, or individual celebrity.

12 “(2) Paragraph (1) shall not apply to any to-
13 bacco product brand name in existence as of July 1,
14 1998.

15 “(3) For the purposes of this section, the term
16 ‘other valuable consideration’ shall not include an
17 agreement between two entities who enter into such
18 agreement for the sole purpose of avoiding infringe-
19 ment claims.

20 “(o) LIMITATION ON THIRD PARTY USE OF TO-
21 BACCO BRAND NAMES.—

22 “(1) No manufacturer may license or otherwise
23 expressly authorize any third party to use or adver-
24 tise any brand name in a manner prohibited by this
25 Act if done by such manufacturer itself.

1 “(2) Nothing in this subsection shall require
2 any manufacturer to retrieve, collect, or otherwise
3 recover any item that prior to the enactment of this
4 chapter was marketed, distributed, offered, sold, li-
5 censed, or caused to be marketed, distributed, of-
6 fered, sold, or licensed by such manufacturer.

7 “(p) BAR ON PRODUCT PLACEMENT IN CERTAIN
8 MEDIA.—

9 “(1) Except as provided in paragraph (2), no
10 manufacturer may make, or cause to be made, any
11 payment or other consideration to any other person
12 or entity to use, display, make reference to, or use
13 as a prop any tobacco product, tobacco product
14 package, advertisement for a tobacco product, or any
15 other item bearing a brand name in any motion pic-
16 ture, television show, theatrical production or other
17 live performance, live or recorded performance of
18 music, commercial film or video, or video game
19 (‘media’).

20 “(2) Paragraph (1) shall not apply to—

21 “(A) media where the audience or viewers
22 are within an adult-only facility (provided such
23 media are not visible to persons outside such
24 adult-only facility);

1 “(B) media not intended for distribution or
2 display to the public; or

3 “(C) instructional media concerning non-
4 conventional tobacco products or tobacco prod-
5 ucts designated as reduced risk viewed only by
6 or provided only to consumers who are adults.

7 “(q) SEVERABILITY.—If any provision of this section
8 is held invalid, those subsections, and paragraphs which
9 are not so held shall continue to be in effect.

10 “(r) EFFECTIVE DATES.—The provisions of this sec-
11 tion shall take effect on the date that is six months after
12 the date of enactment of this section, except for the provi-
13 sions of subsections (e) and (k), which shall take effect
14 on the date that is one year after the effective date of
15 this section.

16 **“SEC. 916. MANDATORY DISCLOSURES.**

17 “(a) DISCLOSURE OF INGREDIENTS TO THE PUB-
18 LIC.—

19 “(1) Not later than 12 months after the effec-
20 tive date of this section, the Secretary shall promul-
21 gate regulations requiring the disclosure to the pub-
22 lic on a brand-by-brand basis of the common or
23 usual name of each ingredient of a tobacco product
24 in descending order of predominance by weight, ex-
25 cept that spices, flavorings, and colorings may at the

1 manufacturer's election be designated as spices,
2 flavorings, and colorings without naming each. Any
3 ingredient that has been disclosed to the public pur-
4 suant to any other law or regulation with respect to
5 a particular brand may be required to be disclosed
6 for such brand pursuant to this subsection.

7 “(2) The regulations required by this subsection
8 shall provide that incidental additives that are
9 present in a tobacco product at insignificant levels
10 and that do not have any technical or functional ef-
11 fect in the finished tobacco product shall be exempt
12 from disclosure.

13 “(3) The requirement of this subsection to dis-
14 close ingredients in descending order of predomi-
15 nance shall not apply to ingredients in amounts of
16 2 percent or less by weight when a listing of such
17 ingredients is placed at the end of the ingredients
18 statement following an appropriate quantifying
19 statement, such as ‘contains ____ percent or less of
20 ____’, or ‘less than ____ percent of ____’.

