

107TH CONGRESS
2^D SESSION

S. 2764

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 domestic and imported tobacco, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JULY 19, 2002

Mr. MILLER introduced the following bill; which was read twice and referred to the Committee on Finance

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 domestic and 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,*

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

4 (a) **SHORT TITLE.**—This Act may be cited as the
5 “Tobacco Livelihood and Economic Assistance for Our
6 Farmers Act of 2002”.

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

Sec. 1. Short title; table of contents.

TITLE I—TERMINATION OF CURRENT TOBACCO PROGRAMS

- Sec. 101. Termination of tobacco production adjustment programs.
- Sec. 102. Termination of tobacco price support program.
- 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. Definitions.
- Sec. 302. Establishment of Board.
- Sec. 303. Duties.
- Sec. 304. Administration.

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.

Subtitle A—FDA Jurisdiction Over Tobacco Products

- Sec. 511. Definition of tobacco product.
- Sec. 512. Tobacco products.
- Sec. 513. Conforming and technical amendments.

Subtitle B—Cigarette Labeling and Advertising

- Sec. 521. Definition of cigarette.
- Sec. 522. Cigarette label and advertising warnings.

Subtitle C—Smokeless Tobacco Labels and Advertising Warnings

Sec. 531. Smokeless tobacco labels and advertising warnings.

Subtitle D—Administration

Sec. 541. FTC jurisdiction not affected.

1 **TITLE I—TERMINATION OF**
2 **CURRENT TOBACCO PROGRAMS**

3 **SEC. 101. TERMINATION OF TOBACCO PRODUCTION AD-**
4 **JUSTMENT PROGRAMS.**

5 (a) TOBACCO CONTROL.—The Act of April 25, 1936
6 (commonly known as the Tobacco Control Act; 7 U.S.C.
7 515 et seq.), is repealed.

8 (b) COMMODITY HANDLING ORDERS.—Section
9 8c(2)(A) of the Agricultural Adjustment Act (7 U.S.C.
10 608c(2)(A)), reenacted with amendments by the Agricul-
11 tural Marketing Agreement Act of 1937, is amended by
12 striking “tobacco,”.

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

17 (1) in paragraph (2), by striking “tobacco,”;
18 and

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

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

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

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

6 (1) in paragraph (3)—

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

8 (B) by redesignating subparagraph (D) as
9 subparagraph (C);

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

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

12 “Tobacco (Flue-cured), July 1–June 30;

13 “Tobacco (other than Flue-cured), October
14 1–September 30;”;

15 (4) in paragraph (10)—

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

17 (B) by redesignating subparagraph (C) as
18 subparagraph (B);

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

21 (6) in paragraph (12), by striking “tobacco,”;

22 (7) in paragraph (14)—

23 (A) in subparagraph (A), by striking
24 “(A)”; and

1 (B) by striking subparagraphs (B), (C),
2 and (D);
3 (8) by striking paragraph (15);
4 (9) in paragraph (16)—
5 (A) by striking subparagraph (B); and
6 (B) by redesignating subparagraph (C) as
7 subparagraph (B);
8 (10) by striking paragraph (17); and
9 (11) by redesignating paragraph (16) as para-
10 graph (15).

11 (g) PARITY PAYMENTS.—Section 303 of the Agricul-
12 tural Adjustment Act of 1938 (7 U.S.C. 1303) is amended
13 in the first sentence by striking “rice, or tobacco,” and
14 inserting “or rice”.

15 (h) MARKETING QUOTAS.—Part I of subtitle B of
16 title III of the Agricultural Adjustment Act of 1938 (7
17 U.S.C. 1311 et seq.) is repealed.

18 (i) ADMINISTRATIVE PROVISIONS.—Section 361 of
19 the Agricultural Adjustment Act of 1938 (7 U.S.C. 1361)
20 is amended by striking “tobacco”.

21 (j) ADJUSTMENT OF QUOTAS.—Section 371 of the
22 Agricultural Adjustment Act of 1938 (7 U.S.C. 1371) is
23 amended—

1 (1) in the first sentence of subsection (a), by
2 striking “rice, or tobacco” and inserting “or rice”;
3 and

4 (2) in the first sentence of subsection (b), by
5 striking “rice, or tobacco” and inserting “or rice”.

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

9 (1) by striking “rice, or tobacco” each place it
10 appears in subsections (a) and (b) and inserting “or
11 rice”; and

12 (2) in subsection (a)—

13 (A) in the first sentence, by striking “all
14 persons engaged in the business of redrying,
15 prizing, or stemming tobacco for producers,”;
16 and

17 (B) in the last sentence, by striking
18 “\$500;” and all that follows through the period
19 at the end of the sentence and inserting
20 “\$500.”.

21 (l) REGULATIONS.—Section 375(a) of the Agricul-
22 tural Adjustment Act of 1938 (7 U.S.C. 1375(a)) is
23 amended by striking “peanuts, or tobacco” and inserting
24 “or peanuts”.

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

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

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

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

11 (1) in subsection (a)—

12 (A) by striking “(a)”; and

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

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

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

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

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

1 (r) ADVANCE RECOURSE LOANS.—Section
 2 13(a)(2)(B) of the Food Security Improvements Act of
 3 1986 (7 U.S.C. 1433c–1(a)(2)(B)) is amended by striking
 4 “tobacco and”.

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

8 (t) LIABILITY.—The amendments made by this sec-
 9 tion shall not affect the liability of any person under any
 10 provision of law as in effect before the effective date under
 11 subsection (u).

12 (u) CROPS.—This section and the amendments made
 13 by this section shall apply with respect to the 2003 and
 14 subsequent crops of the kind of tobacco involved.

15 **SEC. 102. TERMINATION OF TOBACCO PRICE SUPPORT**
 16 **PROGRAM.**

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

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

22 (2) by striking subsections (c), (g), (h), and (i);

23 (3) in subsection (d)(3)—

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

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

5 (4) by redesignating subsections (d) and (e) as
6 subsections (c) and (d), respectively.

7 (b) TERMINATION OF TOBACCO PRICE SUPPORT AND
8 NO NET COST PROVISIONS.—Sections 106, 106A, and
9 106B of the Agricultural Act of 1949 (7 U.S.C. 1445,
10 1445–1, 1445–2) are repealed.

11 (c) DEFINITION OF BASIC AGRICULTURAL COM-
12 MODITY.—Section 408(c) of the Agricultural Act of 1949
13 (7 U.S.C. 1428(c)) is amended by striking “tobacco,”.

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

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

21 (f) TRANSITION PROVISIONS.—

22 (1) LIABILITY.—The amendments made by this
23 section shall not affect the liability of any person
24 under any provision of law as in effect before the
25 date of enactment of this Act.

1 (2) TOBACCO STOCKS AND LOANS.—The Sec-
2 retary of Agriculture shall promulgate regulations
3 that require—

4 (A) the orderly disposition of quota to-
5 bacco held by any producer-owned cooperative
6 marketing association that has entered into a
7 loan agreement with the Commodity Credit
8 Corporation to make price support available to
9 producers of quota tobacco; and

10 (B) the repayment of all tobacco price sup-
11 port loans or surrender of collateral by the as-
12 sociations not later than 1 year after the date
13 of enactment of this Act.

14 (3) SPECIAL RULES FOR TERMINATION OF NO
15 NET COST FUNDS AND ACCOUNTS.—Notwithstanding
16 any other provision of law, on the repeal by sub-
17 section (b) of the authority under section 106A and
18 106B of the Agricultural Act of 1949 (7 U.S.C.
19 1445–1, 1445–2) for the establishment of the No
20 Net Cost Tobacco Funds and Accounts,
21 respectively—

22 (A) any obligation of a tobacco producer,
23 purchaser, or importer to make payments into
24 the Fund or Account shall terminate; and

1 (B) any amounts in the Fund or Account
2 shall be disposed of in the manner prescribed by
3 the Secretary of Agriculture, except that—

4 (i) to the extent necessary, the
5 amounts shall be applied or used for the
6 purposes prescribed by that section; and

7 (ii) if any funds remain, the Secretary
8 shall transfer the funds to the Secretary of
9 Health and Human Services for use in ac-
10 cordance with section 402.

11 (g) CROPS.—This section and the amendments made
12 by this section shall apply with respect to the 2003 and
13 subsequent crops of the kind of tobacco involved.

14 **SEC. 103. GEOGRAPHICAL RESTRICTIONS ON EXPANSION**
15 **OF TOBACCO PRODUCTION.**

16 (a) PURPOSES.—The purposes of this section are—

17 (1) to provide an orderly economic transition
18 from the marketing of tobacco based on quotas and
19 price support; and

20 (2) to address the economic dislocation, and the
21 resulting impact on interstate commerce, that the
22 termination of the tobacco program might cause for
23 producers of certain agricultural communities.

24 (b) DEFINITIONS.—In this section:

1 (1) **MARKETING QUOTA.**—The term “marketing
2 quota in the 2002 marketing year” means a quota
3 established for the 2002 marketing year pursuant to
4 part I of subtitle B of title III of the Agricultural
5 Adjustment Act of 1938 (7 U.S.C. 1311 et seq.) (as
6 in effect before the amendment made by section
7 101(h)) and related provisions of law, as in effect
8 for that marketing year.

9 (2) **MARKETING YEAR.**—The term “marketing
10 year” means—

11 (A) in the case of Flue-cured tobacco, July
12 1 through June 30; and

13 (B) in the case of each other kind of to-
14 bacco, October 1 through September 30.

15 (c) **PENALTY APPLICABLE TO TOBACCO GROWN IN**
16 **NONQUOTA COUNTIES AND STATES.**—The marketing in
17 the 2003 or subsequent marketing years of a kind of to-
18 bacco that was subject to a marketing quota in the 2002
19 marketing year shall be subject to a penalty equal to 100
20 percent of the total amount received for the marketing of
21 the tobacco, unless the Secretary of Agriculture deter-
22 mines that the tobacco was grown in a county in which
23 the kind of tobacco was grown pursuant to a marketing
24 quota in the 2002 marketing year.

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

3 Nothing in this title affects the eligibility of a tobacco
4 producer to obtain crop insurance for a crop of the pro-
5 ducer under the Federal Crop Insurance Act (7 U.S.C.
6 1501 et seq.).

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

10 **SEC. 201. DEFINITIONS.**

11 In this title:

12 (1) **ACTIVE PRODUCER OF QUOTA TOBACCO.—**

13 The term “active producer of quota tobacco” means
14 a person that was the actual producer of tobacco
15 marketed under a marketing quota for the 2001 to-
16 bacco marketing year, as determined by the Sec-
17 retary.

18 (2) **QUOTA TOBACCO.—**The term “quota to-

19 bacco” means a kind of tobacco that is subject to a
20 farm marketing quota or farm acreage allotment for
21 the 1999, 2000, 2001, and 2002 tobacco marketing
22 years under a marketing quota or allotment program
23 established under part I of subtitle B of title III of
24 the Agricultural Adjustment Act of 1938 (7 U.S.C.
25 1281 et seq.) (as in effect before the amendment
26 made by section 101(h)).

1 (3) SECRETARY.—The term “Secretary” means
2 the Secretary of Agriculture.