21 “(4) Any disclosure required pursuant to this
22 subsection may be required by appropriate means,
23 except that, notwithstanding any other provision of
24 this Act, the Secretary shall not require the listing

1 of any ingredient on any package or in any adver-
2 tisement.

3 “(b) DISCLOSURE OF PERCENTAGE OF DOMESTIC
4 AND FOREIGN TOBACCO.—Not later than 12 months after
5 the effective date of this section, the Secretary shall pro-
6 mulgate regulations that require that each package of a
7 tobacco product disclose, with respect to the tobacco con-
8 tained in that brand—

9 “(1) the percentage of tobacco that is domestic
10 tobacco; and

11 “(2) the percentage of tobacco that is foreign
12 tobacco.

13 “(c) MANDATORY DISCLAIMER.—

14 “(1) Any tobacco product advertising which in-
15 cludes a term classifying a brand of tobacco product
16 according to its ‘tar’ yield or the yield to consumers
17 of any substance, including but not limited to terms
18 such as ‘light’, or ‘low tar’, shall also include the fol-
19 lowing disclaimer: ‘[Brand] not shown to be less
20 hazardous than other [type of tobacco product]’.

21 This section shall not be deemed to apply to the use
22 of the terms ‘filtered’ or ‘filter’. In no event shall
23 any such disclaimer be required on any tobacco
24 product package.

1 “(2) In addition to the provisions of paragraph
2 (1), not later than 12 months after the effective date
3 of this section, the Secretary shall promulgate regu-
4 lations relating to the use of such terms, to ensure
5 that they are not false or misleading.

6 “(3) The Secretary may modify or waive any
7 requirement under this subsection with respect to
8 any product that has been designated by the Sec-
9 retary as a reduced risk product under section
10 912.”.

11 **SEC. 504. REGULATORY RECORD.**

12 Notwithstanding the provisions of subchapter II of
13 chapter 5 of title 5, United States Code, in promulgating
14 regulations under this chapter, the record developed and
15 utilized by the Secretary for the purposes of promulgating
16 subparts (B) and (D) of the regulations relating to the
17 sale, distribution, and use of tobacco products on or about
18 August 28, 1996, as reflected in articles IV and VI of the
19 preamble to the 1996 Food and Drug Administration To-
20 bacco Rule (including public comments, Food and Drug
21 Administration documents, and any other information
22 generated or compiled for purposes of promulgating such
23 regulations), shall be deemed to have the same legal status
24 as if such record had been developed under a rulemaking
25 proceeding conducted pursuant to section 906(d)(1). In all

1 other respects, including with respect to the issue of
2 whether such regulations conform to section 906(d)(1),
3 the procedural requirements of this chapter and the Ad-
4 ministration Procedure Act will apply.

5 **SEC. 505. CONFORMING AND OTHER AMENDMENTS TO GEN-**
6 **ERAL PROVISIONS.**

7 (a) AMENDMENT OF FEDERAL FOOD, DRUG, AND
8 COSMETIC ACT.—Except as otherwise expressly provided,
9 whenever in this section an amendment is expressed in
10 terms of an amendment to, or repeal of, a section or other
11 provision, the reference is to a section or other provision
12 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
13 301 et seq.).

14 (b) SECTION 301.—Section 301 (21 U.S.C. 331) is
15 amended—

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

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

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

22 (4) in subsection (e), by striking “515(f), or
23 519” and inserting “515(f), 519, or 909”;

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

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

3 (7) in subsection (j), by striking “708, or 721”
4 and inserting “708, 721, 903, 904, 905, 906, 907,
5 908, 909, 910, or 912”;

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

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

10 “(p) The failure to register in accordance with section
11 510 or 905, the failure to provide any information re-
12 quired by section 510(j), 510(k), 905(i), or 905(j), or the
13 failure to provide a notice required by section 510(j)(2)
14 or 905(j)(2).”;

15 (10) in subsection (q), by striking paragraph
16 (1) and inserting the following:

17 “(1) The failure or refusal—

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

20 “(B) to furnish any notification or other mate-
21 rial or information required by or under section 519,
22 520(g), 904, 906(f), or 909; or

23 “(C) to comply with a requirement under sec-
24 tion 522.”;

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

3 (12) in subsection (r), by inserting “or tobacco
4 product” after “device” each time that it appears;
5 and

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

7 “(aa) The sale of tobacco products in violation
8 of a no-tobacco-sale order issued under section
9 303(f).”.

10 (c) SECTION 303.—Section 303(f) (21 U.S.C. 333(f))
11 is amended—

12 (1) by striking the subsection heading and in-
13 serting the following:

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

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

18 (3) by redesignating paragraphs (3), (4), and
19 (5) as paragraphs (4), (5), and (6), respectively;

20 (4) by inserting after paragraph (2) the fol-
21 lowing:

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

1 order on that person prohibiting the sale of tobacco
2 products in that outlet. A no-tobacco-sale order may
3 be imposed with a civil penalty under paragraph
4 (1).”;

5 (5) in subparagraph (A) of paragraph (4), as so
6 redesignated—

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

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

13 (6) in subparagraph (B) of paragraph (4), as so
14 redesignated—

15 (A) by inserting after “penalty,” the fol-
16 lowing: “or the period to be covered by a no-to-
17 bacco-sale order,”; and

18 (B) by adding at the end the following: “A
19 no-tobacco-sale order permanently prohibiting
20 an individual retail outlet from selling tobacco
21 products shall include provisions that allow the
22 outlet, after a specified period of time, to re-
23 quest that the Secretary compromise, modify,
24 or terminate the order.”;

1 (7) by adding at the end of paragraph (4), as
2 so redesignated, the following:

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

6 (8) in paragraph (5), as so redesignated—

7 (A) by striking “(3)(A)” and inserting
8 “(4)(A)”;

9 (B) by inserting “or the imposition of a
10 no-tobacco-sale order” after “penalty” the first
11 2 places it appears;

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

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

18 (d) SECTION 304.—Section 304 (21 U.S.C. 334) is
19 amended—

20 (1) in subsection (a)(2), by striking “and” be-
21 fore “(D)”;

22 (2) in subsection (a)(2), by striking “device.”
23 and inserting a comma and the following:

24 “(E) Any adulterated or misbranded to-
25 bacco product.”;

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

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

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

8 (e) SECTION 702.—Section 702(a) (21 U.S.C.
9 372(a)) is amended—

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

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

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

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

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

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

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

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

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

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

9 (h) SECTION 705.—Section 705(b) (21 U.S.C.
10 375(b)) is amended by inserting “tobacco products,” after
11 “devices,”.

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

14 (j) SECTION 801.—Section 801 (21 U.S.C. 381) is
15 amended—

16 (1) in subsection (a), by inserting “tobacco
17 products,” after “devices,” the first time it appears;

18 (2) in subsection (a), by inserting “or sub-
19 section (j) of section 905” after “section 510”;

20 (3) in subsection (a), by striking “drugs or de-
21 vices” each time it appears and inserting “drugs, de-
22 vices, or tobacco products”; and

23 (4) in subsection (e)(1), by inserting ‘tobacco
24 product’ after ‘device’.

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

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

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

6 (l) EFFECTIVE DATE FOR NO-TOBACCO-SALE
7 ORDER AMENDMENTS.—The amendments made by sub-
8 section (c), other than the amendment made by paragraph
9 (2) thereof, shall take effect only upon the promulgation
10 of final regulations by the Secretary—

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

17 (2) providing for notice to the retailer of each
18 violation at a particular retail outlet;

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

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

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

3 (5) providing that good faith reliance on false
4 identification does not constitute a violation of any
5 minimum age requirement for the sale of tobacco
6 products.