3 (4) TOBACCO QUOTA HOLDER.—The term “to-
4 bacco quota holder” means an owner of a farm on
5 January 1, 2002, for which a tobacco farm mar-
6 keting quota or farm acreage allotment for quota to-
7 bacco was established with respect to the 2002 to-
8 bacco marketing year under a marketing quota pro-
9 gram established under part I of subtitle B of title
10 III of the Agricultural Adjustment Act of 1938 (7
11 U.S.C. 1281 et seq.) (as in effect before the amend-
12 ment made by section 101(h)).

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

14 (a) PAYMENT REQUIRED.—The Secretary shall make
15 payments to each eligible tobacco quota holder for the ter-
16 mination of tobacco marketing quotas and related price
17 support under the amendments made by title I, which
18 shall constitute full and fair compensation for any losses
19 relating to the termination of the quotas and support.

20 (b) ELIGIBILITY.—

21 (1) IN GENERAL.—To be eligible to receive a
22 payment under this section, a person shall submit to
23 the Secretary an application containing such infor-
24 mation as the Secretary may require to demonstrate

1 to the satisfaction of the Secretary that the person
2 is a tobacco quota holder.

3 (2) ADMINISTRATION.—The application shall be
4 submitted within such time, in such form, and in
5 such manner as the Secretary may require.

6 (c) BASE QUOTA LEVEL.—

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

10 (2) POUNDAGE QUOTAS.—For each kind of to-
11 bacco for which a marketing quota is expressed in
12 pounds, the base quota level for each tobacco quota
13 holder shall be equal to the basic tobacco marketing
14 quota under part I of subtitle B of title III of the
15 Agricultural Adjustment Act of 1938 (7 U.S.C.
16 1281 et seq.) (as in effect before the amendment
17 made by section 101(h)) for the 1998 marketing
18 year for quota tobacco on the farm owned by the to-
19 bacco quota holder.

20 (3) MARKETING QUOTAS OTHER THAN POUND-
21 AGE QUOTAS.—For each kind of tobacco for which
22 there is a marketing quota or allotment on an acre-
23 age basis, the base quota level for each tobacco
24 quota holder shall be the quantity obtained by
25 multiplying—

1 (A) the basic tobacco farm marketing
2 quota or allotment for the 1998 marketing year
3 established by the Secretary for quota tobacco
4 on the farm owned by the tobacco quota holder;
5 by

6 (B) the average county production yield
7 per acre for the county in which the farm is lo-
8 cated for the kind of tobacco for the 1998 mar-
9 keting year.

10 (d) PAYMENT.—The Secretary shall make payments
11 to each eligible tobacco quota holder under subsection (b)
12 in an amount obtained by multiplying—

13 (1) \$8 per pound; by

14 (2) the base quota level established for the
15 quota holder under subsection (c).

16 (e) TIME FOR PAYMENT.—The payments to eligible
17 tobacco quota holders required under this section shall be
18 made in 5 equal installments during fiscal years 2003,
19 2004, 2005, 2006, and 2007.

20 (f) RESOLUTION OF DISPUTES.—Any dispute regard-
21 ing the eligibility of a person to receive a payment under
22 this section, or the amount of the payment, shall be re-
23 solved by the county committee established under section
24 8(b)(5) of the Soil Conservation and Domestic Allotment

1 Act (16 U.S.C. 590h(b)(5)) for the county or other area
2 in which the farm owned by the person is located.

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

6 **SEC. 203. TRANSITION PAYMENTS FOR ACTIVE PRODUCERS**
7 **OF QUOTA TOBACCO.**

8 (a) TRANSITION PAYMENTS REQUIRED.—The Sec-
9 retary shall make transition payments under this section
10 to eligible active producers of quota tobacco.

11 (b) ELIGIBILITY.—

12 (1) IN GENERAL.—To be eligible to receive a
13 transition payment under this section, a person shall
14 submit to the Secretary an application containing
15 such information as the Secretary may require to
16 demonstrate to the satisfaction of the Secretary that
17 the person is an active producer of quota tobacco.

18 (2) ADMINISTRATION.—The application shall be
19 submitted within such time, in such form, and in
20 such manner as the Secretary may require.

21 (c) PRODUCTION BASE.—

22 (1) IN GENERAL.—The Secretary shall establish
23 a production base applicable to each eligible active
24 producer of quota tobacco, as determined under sub-
25 section (b).

1 (2) QUANTITY.—The production base of a pro-
2 ducer shall be equal to the quantity, in pounds, of
3 quota tobacco subject to the basic marketing quota
4 produced and marketed by the producer under part
5 I of subtitle B of title III of the Agricultural Adjust-
6 ment Act of 1938 (7 U.S.C. 1281 et seq.) (as in ef-
7 fect before the amendment made by section 101(h))
8 for the 2001 marketing year.

9 (d) PAYMENT.—The Secretary shall make payments
10 to each eligible active producer of quota tobacco, as deter-
11 mined under subsection (b), in an amount obtained by
12 multiplying—

13 (1) \$4 per pound; by

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

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

20 (f) RESOLUTION OF DISPUTES.—Any dispute regard-
21 ing the eligibility of a person to receive a payment under
22 this section, or the amount of the payment, shall be re-
23 solved by the county committee established under section
24 8(b)(5) of the Soil Conservation and Domestic Allotment

1 Act (16 U.S.C. 590h(b)(5)) for the county or other area
 2 in which the farming operation of the person is located.

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

6 **TITLE III—TOBACCO QUALITY** 7 **BOARD**

8 **SEC. 301. DEFINITIONS.**

9 In this title:

10 (1) BOARD.—The term “Board” means the To-
 11 bacco Quality Board established under section 302.

12 (2) SECRETARY.—The term “Secretary” means
 13 the Secretary of Agriculture.

14 **SEC. 302. ESTABLISHMENT OF BOARD.**

15 (a) IN GENERAL.—The Secretary shall establish a
 16 permanent advisory board within the Department of Agri-
 17 culture to be known as the Tobacco Quality Board.

18 (b) NOMINATION AND APPOINTMENT.—The Board
 19 shall consist of 11 members, of which—

20 (1) 5 members shall be appointed by the Sec-
 21 retary from nominations submitted by representa-
 22 tives of tobacco producers in the United States;

23 (2) 5 members shall be appointed by the Sec-
 24 retary from nominations submitted by representa-

1 tives of tobacco product manufacturers in the United
2 States; and

3 (3) 1 member shall be an officer or employee of
4 the Department of Agriculture appointed by the Sec-
5 retary, who shall serve as Chairperson of the Board.

6 (c) TERMS.—

7 (1) CHAIRPERSON.—The Chairperson of the
8 Board shall serve at the pleasure of the Secretary.

9 (2) OTHER MEMBERS.—Other members of the
10 Board shall serve for 2-year terms, except that of
11 the members first appointed to the Board, 2 pro-
12 ducer representatives and 2 manufacturer represent-
13 atives shall have initial terms of 1 year, as deter-
14 mined by the Secretary.

15 **SEC. 303. DUTIES.**

16 The Board shall—

17 (1) determine and describe the physical charac-
18 teristics of tobacco produced in the United States
19 and unmanufactured tobacco imported into the
20 United States;

21 (2) assemble and evaluate, in a systematic man-
22 ner, concerns and problems with the quality of to-
23 bacco produced in the United States, expressed by
24 domestic and foreign buyers and manufacturers of
25 tobacco products;

1 (3) review data collected by Federal agencies on
2 the physical and chemical integrity of tobacco pro-
3 duced in the United States and unmanufactured to-
4 bacco imported into the United States, to ensure
5 that tobacco being used in domestically-manufac-
6 tured tobacco products is of the highest quality and
7 is free from prohibited physical and chemical agents;

8 (4) investigate and communicate to the
9 Secretary—

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

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

17 (5) carry out such other related activities as are
18 assigned to the Board by the Secretary.

19 **SEC. 304. ADMINISTRATION.**

20 (a) IN GENERAL.—The Secretary shall provide the
21 Board with (as determined by the Secretary)—

22 (1) a staff that is—

23 (A) experienced in the sampling and anal-
24 ysis of unmanufactured tobacco; and

1 (B) capable of collecting data and moni-
 2 toring tobacco production information; and

3 (2) other resources necessary for the Board to
 4 perform the duties of the Board under this title.

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

8 **TITLE IV—TOBACCO PRODUCT**
 9 **MANUFACTURER AND IM-**
 10 **PORTER USER FEES**

11 **SEC. 401. USER FEE.**

12 (a) IN GENERAL.—

13 (1) ASSESSMENT.—The Secretary of Health
 14 and Human Services shall assess an annual user fee,
 15 calculated in accordance with this section, on each
 16 tobacco product manufacturer and tobacco product
 17 importer that sells tobacco products in domestic
 18 commerce in the United States.

19 (2) COMMENCEMENT.—The assessments shall
 20 commence during calendar year 2003, based on do-
 21 mestic sales of tobacco products during fiscal year
 22 2003.

23 (b) BASE AMOUNT OF USER FEE FOR EACH CLASS
 24 OF TOBACCO PRODUCT.—The base amount of the user fee
 25 shall be—

1 (1) for cigarette manufacturers and importers,
2 \$2,116,252,000;

3 (2) for small cigar manufacturers and import-
4 ers, \$1,051,000;

5 (3) for large cigar manufacturers and import-
6 ers, \$164,274,000;

7 (4) for snuff manufacturers and importers,
8 \$9,920,000;

9 (5) for chewing tobacco manufacturers and im-
10 porters, \$2,275,000;

11 (6) for pipe tobacco manufacturers and import-
12 ers, \$1,505,000; and

13 (7) for roll-your-own tobacco manufacturers
14 and importers, \$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 on, 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 amount obtained by multiplying—

21 (1) the base amount for that class of tobacco
22 product provided under subsection (b); by

23 (2) a fraction—

24 (A) the numerator of which is the total vol-
25 ume of domestic sales of that class of tobacco

1 product during the fiscal year ending on Sep-
2 tember 30 of that calendar year; and

3 (B) the denominator of which is the total
4 volume of domestic sales of that class of to-
5 bacco product during fiscal year 2003.

6 (d) ALLOCATION OF TOTAL USER FEE AMOUNTS BY
7 MARKET SHARE—

8 (1) DEFINITION OF MARKET SHARE.—In this
9 subsection, the term “market share” means the
10 share of each manufacturer or importer of a class of
11 tobacco product (expressed as a decimal to the
12 fourth place) of the total volume of domestic sales
13 of the class of tobacco product during the calendar
14 year immediately preceding the calendar year of an
15 assessment under this section.

16 (2) ALLOCATION.—The amount of the user fee
17 for each class of tobacco product to be paid by each
18 manufacturer or importer of the class of tobacco
19 product under subsection (a) shall be determined for
20 each calendar year by multiplying—

21 (A) the market share of the manufacturer
22 or importer, as calculated with respect to the
23 calendar year, of the class of tobacco product;
24 by

1 (B) the total user fee amount for the cal-
2 endar year, as determined under subsection (c),
3 for the class of tobacco product.

4 (e) DETERMINATION OF VOLUME OF DOMESTIC
5 SALES.—

6 (1) IN GENERAL.—The calculation of the vol-
7 ume of domestic sales of a class of tobacco product
8 by a manufacturer or importer, and by all manufac-
9 turers and importers as a group, shall be made by
10 the Secretary of Health and Human Services based
11 on certified reports submitted by the manufacturers
12 and importers pursuant to subsection (f).