7 **SEC. 506. CIGARETTE LABEL AND ADVERTISING WARNINGS.**

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

11 **“SEC. 4. LABELING.**

12 **“(a) LABEL REQUIREMENTS.—**

13 **“(1) IN GENERAL.—**It shall be unlawful for any
14 person to manufacture, package, or import for sale
15 or distribution within the United States any ciga-
16 rettes the package of which fails to bear, in accord-
17 ance with the requirements of this section, one of
18 the following labels:

19 **“WARNING: Cigarettes are addictive”**

20 **“WARNING: Tobacco smoke can harm your chil-**
21 **dren”**

22 **“WARNING: Cigarettes cause fatal lung disease”**

23 **“WARNING: Cigarettes cause cancer”**

24 **“WARNING: Cigarettes cause strokes and heart**
25 **disease”**

1 “WARNING: Smoking during pregnancy can harm
2 your baby”

3 “WARNING: Smoking can kill you”

4 “WARNING: Tobacco smoke causes fatal lung dis-
5 ease in non-smokers”

6 “WARNING: Quitting smoking now greatly reduces
7 serious risks to your health”

8 “(2) PLACEMENT; TYPOGRAPHY; ETC.—

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

1 white on a black background, in a manner that
2 contrasts, by typography, layout, or color, with
3 all other printed material on the package, in an
4 alternating fashion under the plan submitted
5 under subsection (b)(4).

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

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

23 “(b) ADVERTISING REQUIREMENTS.—

24 “(1) IN GENERAL.—It shall be unlawful for any
25 tobacco product manufacturer, importer, distributor,

1 or retailer of cigarettes to advertise or cause to be
2 advertised within the United States any cigarette
3 unless its advertising bears, in accordance with the
4 requirements of this section, one of the labels speci-
5 fied in subsection (a) of this section.

6 “(2) TYPOGRAPHY, ETC.—Each label statement
7 required by subsection (a) of this section in cigarette
8 advertising shall comply with the standards set forth
9 in this paragraph. For press and poster advertise-
10 ments, each such statement and (where applicable)
11 any required statement relating to tar, nicotine, or
12 other constituent yield shall comprise at least 20
13 percent of the area of the advertisement and shall
14 appear in a conspicuous and prominent format and
15 location at the top of each advertisement within the
16 trim area. The Secretary may revise the required
17 type sizes in such area in such manner as the Sec-
18 retary determines appropriate. The word “WARN-
19 ING” shall appear in capital letters, and each label
20 statement shall appear in conspicuous and legible
21 type. The text of the label statement shall be black
22 if the background is white and white if the back-
23 ground is black, under the plan submitted under
24 paragraph (4) of this subsection. The label state-
25 ments shall be enclosed by a rectangular border that

1 is the same color as the letters of the statements
2 and that is the width of the first downstroke of the
3 capital “W” of the word “WARNING” in the label
4 statements. The text of such label statements shall
5 be in a typeface pro rata to the following require-
6 ments: 45-point type for a whole-page broadsheet
7 newspaper advertisement; 39-point type for a half-
8 page broadsheet newspaper advertisement; 39-point
9 type for a whole-page tabloid newspaper advertise-
10 ment; 27-point type for a half-page tabloid news-
11 paper advertisement; 31.5-point type for a double
12 page spread magazine or whole-page magazine ad-
13 vertisement; 22.5-point type for a 28 centimeter by
14 3 column advertisement; and 15-point type for a 20
15 centimeter by 2 column advertisement. The label
16 statements shall be in English, except that in the
17 case of—

18 “(A) an advertisement that appears in a
19 newspaper, magazine, periodical, or other publi-
20 cation that is not in English, the statements
21 shall appear in the predominant language of the
22 publication; and

23 “(B) in the case of any other advertise-
24 ment that is not in English, the statements

1 shall appear in the same language as that prin-
2 cipally used in the advertisement.