13 (2) MEASUREMENT.—For purposes of the cal-
14 culations under this subsection and the certifications
15 under subsection (f) by the Secretary of Health and
16 Human Services, the volumes of domestic sales shall
17 be measured by—

18 (A) in the case of cigarettes, the numbers
19 of cigarettes sold; and

20 (B) in the case of each other class of to-
21 bacco products, such unit as is specified by reg-
22 ulation by the Secretary.

23 (f) CERTIFICATION OF VOLUME OF DOMESTIC
24 SALES.—

1 (1) IN GENERAL.—Each manufacturer and im-
2 porter of tobacco products shall submit for each year
3 a certified report to the Secretary of Health and
4 Human Services setting forth for each class of to-
5 bacco products marketed or imported the total, for
6 the preceding year, of domestic sales of the tobacco
7 products by the manufacturer and importer, respec-
8 tively, to wholesalers and retailers and directly to
9 consumers.

10 (2) DEADLINE.—The certified report shall be
11 submitted to the Secretary of Health and Human
12 Services not later than March 1 of the year after the
13 year for which the certified report is made.

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

15 (a) IN GENERAL.—The user fees collected pursuant
16 to section 401 and any funds transferred to the Secretary
17 of Health and Human Services by the Secretary of Agri-
18 culture pursuant to section 102(f)(3)(B)(ii) shall be avail-
19 able, without further appropriation, in accordance with,
20 and for the purposes described in, this section, to remain
21 available until expended.

22 (b) FUNDING FOR FDA REGULATION OF TOBACCO
23 PRODUCTS.—The Secretary of Health and Human Serv-
24 ices shall make 15 percent of the user fee amounts col-
25 lected pursuant to section 401 for each year available to

1 the Secretary, acting through the Commissioner of Food
2 and Drugs, for the regulation of tobacco products under
3 chapter IX of the Federal Food, Drug, and Cosmetic Act
4 (21 U.S.C. 391 et seq.).

5 (c) FUNDING FOR OTHER TOBACCO-RELATED PRO-
6 GRAMS.—The Secretary of Health and Human Services
7 shall use the remaining 85 percent of the user fee amounts
8 collected each year pursuant to section 401 and any
9 amounts transferred to the Secretary of Health and
10 Human Services by the Secretary of Agriculture pursuant
11 to section 102(f)(3)(B)(ii)—

12 (1) to reimburse the Commodity Credit Cor-
13 poration for the expenditures made by the Com-
14 modity Credit Corporation under title II; and

15 (2) if any funds remain after carrying out para-
16 graph (1), to fund any other program that relates to
17 tobacco products.

18 **TITLE V—FDA REGULATION OF** 19 **TOBACCO PRODUCTS**

20 **SEC. 501. FINDINGS.**

21 Congress finds that—

22 (1) the use of tobacco products by the children
23 of the United States is a pediatric disease of epic
24 proportions that results in new generations of to-
25 bacco-dependent children and adults;

1 (2) a consensus exists within the scientific and
2 medical communities that tobacco products are in-
3 herently dangerous and cause cancer, heart disease,
4 and other serious adverse health effects;

5 (3) nicotine is addictive;

6 (4) virtually all new users of tobacco products
7 are under the minimum legal age to purchase to-
8 bacco products;

9 (5) tobacco advertising and marketing con-
10 tribute significantly to the use of nicotine-containing
11 tobacco products by adolescents;

12 (6) since past efforts to restrict advertising and
13 marketing of tobacco products have failed adequately
14 to curb tobacco use by adolescents, comprehensive
15 restrictions on the sale, promotion, and distribution
16 of tobacco products are needed;

17 (7) Federal and State governments have lacked
18 the legal and regulatory authority and resources to
19 address comprehensively the public health and soci-
20 etal problems caused by the use of tobacco products;

21 (8) Federal and State public health officials,
22 the public health community, and the public at large
23 recognize that the tobacco industry should be subject
24 to ongoing oversight;

1 (9) under article I, section 8 of the Constitu-
2 tion, Congress is vested with the responsibility for
3 regulating interstate commerce and commerce with
4 Indian tribes;

5 (10) the sale, distribution, marketing, adver-
6 tising, and use of tobacco products are activities in
7 and substantially affect interstate commerce because
8 tobacco products are sold, marketed, advertised, and
9 distributed in interstate commerce on a nationwide
10 basis;

11 (11) the sale, distribution, marketing, adver-
12 tising, and use of tobacco products substantially af-
13 fect interstate commerce through the health care
14 and other costs attributable to the use of tobacco
15 products;

16 (12) it is in the public interest for Congress to
17 adopt comprehensive public health legislation be-
18 cause of—

19 (A) the unique position of tobacco in the
20 history and economy of the United States; and

21 (B) the need to prevent the sale, distribu-
22 tion, marketing and advertising of tobacco
23 products to persons under the minimum legal
24 age to purchase tobacco products;

1 (13) the public interest requires a timely, fair,
2 equitable, and consistent result that will serve the
3 public interest by restricting throughout the United
4 States the sale, distribution, marketing, and adver-
5 tising of tobacco products only to persons of legal
6 age to purchase tobacco products;

7 (14) public health authorities estimate that the
8 benefits to the United States of enacting Federal
9 legislation to accomplish the goals described in this
10 section would be significant in human and economic
11 terms;

12 (15) reducing the use of tobacco by minors by
13 50 percent would prevent well over 60,000 early
14 deaths each year and save up to \$43,000,000,000
15 each year in reduced medical costs, improved pro-
16 ductivity, and the avoidance of premature deaths;

17 (16)(A) advertising, marketing, and promotion
18 of tobacco products have been especially directed to
19 attract young persons to use tobacco products, re-
20 sulting in increased use of tobacco products by
21 youth; and

22 (B) past efforts to oversee those activities have
23 not been successful in adequately preventing the in-
24 creased use;

1 (17) tobacco advertising increases the size of
2 the market consumption of tobacco products and the
3 use of tobacco by young people;

4 (18) children—

5 (A) are more influenced by tobacco adver-
6 tising than adults; and

7 (B) smoke the most advertised brands;

8 (19) tobacco company documents indicate that
9 young people are an important and often crucial seg-
10 ment of the tobacco market;

11 (20) advertising restrictions will have a positive
12 effect on the smoking rates of young people;

13 (21) restrictions on advertising are necessary to
14 prevent unrestricted tobacco advertising from under-
15 mining legislation prohibiting access to young peo-
16 ple; and

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

20 **Subtitle A—FDA Jurisdiction Over** 21 **Tobacco Products**

22 **SEC. 511. DEFINITION OF TOBACCO PRODUCT.**

23 Section 201 of the Federal Food, Drug, and Cosmetic
24 Act (21 U.S.C. 321) is amended by adding at the end the
25 following:

1 “(II) TOBACCO PRODUCT.—

2 “(A) IN GENERAL.—The term ‘tobacco
3 product’ means any product made or derived
4 from tobacco that is intended for human con-
5 sumption.

6 “(B) INCLUSIONS.—The term ‘tobacco
7 product’ includes any component, part, or ac-
8 cessory of a tobacco product.

9 “(C) EXCLUSIONS.—The term ‘tobacco
10 product’ does not include any raw material,
11 other than tobacco, used in manufacturing a
12 component, part, or accessory of a tobacco
13 product.”.

14 **SEC. 512. TOBACCO PRODUCTS.**

15 The Federal Food, Drug, and Cosmetic Act (21
16 U.S.C. 301 et seq.) is amended—

17 (1) by redesignating chapter IX (21 U.S.C. 391
18 et seq.) as chapter X;

19 (2) by redesignating sections 901 through 907
20 (21 U.S.C. 391 through 397) as sections 1001
21 through 1007, respectively; and

22 (3) by inserting after chapter VIII (21 U.S.C.
23 381 et seq.) the following:

1 **“CHAPTER IX—TOBACCO PRODUCTS**

2 **“SEC. 901. DEFINITIONS.**

3 “In this title:

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

10 “(2) CIGARETTE.—The term ‘cigarette’ has the
11 meaning given the term in section 3 of the Federal
12 Cigarette Labeling and Advertising Act (15 U.S.C.
13 1332).

14 “(3) COMMERCE.—The term ‘commerce’ has
15 the meaning given the term in section 3 of the Fed-
16 eral Cigarette Labeling and Advertising Act (15
17 U.S.C. 1332).

18 “(4) CONSTITUENT.—The term ‘constituent’
19 means, with respect to cigarettes, any element of
20 mainstream or sidestream smoke.

21 “(5) DISTRIBUTOR.—

22 “(A) IN GENERAL.—The term ‘distributor’
23 means, with respect to a tobacco product, any
24 person that furthers the distribution of ciga-
25 rette or smokeless tobacco, whether domestic or

1 imported, at any point from the original place
2 of manufacture to the place of business of a
3 person that sells or distributes the product to
4 individuals for personal consumption.

5 “(B) EXCLUSION.—The term ‘distributor’
6 does not include a common carrier.

7 “(6) INGREDIENT.—

8 “(A) IN GENERAL.—The term ‘ingredient’
9 means, with respect to cigarettes or smokeless
10 tobacco products, any substance, chemical, or
11 compound (other than tobacco, water, or recon-
12 stituted tobacco sheet made wholly from to-
13 bacco) added, or specified for addition, by a
14 manufacturer to the tobacco, paper, or filter of
15 a cigarette, or to the tobacco of a smokeless to-
16 bacco product.

17 “(B) INCLUSIONS.—The term ‘ingredient’
18 includes, with respect to cigarettes or smokeless
19 tobacco products, flavorants, processing aids,
20 casing sauces, preservatives, and combustion
21 modifiers.

22 “(7) MANUFACTURER.—

23 “(A) IN GENERAL.—The term ‘manufac-
24 turer’ means any person that manufactures a

1 tobacco product intended to be sold in the
2 United States.

3 “(B) INCLUSIONS.—The term “manufac-
4 turer” includes an importer, or other first pur-
5 chaser for resale in the United States, of—

6 “(i) a tobacco product manufactured
7 outside of the United States; or

8 “(ii) a tobacco product manufactured
9 in the United States but not intended for
10 sale in the United States.

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

15 “(9) PACKAGE.—The term ‘package’ means—

16 “(A) a pack, box, carton, or container of
17 any kind; or

18 “(B) if no other container is used, any
19 wrapping (including cellophane) in which ciga-
20 rettes or smokeless tobacco is offered for sale,
21 sold, or otherwise distributed to consumers.

22 “(10) RETAILER.—The term ‘retailer’ means
23 any person that—

24 “(A) sells cigarettes or smokeless tobacco
25 to individuals for personal consumption; or

1 “(B) operates a facility at which self-serv-
2 ice displays of tobacco products are permitted.

3 “(11) SMOKELESS TOBACCO.—The term
4 ‘smokeless tobacco’ means any product that—

5 “(A) consists of cut, ground, powdered, or
6 leaf tobacco; and

7 “(B) is intended to be placed in the oral or
8 nasal cavity.

9 **“SEC. 902. FDA JURISDICTION OVER TOBACCO PRODUCTS.**

10 “(a) IN GENERAL.—A tobacco product shall be regu-
11 lated by the Secretary under this chapter and shall not
12 be subject to the provisions of chapter V, except to the
13 extent that—

14 “(1) the tobacco product is intended for use in
15 the diagnosis, cure, mitigation, treatment, or preven-
16 tion of disease (within the meaning of section
17 201(g)(1)(B) or 201(h)(2)); or

18 “(2) a health claim is made for the tobacco
19 product under section 201(g)(1)(C) or 201(h)(3), ex-
20 cept that this paragraph shall not apply to a reduced
21 exposure tobacco product or a reduced risk tobacco
22 product covered by section 913.

23 “(b) APPLICABILITY.—This chapter shall apply to—

1 “(1) all tobacco products subject to part 897 of
2 title 21, Code of Federal Regulations and any suc-
3 cessor regulations; and

4 “(2) any other tobacco product that the Sec-
5 retary by regulation determines to be subject to this
6 chapter.

7 “(c) SCOPE.—

8 “(1) OTHER PRODUCTS.—Nothing in this chap-
9 ter affects the authority of the Secretary over, or the
10 regulation of, products under this Act that are not
11 tobacco products under chapter V or any other chap-
12 ter of this Act.

13 “(2) LEAF TOBACCO.—

14 “(A) DEFINITION OF CONTROLLED BY.—

15 In this paragraph, the term ‘controlled by’
16 means, when used with respect to a tobacco
17 product manufacturer, that the tobacco product
18 manufacturer—

19 “(i) is a member of the same con-
20 trolled group of corporations (as that term
21 is used in section 52(a) of the Internal
22 Revenue Code of 1986); or

23 “(ii) is under common control (within
24 the meaning of the regulations promul-
25 gated under section 52(b) of that Code).

1 “(B) NONAPPLICABILITY.—This chapter
2 shall not apply to—

3 “(i) leaf tobacco that is not in the
4 possession of a manufacturer; or

5 “(ii) a producer of leaf tobacco, in-
6 cluding a tobacco grower, tobacco ware-
7 house, and tobacco grower cooperative.

8 “(C) ENTRY ONTO FARMS.—An officer or
9 employee of the Food and Drug Administration
10 shall not have any authority to enter onto a
11 farm owned by a producer of leaf tobacco with-
12 out the written consent of the producer.

13 “(D) DUAL CAPACITY AS LEAF TOBACCO
14 PRODUCER AND MANUFACTURER.—Notwith-
15 standing any other provision of this subpara-
16 graph, if a producer of leaf tobacco is also a to-
17 bacco product manufacturer or is controlled by
18 a tobacco product manufacturer, the producer
19 shall be subject to this chapter in the pro-
20 ducer’s capacity as a manufacturer.

21 “(E) REGULATIONS ON LEAF TOBACCO
22 PRODUCTION.—Nothing in this chapter grants
23 the Secretary authority to promulgate regula-
24 tions on any matter that involves the produc-
25 tion of leaf tobacco or a producer of leaf to-

1 bacco, other than activities by a manufacturer
2 affecting production.

3 **“SEC. 903. ADULTERATED TOBACCO PRODUCTS.**

4 “(a) CONTAMINATED SUBSTANCES.—A tobacco prod-
5 uct shall be deemed adulterated if the tobacco product—

6 “(1) consists in whole or in part of any filthy,
7 putrid, or decomposed substance; or

8 “(2) is otherwise contaminated by any poi-
9 sonous or deleterious substance that may render the
10 tobacco product more injurious to health.

11 “(b) UNSANITARY CONDITIONS.—A tobacco product
12 shall be deemed adulterated if the tobacco product has
13 been prepared, packed, or held under unsanitary condi-
14 tions under which the tobacco product may have been con-
15 taminated with filth, or under which the tobacco product
16 may have been rendered more injurious to health.

17 “(c) CONTAINERS.—A tobacco product shall be
18 deemed adulterated if the container of the tobacco product
19 is composed, in whole or in part, of any poisonous or dele-
20 terious substance that may render the contents more inju-
21 rious to health.

22 “(d) PERFORMANCE STANDARDS.—A tobacco prod-
23 uct shall be deemed adulterated if the tobacco product is,
24 purports to be, or is represented as a tobacco product that
25 is subject to a performance standard established under

1 section 908 unless the tobacco product is in all respects
2 in conformity with the standard.

3 “(e) **PREMARKET APPROVAL.**—A tobacco product
4 shall be deemed adulterated if the tobacco product—

5 “(1) is required by section 911(b) to have pre-
6 market approval;

7 “(2) is not exempt under section 907(f); and

8 “(3) does not have an approved application in
9 effect.

10 “(f) **MANUFACTURING PRACTICES.**—A tobacco prod-
11 uct shall be deemed adulterated if the methods used in,
12 or the facilities or controls used for, the manufacture,
13 packing, or storage of the tobacco product are not in con-
14 formity with applicable requirements under section
15 907(e)(1) or an applicable condition prescribed by an
16 order under section 907(e)(2).

17 “(g) **INVESTIGATIONAL USE.**—A tobacco product
18 shall be deemed adulterated if—

19 “(1) the tobacco product is a tobacco product
20 for which an exemption has been granted under sec-
21 tion 907(f) for investigational use; and

22 “(2) the person that is granted the exemption
23 or any investigator that uses the tobacco product
24 under the exemption fails to comply with a require-
25 ment prescribed by or under section 907(f).

1 “(h) IMPORTED CIGARETTES.—A tobacco product
2 shall be deemed adulterated if the tobacco product is im-
3 ported, or offered for import, into the United States in
4 violation of section 5754 of the Internal Revenue Code of
5 1986 or title VIII of the Tariff Act of 1930 (19 U.S.C.
6 1681 et seq.).

7 **“SEC. 904. MISBRANDED TOBACCO PRODUCTS.**

8 “(a) FALSE LABELING.—A tobacco product shall be
9 deemed misbranded if the labeling of the tobacco product
10 is false or misleading.

11 “(b) MISLABELED PACKAGES.—

12 “(1) IN GENERAL.—Subject to paragraph (2), a
13 tobacco product in package form shall be deemed
14 misbranded unless the tobacco product bears a label
15 containing—

16 “(A) the name and place of business of the
17 tobacco product manufacturer, packer, or dis-
18 tributor; and

19 “(B) an accurate statement of the quantity
20 of the contents in terms of weight, measure, or
21 numerical count.

22 “(2) ADMINISTRATION.—In carrying out para-
23 graph (1)(B), the Secretary shall (by regulation)—

24 “(A) permit reasonable variations; and

1 “(B) establish exemptions for small pack-
2 ages.

3 “(c) INFORMATION.—A tobacco product shall be
4 deemed misbranded if any word, statement, or other infor-
5 mation required by or under authority of this chapter to
6 appear on the label or labeling is not prominently placed
7 on the label or labeling with such conspicuousness (as
8 compared with other words, statements, or designs in the
9 labeling) and in such terms as to render the information
10 likely to be read and understood by the ordinary individual
11 under customary conditions of purchase and use.

12 “(d) ESTABLISHED NAME.—A tobacco product shall
13 be deemed misbranded if—

14 “(1) the tobacco product has an established
15 name; and

16 “(2) the label of the tobacco product does not
17 bear, to the exclusion of any other nonproprietary
18 name, the established name of the tobacco product
19 prominently printed in type, as required by the Sec-
20 retary by regulation.

21 “(e) DIRECTIONS.—A tobacco product shall be
22 deemed misbranded if the Secretary has promulgated reg-
23 ulations requiring that the labeling of the tobacco product
24 bear adequate directions for use, or adequate warnings
25 against use by children, that are necessary for the protec-

1 tion of users unless the labeling of the tobacco product
2 conforms in all respects to the regulations.

3 “(f) PROCESSING.—A tobacco product shall be
4 deemed misbranded if—

5 “(1) the tobacco product was manufactured,
6 prepared, propagated, compounded, or processed in
7 any State in an establishment not duly registered
8 under section 906(b);

9 “(2) the tobacco product was not included in a
10 list required by section 906(i);

11 “(3) a notice or other information with respect
12 to the tobacco product was not provided as required
13 by section 906(i) or 906(j); or

14 “(4) the tobacco product does not bear such
15 symbols from the uniform system for identification
16 of tobacco products prescribed under section 906(e)
17 as the Secretary by regulation requires.

18 “(g) FALSE ADVERTISING.—In the case of any to-
19 bacco product distributed or offered for sale in any State,
20 a tobacco product shall be deemed misbranded if—

21 “(1) the advertising of the tobacco product is
22 false or misleading; or

23 “(2) the tobacco product is sold, distributed,
24 advertised, or promoted in violation of section 916
25 or regulations prescribed under section 907(d).

1 “(h) REQUIRED STATEMENTS.—In the case of any
2 tobacco product distributed or offered for sale in any
3 State, a tobacco product shall be deemed misbranded un-
4 less the manufacturer, packer, or distributor of the to-
5 bacco product includes in all advertisements and other de-
6 scriptive printed matter issued or caused to be issued by
7 the manufacturer, packer, or distributor with respect to
8 the tobacco product—

9 “(1) a true statement of the established name
10 of the tobacco product (as required under subsection
11 (d)), printed prominently; and

12 “(2) a brief description of—

13 “(A) the uses of the tobacco product and
14 relevant warnings, precautions, side effects, and
15 contraindications; and

16 “(B) in the case of specific tobacco prod-
17 ucts made subject to a finding by the Secretary
18 after notice and opportunity for comment that
19 the action is necessary to protect the public
20 health, a full description of the components of
21 the tobacco product or the formula showing
22 quantitatively each ingredient of the tobacco
23 product, to the extent required in regulations
24 which shall be promulgated by the Secretary
25 after an opportunity for a hearing.

1 “(i) MANDATORY DISCLAIMERS.—In the case of any
2 tobacco product distributed or offered for sale in any
3 State, a tobacco product shall be deemed misbranded un-
4 less the manufacturer, packer, or distributor of the to-
5 bacco product includes in all advertisements the informa-
6 tion required by section 917(c).

7 “(j) PERFORMANCE STANDARDS.—A tobacco product
8 shall be deemed misbranded if the tobacco product is a
9 tobacco product subject to a performance standard estab-
10 lished under section 908, unless the tobacco product bears
11 such labeling as may be prescribed in the performance
12 standard.

13 “(k) NOTICE.—A tobacco product shall be deemed
14 misbranded if there is a failure or refusal—

15 “(1) to comply with any requirement prescribed
16 under section 905 or 909; or

17 “(2) to furnish any material or information re-
18 quired by or under section 910.

19 “(l) LABELING.—A tobacco product shall be deemed
20 misbranded if the tobacco product is not in compliance
21 with—

22 “(1) the Federal Cigarette Labeling and Adver-
23 tising Act (15 U.S.C. 1331 et seq.); or

1 “(2) the Comprehensive Smokeless Tobacco
2 Health Education Act of 1986 (15 U.S.C. 4401 et
3 seq.).

4 “(m) PRIOR APPROVAL OF STATEMENTS ON
5 LABEL.—

6 “(1) IN GENERAL.—Subject to paragraphs (2)
7 and (3), the Secretary may, by regulation, require
8 prior approval of statements made on the label of a
9 tobacco product.