3 “(3) ADJUSTMENT BY SECRETARY.—The Sec-
4 retary may, through a rulemaking under section 553
5 of title 5, United States Code, adjust the format and
6 type sizes for the label statements required by this
7 section or the text, format, and type sizes of any re-
8 quired tar, nicotine yield, or other constituent disclo-
9 sures, or to establish the text, format, and type sizes
10 for any other disclosures required under the Federal
11 Food, Drug, and Cosmetic Act (21 U.S.C. 301 et
12 seq.). The text of any such label statements or dis-
13 closures shall be required to appear only within the
14 20 percent area of cigarette advertisements provided
15 by paragraph (2) of this subsection. The Secretary
16 shall promulgate regulations which provide for ad-
17 justments in the format and type sizes of any text
18 required to appear in such area to ensure that the
19 total text required to appear by law will fit within
20 such area.

21 “(4) MARKETING REQUIREMENTS.—

22 “(A) The label statements specified in sub-
23 section (a)(1) shall be randomly displayed in
24 each 12-month period, in as equal a number of
25 times as is possible on each brand of the prod-

1 uct and be randomly distributed in all areas of
2 the United States in which the product is mar-
3 keted in accordance with a plan submitted by
4 the tobacco product manufacturer, importer,
5 distributor, or retailer and approved by the Sec-
6 retary.

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

14 “(C) The Secretary shall review each plan
15 submitted under subparagraph (B) and approve
16 it if the plan—

17 “(i) will provide for the equal distribu-
18 tion and display on packaging and the ro-
19 tation required in advertising under this
20 subsection; and

21 “(ii) assures that all of the labels re-
22 quired under this section will be displayed
23 by the tobacco product manufacturer, im-
24 porter, distributor, or retailer at the same
25 time.”.

1 **SEC. 507. AUTHORITY TO REVISE CIGARETTE WARNING**
2 **LABEL STATEMENTS.**

3 Section 4 of the Federal Cigarette Labeling and Ad-
4 vertising Act (15 U.S.C. 1333), as amended by section
5 506, is further amended by adding at the end the fol-
6 lowing:

7 “(c) CHANGE IN REQUIRED STATEMENTS.—The Sec-
8 retary may, by a rulemaking conducted under section 553
9 of title 5, United States Code, adjust the format, type size,
10 and text of any of the warning label statements required
11 by subsection (a) of this section subject to the limitation
12 on proportional size of the warning contained in sub-
13 sections (a)(2) and (b)(2), or establish the format, type
14 size, and text of any other disclosures required under the
15 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301
16 et seq.), if the Secretary finds that such a change would
17 promote greater public understanding of the risks associ-
18 ated with the use of smokeless tobacco products.”.

19 **SEC. 508. SMOKELESS TOBACCO LABELS AND ADVERTISING**
20 **WARNINGS.**

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

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

25 **“(a) GENERAL RULE.—**

1 “(1) It shall be unlawful for any person to man-
2 ufacture, package, or import for sale or distribution
3 within the United States any smokeless tobacco
4 product unless the product package bears, in accord-
5 ance with the requirements of this Act, one of the
6 following labels:

7 “WARNING: This product can cause mouth cancer”

8 “WARNING: This product can cause gum disease
9 and tooth loss”

10 “WARNING: This product is not a safe alternative
11 to cigarettes”

12 “WARNING: Smokeless tobacco is addictive”

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

15 “(A) located on the 2 principal display
16 panels of the package, and each label statement
17 shall comprise at least 25 percent of each such
18 display panel; and

19 “(B) in 17-point conspicuous and legible
20 type and in black text on a white background,
21 or white text on a black background, in a man-
22 ner that contrasts by typography, layout, or
23 color, with all other printed material on the
24 package, in an alternating fashion under the
25 plan submitted under subsection (b)(3), except

1 that if the text of a label statement would oc-
2 cupy more than 70 percent of the area specified
3 by subparagraph (A), such text may appear in
4 a smaller type size, so long as at least 60 per-
5 cent of such warning area is occupied by the
6 label statement.