10 “(2) ADVERTISEMENT CONTENT.—In the case
11 of matters specified in this section or covered by reg-
12 ulations promulgated under this section—

13 “(A) no regulation promulgated under this
14 subsection may require prior approval by the
15 Secretary of the content of any advertisement;
16 and

17 “(B) no advertisement of a tobacco prod-
18 uct, published after the date of enactment of
19 the Tobacco Livelihood and Economic Assist-
20 ance for Our Farmers Act of 2002, shall be
21 subject to sections 12 through 15 of the Fed-
22 eral Trade Commission Act (15 U.S.C. 52
23 through 55).

1 “(3) LABELING.—This subsection does not
2 apply to any printed matter that the Secretary de-
3 termines to be labeling (as defined in section 201).

4 **“SEC. 905. SUBMISSION OF HEALTH INFORMATION TO THE**
5 **SECRETARY.**

6 “(a) REQUIREMENT.—Not later than 180 days after
7 the date of enactment of the Tobacco Livelihood and Eco-
8 nomic Assistance for Our Farmers Act of 2002, each to-
9 bacco product manufacturer or importer of tobacco prod-
10 ucts, or their agents, shall submit to the Secretary the
11 following information:

12 “(1) A listing of all tobacco ingredients, sub-
13 stances, and compounds that are, as of that date,
14 added by the manufacturer to the tobacco, paper, fil-
15 ter, or other component of each tobacco product by
16 brand and by quantity in each brand and subbrand.

17 “(2) A description of the content, delivery, and
18 form of nicotine in each tobacco product measured
19 in milligrams of nicotine.

20 “(3) All documents (including underlying sci-
21 entific information) relating to research activities
22 and research findings conducted, supported, or pos-
23 sessed by the manufacturer (or agents) on the
24 health, behavioral, or physiological effects of tobacco
25 products, their constituents, ingredients, and compo-

1 nents, and tobacco additives described in paragraph
2 (1).

3 “(4) All documents (including underlying sci-
4 entific information) relating to research activities,
5 and research findings, conducted, supported, or pos-
6 sessed by the manufacturer (or agents) that relate
7 to the issue of whether a reduction in risk to health
8 from tobacco products can occur on the employment
9 of technology available or known to the manufac-
10 turer.

11 “(5) All documents (including underlying sci-
12 entific information) relating to marketing research
13 involving the use of tobacco products.

14 “(b) ANNUAL SUBMISSION OF INFORMATION.—A to-
15 bacco product manufacturer or importer that is required
16 to submit information under subsection (a) shall update
17 the information on an annual basis in accordance with a
18 schedule determined by the Secretary.

19 “(c) TIME FOR SUBMISSION.—

20 “(1) NEW PRODUCTS.—At least 90 days prior
21 to the delivery for introduction into interstate com-
22 merce of a tobacco product not on the market on the
23 date of enactment of the Tobacco Livelihood and
24 Economic Assistance for Our Farmers Act of
25 2002—

1 “(A) the manufacturer of the tobacco
2 product shall provide the information required
3 under subsection (a); and

4 “(B) the tobacco product shall be subject
5 to the annual submission requirement under
6 subsection (b).

7 “(2) MODIFICATION OF EXISTING PRODUCTS.—
8 Not later than 60 days after the date of an action
9 described in this paragraph, a tobacco product man-
10 ufacturer shall advise the Secretary of the action in
11 writing, and reference the action in submissions
12 made under subsection (b), if the manufacturer—

13 “(A) adds to the tobacco product a new to-
14 bacco additive;

15 “(B) increases or decreases the quantity of
16 an existing tobacco additive or the nicotine con-
17 tent, delivery, or form; or

18 “(C) eliminates a tobacco additive from the
19 tobacco product.

20 **“SEC. 906. ANNUAL REGISTRATION.**

21 “(a) DEFINITIONS.—In this section:

22 “(1) MANUFACTURE, PREPARATION,
23 COMPOUNDING, OR PROCESSING.—The term ‘manu-
24 facture, preparation, compounding, or processing’ in-
25 cludes (consistent with section 902(c)(2)) repack-

1 aging or otherwise changing the container, wrapper,
2 or labeling of any tobacco product package in fur-
3 therance of the distribution of the tobacco product
4 from the original place of manufacture of the to-
5 bacco product to the place of business of the person
6 that makes final delivery or sale to the ultimate con-
7 sumer or user.

8 “(2) NAME.—The term ‘name’ includes—

9 “(A) in the case of a partnership, the
10 name of each partner; and

11 “(B) in the case of a corporation—

12 “(i) the name of each corporate offi-
13 cer and director; and

14 “(ii) the State of incorporation.

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

16 On or before December 31 of each year, each person that
17 owns or operates any establishment in any State engaged
18 in the manufacture, preparation, compounding, or proc-
19 essing of 1 or more tobacco products shall register with
20 the Secretary the name, places of business, and all such
21 establishments of the person.

22 “(c) REGISTRATION OF NEW OWNERS AND OPERA-
23 TORS.—On first engaging in the manufacture, prepara-
24 tion, compounding, or processing of a tobacco product or
25 tobacco products in an establishment owned or operated

1 in any State by a person, the person shall immediately
2 register with the Secretary the person's name, place of
3 business, and the establishment.

4 “(d) REGISTRATION OF ADDED ESTABLISHMENTS.—
5 Each person required to register under subsection (b) or
6 (c) shall immediately register with the Secretary any addi-
7 tional establishment that person owns or operates in any
8 State and at which the person begins the manufacture,
9 preparation, compounding, or processing of 1 or more to-
10 bacco products.

11 “(e) UNIFORM PRODUCT IDENTIFICATION SYS-
12 TEM.—The Secretary may by regulation—

13 “(1) prescribe a uniform system for the identi-
14 fication of tobacco products; and

15 “(2) require that persons that are required to
16 list the tobacco products under subsection (i) shall
17 list the tobacco products in accordance with the sys-
18 tem.

19 “(f) PUBLIC ACCESS TO REGISTRATION INFORMA-
20 TION.—On request, the Secretary shall make available for
21 inspection any registration filed under this section.

22 “(g) BIENNIAL INSPECTION OF REGISTERED ESTAB-
23 LISHMENTS.—

1 “(1) IN GENERAL.—Each establishment in any
2 State registered with the Secretary under this sec-
3 tion shall be subject to inspection under section 704.

4 “(2) ADMINISTRATION.—Each such establish-
5 ment engaged in the manufacture, compounding, or
6 processing of a tobacco product or tobacco products
7 shall be so inspected by 1 or more officers or em-
8 ployees duly designated by the Secretary—

9 “(A) at least once during the 2-year period
10 beginning with the date of registration of the
11 establishment under this section; and

12 “(B) at least once in every successive 2-
13 year period thereafter.

14 “(h) FOREIGN ESTABLISHMENTS.—

15 “(1) REGISTRATION.—Any establishment within
16 any foreign country engaged in the manufacture of
17 a tobacco product that is imported, or offered for
18 import, into the United States shall register with the
19 Secretary the name and place of business of the es-
20 tablishment and the name of the United States
21 agent for the establishment.

22 “(2) REGISTRATION INFORMATION.—Any estab-
23 lishment required to be registered under paragraph
24 (1) shall—

1 “(A) provide to the Secretary the informa-
2 tion required by subsection (i); and

3 “(B) comply with any other requirement of
4 this section that is applicable to domestic man-
5 ufacturers.

6 “(3) INSPECTIONS.—Any establishment re-
7 quired to be registered under paragraph (1) shall—

8 “(A) be subject to inspection under section
9 704; and

10 “(B) be inspected under that section by 1
11 or more officers or employees designated by the
12 Secretary at least once during—

13 “(i) the 2-year period beginning on
14 the date of the registration of the estab-
15 lishment under paragraph (1); and

16 “(ii) each 2-year period thereafter.

17 “(4) COOPERATIVE AGREEMENTS.—The Sec-
18 retary may enter into cooperative agreements with
19 officials of foreign countries to ensure that adequate
20 and effective means are available for purposes of de-
21 termining, from time to time, whether tobacco prod-
22 ucts manufactured by an establishment required to
23 be registered under paragraph (1), if imported or of-
24 fered for import into the United States, shall be re-
25 fused admission under section 801(a).

1 “(i) REGISTRATION INFORMATION.—

2 “(1) PRODUCT LIST.—Each person that reg-
3 isters with the Secretary under subsection (b), (c),
4 or (d) shall, at the time of registration under any of
5 those subsections, file with the Secretary a list of all
6 tobacco products that—

7 “(A) are being manufactured, prepared,
8 compounded, or processed by the person for
9 commercial distribution; and

10 “(B) have not been included in any list of
11 tobacco products filed by that person with the
12 Secretary under this paragraph or paragraph
13 (2) before the time of registration.

14 “(2) CONTENTS OF LIST.—The list shall be
15 prepared in such form and manner as the Secretary
16 may prescribe and shall be accompanied by—

17 “(A) in the case of a tobacco product con-
18 tained in the applicable list with respect to
19 which a performance standard has been estab-
20 lished under section 908 or that is subject to
21 section 911—

22 “(i) a reference to the authority for
23 the marketing of the tobacco product; and

24 “(ii) a copy of all labeling for the to-
25 bacco product;

1 “(B) in the case of any other tobacco prod-
2 uct contained in an applicable list—

3 “(i) a copy of all consumer informa-
4 tion and other labeling for the tobacco
5 product;

6 “(ii) a representative sampling of ad-
7 vertisements for the tobacco product; and

8 “(iii) on request made by the Sec-
9 retary for good cause, a copy of all adver-
10 tisements for a particular tobacco product;
11 and

12 “(C) if the registrant filing a list has de-
13 termined that a tobacco product contained in
14 the list is not subject to a performance stand-
15 ard established under section 908, a brief state-
16 ment of the basis on which the registrant made
17 the determination, if the Secretary requests
18 such a statement with respect to the particular
19 tobacco product.

20 “(3) SEMIANNUAL REPORT OF ANY CHANGE IN
21 PRODUCT LIST.—Each person that registers with the
22 Secretary under this subsection shall report to the
23 Secretary once during the month of June of each
24 year and once during the month of December of
25 each year the following:

1 “(A)(i) A list of each tobacco product in-
2 troduced by the registrant for commercial dis-
3 tribution that has not been included in any list
4 previously filed by the person with the Sec-
5 retary under this subparagraph or paragraph
6 (1).

7 “(ii) A list under this subparagraph shall
8 list a tobacco product by the established name
9 of the tobacco product and shall be accom-
10 panied by the other information required by
11 paragraphs (1) and (2).

12 “(B) If, since the date the registrant last
13 made a report under this paragraph, the person
14 has discontinued the manufacture, preparation,
15 compounding, or processing for commercial dis-
16 tribution of a tobacco product included in a list
17 filed under subparagraph (A) or paragraph
18 (1)—

19 “(i) notice of the discontinuance;

20 “(ii) the date of the discontinuance;

21 and

22 “(iii) the identity of the established
23 name of the tobacco product.

24 “(C) If, since the date the registrant re-
25 ported under subparagraph (B), a notice of dis-

1 continuanance that person has resumed the manu-
2 facture, preparation, compounding, or proc-
3 essing for commercial distribution of the to-
4 bacco product with respect to which a notice of
5 discontinuanance was reported, notice of the re-
6 sumption, the date of the resumption, the iden-
7 tity of the tobacco product by established name,
8 and other information required by paragraphs
9 (1) and (2), unless the registrant has previously
10 reported the resumption to the Secretary under
11 this subparagraph.

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

15 “(j) REPORT PRECEDING INTRODUCTION OF CER-
16 TAIN SUBSTANTIALLY EQUIVALENT PRODUCTS INTO
17 INTERSTATE COMMERCE.—Each person that is required
18 to register under this section and that proposes to begin
19 the introduction or delivery for introduction into interstate
20 commerce for commercial distribution of a tobacco product
21 intended for human use that was not commercially mar-
22 keted in the United States as of the date of enactment
23 of the Tobacco Livelihood and Economic Assistance for
24 Our Farmers Act of 2002 (as defined by the Secretary
25 by regulation) shall, at least 90 days before making the

1 introduction or delivery, report to the Secretary (in such
2 form and manner as the Secretary shall by regulation pre-
3 scribe)—

4 “(1) the basis for the person’s determination
5 that the tobacco product is substantially equivalent
6 (as defined in section 911) to a tobacco product
7 commercially marketed in the United States as of
8 the date of enactment of the Tobacco Livelihood and
9 Economic Assistance for Our Farmers Act of 2002
10 that is in compliance with the requirements of this
11 Act; and

12 “(2) action taken by the person to comply with
13 the requirements under section 908 that are applica-
14 ble to the tobacco product.

15 **“SEC. 907. GENERAL PROVISIONS CONCERNING CONTROL**
16 **OF TOBACCO PRODUCTS.**

17 “(a) IN GENERAL.—

18 “(1) APPLICABLE REQUIREMENTS.—Any re-
19 quirement established by or under section 903, 904,
20 906, or 910 that is applicable to a tobacco product
21 shall apply to the tobacco product until the applica-
22 bility of the requirement to the tobacco product has
23 been changed by action taken under section 908,
24 section 911, or subsection (d).

1 “(2) INAPPLICABLE REQUIREMENTS.—Any re-
2 quirement established by or under section 903, 904,
3 906, or 910 that is inconsistent with a requirement
4 imposed on the tobacco product under section 908,
5 section 911, or subsection (d) shall not apply to the
6 tobacco product.

7 “(b) INFORMATION ON PUBLIC ACCESS AND COM-
8 MENT.—

9 “(1) APPLICATION.—This subsection applies
10 to—

11 “(A) each notice of proposed rulemaking
12 under this section or section 908, 909, 910, or
13 911;

14 “(B) any other notice that is published in
15 the Federal Register with respect to any other
16 action taken under any such section and that
17 states the reasons for the action; and

18 “(C) each publication of findings required
19 to be made in connection with rulemaking
20 under any such section.

21 “(2) INFORMATION.—Each notice and publica-
22 tion described in paragraph (1) shall set forth—

23 “(A) the manner in which interested per-
24 sons may examine data and other information
25 on which the notice or findings are based; and

1 “(B) the period within which interested
2 persons may present their comments on the no-
3 tice or findings (including the need for the no-
4 tice or findings) orally or in writing, which pe-
5 riod shall be not less than 60 days, and not
6 more than 90 days, unless the period is ex-
7 tended by the Secretary by a notice published
8 in the Federal Register stating good cause for
9 the extension.

10 “(c) LIMITED CONFIDENTIALITY OF INFORMA-
11 TION.—

12 “(1) IN GENERAL.—Except as provided in para-
13 graph (2), any information reported to or otherwise
14 obtained by the Secretary or the Secretary’s rep-
15 resentative under section 704, 905, 906, 908, 909,
16 910, 911, or 913, or under subsection (e) or (f),
17 that is exempt from disclosure under section 552(a)
18 of title 5, United States Code, by reason of section
19 552(b)(4) of that title shall be considered confiden-
20 tial and shall not be disclosed.

21 “(2) EXCEPTIONS.—Information described in
22 paragraph (1) may be disclosed—

23 “(A) to other officers or employees that
24 are carrying out this chapter; or

1 “(B) when relevant in any proceeding
2 under this chapter.

3 “(d) RESTRICTIONS.—

4 “(1) IN GENERAL.—The Secretary may by reg-
5 ulation require that a tobacco product be restricted
6 to sale or distribution on such conditions (including
7 restrictions on the access to, and the advertising and
8 promotion of, the tobacco product) as the Secretary
9 may prescribe in the regulation if the Secretary de-
10 termines that the regulation would be appropriate
11 for the prevention of, or decrease in, the use of to-
12 bacco products by children under the age at which
13 tobacco products may be legally purchased.

14 “(2) PRESCRIPTIONS.—No condition under
15 paragraph (1) may require that the sale or distribu-
16 tion of a tobacco product be limited to the written
17 or oral authorization of a practitioner licensed by
18 law to prescribe medical products.

19 “(3) LABELS.—The label of a tobacco product
20 shall bear such appropriate statements of the re-
21 strictions required by a regulation under subsection
22 (a) as the Secretary may by regulation prescribe.

23 “(4) FACE-TO-FACE TRANSACTIONS.—No re-
24 striction under paragraph (1) may prohibit the sale

1 of any tobacco product in face-to-face transactions
2 by a specific category of retail outlets.

3 “(e) GOOD MANUFACTURING PRACTICES.—

4 “(1) METHODS, FACILITIES, AND CONTROLS.—

5 “(A) IN GENERAL.—The Secretary may, in
6 accordance with subparagraph (B), prescribe
7 regulations requiring that the methods used in,
8 and the facilities and controls used for, the
9 manufacture, pre-production design validation
10 (including a process to assess the performance
11 of a tobacco product), and packing, and storage
12 of a tobacco product conform to current good
13 manufacturing practice for an agricultural
14 product, as prescribed in the regulations, to en-
15 sure that the public health is protected and that
16 the tobacco product is in compliance with this
17 chapter.

18 “(B) ADMINISTRATION.—The Secretary
19 shall—

20 “(i) before promulgating any regula-
21 tion under subparagraph (A), afford an ad-
22 visory committee an opportunity to submit
23 recommendations with respect to the regu-
24 lation proposed to be promulgated;

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

4 “(iii) provide the advisory committee a
5 reasonable time to make the recommenda-
6 tion of the advisory committee with respect
7 to a proposed regulation under subpara-
8 graph (A); and

9 “(iv) in establishing the effective date
10 of a regulation promulgated under this
11 subsection—

12 “(I) take into account the dif-
13 ferences in—

14 “(aa) the manner in which
15 the different types of tobacco
16 products have historically been
17 produced;

18 “(bb) the financial resources
19 of the different tobacco product
20 manufacturers; and

21 “(cc) the state of their exist-
22 ing manufacturing facilities; and

23 “(II) provide for a reasonable pe-
24 riod of time for the manufacturers to

1 conform to good manufacturing prac-
2 tices.

3 “(2) EXEMPTIONS; VARIANCES.—

4 “(A) IN GENERAL.—Any person subject to
5 any requirement prescribed under paragraph
6 (1) may petition the Secretary for a permanent
7 or temporary exemption or variance from the
8 requirement.

9 “(B) CONTENT.—The petition shall be
10 submitted to the Secretary in such form and
11 manner as the Secretary shall prescribe and
12 shall—

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

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

1 ods, facilities, and controls prescribed by
2 the requirement; and

3 “(iii) contain such other information
4 as the Secretary shall prescribe.

5 “(C) ADVISORY COMMITTEE.—

6 “(i) REFERRAL.—The Secretary may
7 refer to an advisory committee any petition
8 submitted under subparagraph (A).

9 “(ii) RECOMMENDATIONS.—The advi-
10 sory committee shall report the rec-
11 ommendations of the advisory committee
12 to the Secretary with respect to a petition
13 referred to the advisory committee within
14 60 days after the date of the petition’s re-
15 ferral.

16 “(iii) DEADLINE FOR APPROVAL OR
17 DENIAL.—The Secretary shall by order ei-
18 ther approve or deny the petition not later
19 than 60 days after the later of—

20 “(I) the date on which the peti-
21 tion was submitted to the Secretary
22 under subparagraph (A); or

23 “(II) the day after the date on
24 which the petition was referred to an
25 advisory committee.

1 “(D) GROUNDS FOR APPROVAL.—The Sec-
2 retary may approve—

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

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

19 “(E) CONDITIONS.—An order of the Sec-
20 retary approving a petition for a variance shall
21 prescribe such conditions respecting the meth-
22 ods used in, and the facilities and controls used
23 for, the manufacture, packing, and storage of
24 the tobacco product to be granted the variance
25 under the petition as may be necessary to en-

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

3 “(F) HEARING.—After the issuance of an
4 order under subparagraph (C) with respect to a
5 petition, the petitioner shall have an oppor-
6 tunity for an informal hearing on the order.

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

11 “(g) RESEARCH AND DEVELOPMENT.—The Sec-
12 retary may enter into contracts for research, testing, and
13 demonstrations with respect to tobacco products, and may
14 obtain tobacco products for research, testing, and dem-
15 onstration purposes, without regard to section 3324(a)
16 and (b) of title 31, United States Code, and section 5 of
17 title 41, United States Code.

18 **“SEC. 908. PERFORMANCE STANDARDS.**

19 “(a) IN GENERAL.—

20 “(1) FINDING.—

21 “(A) REQUIREMENT.—The Secretary may
22 adopt a performance standard for a tobacco
23 product if the Secretary finds that the perform-
24 ance standard is appropriate for the protection
25 of the public health.

1 “(B) BASIS.—The finding shall be deter-
2 mined with respect to the risks and benefits to
3 the population as a whole, including users and
4 non-users of the tobacco product, and taking
5 into account—

6 “(i) the increased or decreased likeli-
7 hood that existing users of tobacco prod-
8 ucts will stop using tobacco products; and

9 “(ii) the increased or decreased likeli-
10 hood that those individuals who do not use
11 tobacco products will start using tobacco
12 products.

13 “(2) CONTENT OF PERFORMANCE STAND-
14 ARDS.—A performance standard established under
15 this section for a tobacco product—

16 “(A) shall include provisions to provide
17 performance that is appropriate for the protec-
18 tion of the public health, including provisions,
19 where appropriate—

20 “(i) for the reduction of nicotine
21 yields of the tobacco product;

22 “(ii) for the reduction or elimination
23 of other harmful constituents or harmful
24 components of the tobacco product; or

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

3 “(B) shall, if necessary for the protection
4 of public health, include—

5 “(i) provisions respecting the con-
6 struction, components, ingredients, and
7 properties of the tobacco product;

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

11 “(iii) provisions for the measurement
12 of the performance characteristics of the
13 tobacco product; and

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

21 “(C) shall not render the tobacco product
22 unacceptable for adult consumption.

23 “(3) PERIODIC REEVALUATION OF PERFORM-
24 ANCE STANDARDS.—

1 “(A) IN GENERAL.—The Secretary shall
2 provide for periodic evaluation of performance
3 standards established under this section to de-
4 termine whether the standards should be
5 changed to reflect new medical, scientific, or
6 other technological data.

7 “(B) TESTER.—The Secretary may pro-
8 vide for testing under paragraph (2) by any
9 person.