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

12 “(4) The provisions of this subsection do not
13 apply to a tobacco product manufacturer or dis-
14 tributor of any smokeless tobacco product that does
15 not manufacture, package, or import smokeless to-
16 bacco products for sale or distribution within the
17 United States.

18 “(b) REQUIRED LABELS.—

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

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

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

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

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

1 turer, importer, distributor, or retailer and approved
2 by the Secretary.

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

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

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

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

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

1 **SEC. 509. AUTHORITY TO REVISE SMOKELESS TOBACCO**
2 **PRODUCT WARNING LABEL STATEMENTS.**

3 Section 3 of the Comprehensive Smokeless Tobacco
4 Health Education Act of 1986 (15 U.S.C. 4402), as
5 amended by section 508, is further amended by adding
6 at the end the following:

7 “(d) **AUTHORITY TO REVISE WARNING LABEL**
8 **STATEMENTS.**—The Secretary may, by a rulemaking con-
9 ducted under section 553 of title 5, United States Code,
10 adjust the format, type size, and text of any of the warn-
11 ing label statements required by subsection (a) of this sec-
12 tion, subject to the limitations on proportional size of the
13 warning contained in paragraphs (2) and (3) of subsection
14 (a), or establish the format, type size, and text of any
15 other disclosures required under the Federal Food, Drug,
16 and Cosmetic Act (21 U.S.C. 301 et seq.), if the Secretary
17 finds that such a change would promote greater public un-
18 derstanding of the risks associated with the use of smoke-
19 less tobacco products.”.

20 **SEC. 510. TAR, NICOTINE, AND OTHER SMOKE CON-**
21 **STITUENT DISCLOSURE TO THE PUBLIC.**

22 Section 4(a) of the Federal Cigarette Labeling and
23 Advertising Act (15 U.S.C. 1333(a)), as amended by sec-
24 tion 506, is further amended by adding at the end the
25 following:

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

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

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

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

15 **SEC. 511. REGULATION REQUIREMENT.**

16 (a) TESTING, REPORTING, AND DISCLOSURE.—Not
17 later than 24 months after the date of enactment of this
18 Act, the Secretary, through the Commissioner of Food and
19 Drugs, shall promulgate regulations under the Federal
20 Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)
21 that meet the requirements of subsection (b) of this sec-
22 tion.

23 (b) CONTENTS OF RULES.—The rules promulgated
24 under subsection (a) shall require the testing, reporting,
25 and disclosure of tobacco product smoke constituents and

1 ingredients that the Secretary determines should be dis-
2 closed to the public in order to protect the public health.
3 Such constituents shall include tar, nicotine, carbon mon-
4 oxide, and such other smoke constituents or ingredients
5 as the Secretary may determine to be appropriate. The
6 rule may require that tobacco product manufacturers,
7 packagers, or importers make such disclosures relating to
8 tar and nicotine through labels or advertising, and make
9 such disclosures regarding other smoke constituents or in-
10 gredients as the Secretary determines are necessary to
11 protect the public health.

12 (c) AUTHORITY.—The Food and Drug Administra-
13 tion shall have authority to conduct or to require the test-
14 ing, reporting, or disclosure of tobacco product smoke con-
15 stituents.

16 **SEC. 512. FTC JURISDICTION NOT AFFECTED.**

17 (a) IN GENERAL.—Except where expressly provided
18 in this Act, nothing in this Act shall be construed as lim-
19 iting or diminishing the authority of the Federal Trade
20 Commission to enforce the laws under its jurisdiction with
21 respect to the advertising, sale, or distribution of tobacco
22 products.

23 (b) ENFORCEMENT BY FTC.—Any advertising that
24 violates this Act is an unfair or deceptive act or practice
25 under section 5(a) of the Federal Trade Commission Act

1 (15 U.S.C. 45(a)) and shall be considered a violation of
2 a rule promulgated under section 18 of that Act (15
3 U.S.C. 57a).

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