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

14 “(A) use available personnel, facilities, and
15 other technical support of other Federal agen-
16 cies;

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

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

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

3 “(b) ESTABLISHMENT, AMENDMENT, OR REVOCATION OF STANDARDS.—

4
5 “(1) NOTICE.—

6 “(A) IN GENERAL.—The Secretary shall
7 publish in the Federal Register a notice of proposed rulemaking for the establishment, amendment, or revocation of any performance standard for a tobacco product.

8
9
10
11 “(B) ESTABLISHMENT OR AMENDMENT.—
12 A notice of proposed rulemaking for the establishment or amendment of a performance standard for a tobacco product shall—

13
14
15 “(i) set forth a finding with supporting justification that the performance standard is appropriate for the protection of the public health;

16
17
18
19 “(ii) set forth proposed findings with respect to the risk of illness or injury that the performance standard is intended to reduce or eliminate; and

20
21
22
23 “(iii) invite interested persons to submit an existing performance standard for the tobacco product, including a draft or
24
25

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

3 “(C) REVOCATION.—A notice of proposed
4 rulemaking for the revocation of a performance
5 standard shall set forth a finding with sup-
6 porting justification that the performance
7 standard is no longer necessary for the protec-
8 tion of the public health.

9 “(D) ADMINISTRATION.—The Secretary
10 shall—

11 “(i) consider all information sub-
12 mitted in connection with a proposed
13 standard, including information concerning
14 the countervailing effects of the perform-
15 ance standard on the health of adolescent
16 tobacco users, adult tobacco users, or non-
17 tobacco users, such as the creation of a
18 significant demand for contraband or other
19 tobacco products that do not meet the re-
20 quirements of this chapter and the signifi-
21 cance of the demand; and

22 “(ii) issue the standard, if the Sec-
23 retary determines that the standard would
24 be appropriate for the protection of the
25 public health.

1 “(E) COMMENT PERIOD.—In issuing a
2 standard under this subsection, the Secretary
3 shall provide for a comment period of not less
4 than 60 days.

5 “(2) PROMULGATION.—

6 “(A) IN GENERAL.—After the expiration of
7 the period for comment on a notice of proposed
8 rulemaking published under paragraph (1) with
9 respect to a performance standard and after
10 consideration of the comments and any report
11 from an advisory committee, the Secretary
12 shall—

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

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

21 “(B) EFFECTIVE DATE.—

22 “(i) IN GENERAL.—Subject to clauses
23 (ii) and (iii), a regulation establishing a
24 performance standard shall set forth the 1

1 or more dates on which the standard takes
2 effect.

3 “(ii) EARLIEST EFFECTIVE DATE.—

4 No such regulation may take effect before
5 the date that is 1 year after the date of the
6 publication of the regulation unless the
7 Secretary determines that an earlier effec-
8 tive date is necessary for the protection of
9 the public health.

10 “(iii) BASIS.—The 1 or more effective
11 dates shall be established so as to mini-
12 mize, consistent with the public health,
13 economic loss to, and disruption or disloca-
14 tion of, domestic and international trade.

15 “(3) POWERS RESERVED TO CONGRESS.—Con-
16 gress expressly reserves the power to make a deci-
17 sion establishing a performance standard—

18 “(A) eliminating all cigarettes, all smoke-
19 less tobacco products, or any similar class of to-
20 bacco products; or

21 “(B) requiring the reduction of nicotine
22 yields of a tobacco product to zero.

23 “(4) AMENDMENT; REVOCATION.—

24 “(A) IN GENERAL.—On the Secretary’s
25 own initiative or on petition of an interested

1 person, the Secretary may, by regulation pro-
2 mulgated in accordance with paragraphs (1)
3 and (2)(B), amend or revoke a performance
4 standard.

5 “(B) INTERIM EFFECTIVENESS.—The Sec-
6 retary may declare a proposed amendment of a
7 performance standard to be effective on and
8 after the publication of the amendment in the
9 Federal Register and until the effective date of
10 any final action taken on the amendment, if the
11 Secretary determines that making it so effective
12 is in the public interest.

13 “(5) REFERENCE TO ADVISORY COMMITTEE.—

14 “(A) IN GENERAL.—In the case of a pro-
15 posed regulation for the establishment, amend-
16 ment, or revocation of a performance standard,
17 the Secretary—

18 “(i) on the Secretary’s own initiative,
19 may refer to an advisory committee, for a
20 report and recommendation, any matter in-
21 volved in the proposed regulation that re-
22 quires the exercise of scientific judgment;
23 and

24 “(ii) on the request of an interested
25 person that demonstrates good cause for

1 referral and that is made before the expi-
2 ration of the period for submission of com-
3 ments on a proposed regulation, shall refer
4 to an advisory committee, for a report and
5 recommendation, any matter described in
6 clause (i).

7 “(B) INFORMATION.—If a proposed regu-
8 lation is referred to the advisory committee
9 under this paragraph, the Secretary shall pro-
10 vide the advisory committee with the data and
11 information on which the proposed regulation is
12 based.

13 “(C) REPORT AND RECOMMENDATION.—
14 Not later than 60 days after the referral of a
15 proposed regulation, the advisory committee
16 shall—

17 “(i) conduct an independent study of
18 the data and information furnished to the
19 advisory committee by the Secretary and
20 other data and information before the advi-
21 sory committee; and

22 “(ii) submit to the Secretary a report
23 and recommendation with respect to the
24 proposed regulation, together with all un-
25 derlying data and information and a state-

1 ment of the reason or basis for the rec-
2 ommendation.

3 “(D) COPY.—A copy of the report and rec-
4 ommendation shall be made public by the Sec-
5 retary.

6 **“SEC. 909. NOTIFICATION AND OTHER REMEDIES.**

7 “(a) NOTIFICATION.—

8 “(1) CONDITIONS.—The Secretary may issue
9 an order described in paragraph (2) if the Secretary
10 determines that—

11 “(A) a tobacco product that is introduced
12 or delivered for introduction into interstate
13 commerce for commercial distribution presents
14 a risk of substantial harm to the public health
15 that exceeds the risks posed by similar tobacco
16 products marketed before the date of enactment
17 of the Tobacco Livelihood and Economic Assist-
18 ance for Our Farmers Act of 2002; and

19 “(B)(i) notification under this subsection is
20 necessary to eliminate the unreasonable risk of
21 the harm; and

22 “(ii) no more practicable means is avail-
23 able under the provisions of this chapter (other
24 than this section) to eliminate the risk.

1 “(2) ORDER.—If the Secretary makes a deter-
2 mination described in paragraph (2), the Secretary
3 may issue such order as may be necessary to ensure
4 that adequate notification is provided in an appro-
5 priate form, by the persons and means best suited
6 under the circumstances involved, to all persons that
7 should properly receive the notification in order to
8 eliminate the risk.

9 “(3) MEANS.—The Secretary may order notifi-
10 cation by any appropriate means, including public
11 service announcements.

12 “(4) CONSULTATION.—Before issuing an order
13 under this subsection, the Secretary shall consult
14 with the persons that are to give notice under the
15 order.

16 “(b) NO EXEMPTION FROM OTHER LIABILITY.—
17 Compliance with an order issued under this section shall
18 not relieve any person from liability under Federal or
19 State law.

20 “(c) RECALL AUTHORITY.—

21 “(1) IN GENERAL.—If the Secretary finds that
22 there is a reasonable probability that a tobacco prod-
23 uct contains a manufacturing or other defect not or-
24 dinarily contained in tobacco products on the market
25 that would cause serious, adverse health con-

1 sequences or death, the Secretary shall issue an
2 order requiring the appropriate person (including
3 the manufacturers, importers, distributors, or retail-
4 ers of the tobacco product) to immediately cease dis-
5 tribution of the tobacco product.

6 “(2) HEARING.—The order shall provide the
7 person subject to the order with an opportunity for
8 an informal hearing, to be held not later than 10
9 days after the date of the issuance of the order, on
10 the actions required by the order and on whether the
11 order should be amended to require a recall of the
12 tobacco product.

13 “(3) VACATION OF ORDER.—If, after providing
14 an opportunity for such a hearing, the Secretary de-
15 termines that inadequate grounds exist to support
16 the actions required by the order, the Secretary shall
17 vacate the order.

18 “(4) AMENDMENT OF ORDER TO REQUIRE RE-
19 CALL.—

20 “(A) IN GENERAL.—Except as provided in
21 subparagraph (C), if, after providing an oppor-
22 tunity for an informal hearing under paragraph
23 (1), the Secretary determines that the order
24 should be amended to include a recall of the to-
25 bacco product with respect to which the order

1 was issued, the Secretary shall amend the order
2 to require a recall.

3 “(B) TIMETABLE.—The Secretary shall
4 specify a timetable during which the tobacco
5 product recall will occur and shall require peri-
6 odic reports to the Secretary describing the
7 progress of the recall.

8 “(C) CONTENTS.—An amended order
9 under subparagraph (A)—

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

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

15 “(D) NOTIFICATION BY RETAILERS.—In
16 providing the notice required by subparagraph
17 (C)(ii), the Secretary may use the assistance of
18 retailers and other persons that distribute the
19 tobacco product.

20 “(E) NOTIFICATION BY SECRETARY.—If a
21 significant number of persons described in sub-
22 paragraph (D) cannot be identified, the Sec-
23 retary shall notify the persons under section
24 705(b).

1 “(3) REMEDY NOT EXCLUSIVE.—The remedy
2 provided by this subsection shall be in addition to
3 remedies provided by subsection (a).

4 **“SEC. 910. RECORDS AND REPORTS ON TOBACCO PROD-**
5 **UCTS.**

6 “(a) IN GENERAL.—Each person that is a tobacco
7 product manufacturer or importer of a tobacco product
8 shall establish and maintain such records, make such re-
9 ports, and provide such information as the Secretary may
10 by regulation reasonably require to ensure that the to-
11 bacco product is not adulterated or misbranded and to
12 otherwise protect public health.

13 “(b) ADMINISTRATION.—Regulations promulgated
14 under subsection (a)—

15 “(1) may require a tobacco product manufac-
16 turer or importer to report to the Secretary in any
17 case in which the manufacturer or importer receives
18 or otherwise becomes aware of information that rea-
19 sonably suggests that 1 of the marketed tobacco
20 products of the manufacturer or importer may have
21 caused or contributed to a serious, unexpected ad-
22 verse experience associated with the use of the prod-
23 uct or any significant increase in the frequency of a
24 serious, expected adverse product experience;

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

4 “(3) shall not impose requirements that are un-
5 duly burdensome to a tobacco product manufacturer
6 or importer, taking into account the cost of com-
7 plying with the requirements and the need for the
8 protection of the public health and the implementa-
9 tion of this chapter;

10 “(4) when prescribing the procedure for making
11 requests for reports or information, shall require
12 that each request made under the regulations for
13 submission of a report or information to the Sec-
14 retary state the reason or purpose for the request
15 and identify, to the maximum extent practicable, the
16 report or information;

17 “(5) when requiring submission of a report or
18 information to the Secretary, shall state the reason
19 or purpose for the submission of the report or infor-
20 mation and identify to the maximum extent prac-
21 ticable the report or information; and

22 “(6) may not require that the identity of any
23 patient or user be disclosed in records, reports, or
24 information required under this subsection unless
25 disclosure is necessary—

1 “(A) to protect the medical welfare of an
2 individual;

3 “(B) to determine risks to public health of
4 a tobacco product; or

5 “(C) to verify a record, report, or informa-
6 tion submitted under this chapter.

7 “(c) MEDICAL ETHICS AND PATIENT INTERESTS.—

8 “(1) IN GENERAL.—In promulgating regula-
9 tions under this section, the Secretary shall have due
10 regard for the professional ethics of the medical pro-
11 fession and the interests of patients.

12 “(2) CONFIDENTIALITY.—The prohibitions of
13 subsection (b)(6) shall continue to apply to records,
14 reports, and information concerning any individual
15 that has been a patient, irrespective of whether or
16 when the individual ceases to be a patient.

17 “(d) REPORTS OF REMOVALS AND CORRECTIONS.—

18 “(1) IN GENERAL.—Except as provided in para-
19 graph (3), the Secretary shall by regulation require
20 a tobacco product manufacturer or importer of a to-
21 bacco product to report promptly to the Secretary
22 any corrective action taken, or removal from the
23 market of a tobacco product undertaken, by the
24 manufacturer or importer if the removal or correc-
25 tion was undertaken—

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

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

6 “(2) RECORD.—A tobacco product manufac-
7 turer or importer of a tobacco product that under-
8 takes a corrective action or removal from the market
9 of a tobacco product that is not required to be re-
10 ported under this subsection shall keep a record of
11 the correction or removal.

12 “(3) PREVIOUS REPORT.—No report of the cor-
13 rective action or removal of a tobacco product may
14 be required under paragraph (1) if a report of the
15 corrective action or removal is required and has been
16 submitted under subsection (a).

17 **“SEC. 911. PREMARKET REVIEW OF CERTAIN TOBACCO**
18 **PRODUCTS.**

19 “(a) DEFINITION OF SUBSTANTIALLY EQUIVA-
20 LENT.—

21 “(1) IN GENERAL.—In this section and section
22 906(j), the term ‘substantially equivalent’ or ‘sub-
23 stantial equivalence’ mean, with respect to the to-
24 bacco product being compared to the predicate to-

1 tobacco product, that the Secretary by order has de-
2 termined that—

3 “(A) the tobacco product has the same
4 characteristics as the predicate tobacco product;
5 or

6 “(B) the tobacco product has different
7 characteristics, and the information for the to-
8 bacco product submitted contains information,
9 including clinical data if considered necessary
10 by the Secretary, that demonstrates that it is
11 not appropriate to regulate the product under
12 the applicable section because the product could
13 not reasonably be expected to increase the
14 health risks to consumers compared to a con-
15 ventional tobacco product that is commercially
16 marketed in the United States and that is in
17 compliance with the requirements of this Act.

18 “(2) DEFINITION OF CHARACTERISTICS.—In
19 subparagraph (A), the term ‘characteristics’ means
20 the materials, ingredients, design, composition, heat-
21 ing source, or other features of a tobacco product.

22 “(3) INAPPLICABLE TOBACCO PRODUCTS.—A
23 tobacco product may not be found to be substan-
24 tially equivalent to a predicate tobacco product that
25 has been removed from the market at the initiative

1 of the Secretary or that has been determined by a
2 judicial order to be misbranded or adulterated.

3 “(b) REQUIREMENT FOR PREMARKET APPROVAL.—

4 “(1) IN GENERAL.—Approval under this section
5 of an application for premarket approval for any to-
6 bacco product, other than a reduced exposure to-
7 bacco product or a reduced risk tobacco product
8 under section 913, that is not commercially mar-
9 keted in the United States as of the date of enact-
10 ment of the Tobacco Livelihood and Economic As-
11 sistance for Our Farmers Act of 2002 shall be re-
12 quired unless—

13 “(A) the manufacturer has submitted a re-
14 port under section 906(j); and

15 “(B) the Secretary has not suspended the
16 distribution of the product under this para-
17 graph.

18 “(2) SUSPENSION OF DISTRIBUTION.—Not
19 later than 90 days after the submission of a report
20 under section 906(j), the Secretary may by order
21 suspend the distribution of the tobacco product that
22 is the subject of the report if the Secretary deter-
23 mines that there is a reasonable likelihood that the
24 tobacco product is not substantially equivalent to a
25 tobacco product that is—

1 “(A) commercially marketed in the United
2 States as of the date of the Tobacco Livelihood
3 and Economic Assistance for Our Farmers Act
4 of 2002; and

5 “(B) in compliance with the requirements
6 of this Act.

7 “(3) FAILURE TO ISSUE ORDER.—If the Sec-
8 retary fails to issue an order within the 90-day pe-
9 riod described in paragraph (2), the tobacco product
10 that is the subject of the report shall be deemed to
11 be substantially equivalent to a predicate tobacco
12 product.

13 “(4) FINAL AGENCY ACTION.—

14 “(A) IN GENERAL.—Subject to subpara-
15 graph (B), the issuance of an order under this
16 paragraph shall constitute final agency action
17 for purposes of section 702 of title 5, United
18 States Code.

19 “(B) RESCISSION OR MODIFICATION.—The
20 Secretary may rescind or modify an order
21 issued under this subsection at any time.

22 “(c) HEALTH INFORMATION.—

23 “(1) IN GENERAL.—As part of a submission
24 under section 906(j) with respect to a tobacco prod-
25 uct, the person required to file a premarket notifica-

1 tion under section 906(j) shall provide an adequate
2 summary of any health information relating to the
3 tobacco product or state that the information will be
4 made available on request by any person.

5 “(2) ADMINISTRATION.—Any summary under
6 paragraph (1) respecting a tobacco product shall—

7 “(A) contain detailed information regard-
8 ing data concerning adverse health effects; and

9 “(B) be made available to the public by the
10 Secretary not later than 30 days after the date
11 of issuance of a determination that the tobacco
12 product is substantially equivalent to another
13 tobacco product.

14 “(3) REQUIREMENTS.—The communication
15 that the product is a reduced exposure tobacco prod-
16 uct or a reduced risk tobacco product shall comply
17 with requirements prescribed by the Secretary relat-
18 ing to the communication.

19 “(4) PRIOR APPROVAL.—The Secretary may re-
20 quire prior approval of the communication in each
21 case in accordance with section 913.

22 “(d) APPLICATION.—

23 “(1) CONTENTS.—An application for premarket
24 approval shall contain—

1 “(A) full reports of all information, pub-
2 lished or known to, or that should reasonably be
3 known to, the applicant, concerning investiga-
4 tions that have been made to show the health
5 risks of the tobacco product and whether the to-
6 bacco product presents greater risk than other
7 tobacco products;

8 “(B) a full statement of the components,
9 ingredients, and properties, and of the principle
10 or principles of operation, of the tobacco prod-
11 uct;

12 “(C) a full description of the methods used
13 in, and the facilities and controls used for, the
14 manufacture, processing, and, when relevant,
15 packing and installation of, the tobacco prod-
16 uct;

17 “(D) an identifying reference to any per-
18 formance standard under section 908 that
19 would be applicable to any aspect of the tobacco
20 product, and either adequate information to
21 show that the aspect of the tobacco product
22 fully meets the performance standard or ade-
23 quate information to justify any deviation from
24 the standard;

1 “(E) such samples of the tobacco product
2 and of components of the tobacco product as
3 the Secretary may reasonably require;

4 “(F) specimens of the labeling proposed to
5 be used for the tobacco product; and

6 “(G) such other information relevant to
7 the subject matter of the application as the Sec-
8 retary may require.

9 “(2) REFERENCE TO ADVISORY COMMITTEE.—
10 On receipt of an application meeting the require-
11 ments set forth in paragraph (1), the Secretary—

12 “(A) on the Secretary’s own initiative, may
13 refer the application to an advisory committee
14 for submission (within such period as the Sec-
15 retary may establish) of a report and rec-
16 ommendation respecting approval of the appli-
17 cation, together with all underlying data and
18 the reasons or basis for the recommendation; or

19 “(B) on the request of an applicant, shall
20 refer the application to an advisory committee
21 in accordance with subparagraph (A).

22 “(e) ACTION ON APPLICATION.—

23 “(1) DEADLINE.—

24 “(A) IN GENERAL.—As promptly as prac-
25 ticable, but not later than 180 days, after the

1 date of receipt of an application under sub-
2 section (d), the Secretary, after considering the
3 report and recommendation submitted under
4 subsection (d)(2), shall—

5 “(i) issue an order approving the ap-
6 plication, if the Secretary finds that none
7 of the grounds for denying approval speci-
8 fied in paragraph (2) applies; or

9 “(ii) deny approval of the application,
10 if the Secretary finds (and sets forth the
11 basis for the finding as part of or accom-
12 panying the denial) that 1 or more
13 grounds for denial specified in paragraph
14 (2) apply.

15 “(B) SALES RESTRICTIONS.—An order ap-
16 proving an application for a tobacco product
17 may require as a condition to the approval that
18 the sale and distribution of the tobacco product
19 be restricted, but only to the extent that the
20 sale and distribution of a tobacco product may
21 be restricted under a regulation promulgated
22 under section 907(d).

23 “(2) DENIAL OF APPROVAL.—The Secretary
24 shall deny approval of an application for a tobacco
25 product if, on the basis of the information submitted

1 to the Secretary as part of the application and any
2 other information before the Secretary with respect
3 to the tobacco product, the Secretary finds that—

4 “(A) there is a lack of a showing that per-
5 mitting the tobacco product to be marketed
6 would pose no greater risk to the public health
7 than currently marketed tobacco products;

8 “(B) the methods used in, or the facilities
9 or controls used for, the manufacture, proc-
10 essing, or packing of the tobacco product do not
11 conform to the requirements of section 907(e);

12 “(C) based on a fair evaluation of all mate-
13 rial facts, the proposed labeling is false or mis-
14 leading; or

15 “(D)(i) the tobacco product is not shown
16 to conform in all respects to a performance
17 standard in effect under section 908, compli-
18 ance with which is a condition to approval of
19 the application; and

20 “(ii) there is a lack of adequate informa-
21 tion to justify the deviation from the standard.

22 “(3) DENIAL INFORMATION.—Any denial of an
23 application shall, to the extent that the Secretary de-
24 termines to be practicable, be accompanied by a
25 statement informing the applicant of the measures

1 required to make the application approvable (which
2 measures may include further research by the appli-
3 cant in accordance with 1 or more protocols pre-
4 scribed by the Secretary).

5 “(4) BASIS FOR ACTION.—

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

15 “(B) EVIDENCE.—If the Secretary deter-
16 mines that there exists valid scientific evidence
17 (other than evidence derived from investigations
18 described in subparagraph (A)) that is suffi-
19 cient to evaluate the tobacco product, the Sec-
20 retary may authorize that the determination
21 under paragraph (2)(A) be made on the basis
22 of the evidence.

23 “(f) WITHDRAWAL AND TEMPORARY SUSPENSION.—

24 “(1) IN GENERAL.—The Secretary shall, on ob-
25 taining, where appropriate, advice on scientific mat-

1 ters from an advisory committee, and after due no-
2 tice and opportunity for informal hearing to the
3 holder of an approved application for a tobacco
4 product, issue an order withdrawing approval of the
5 application if the Secretary finds that—

6 “(A) the continued marketing of the to-
7 bacco product poses greater risks to the public
8 health than other available products;

9 “(B) the application contained or was ac-
10 companied by a false or misleading statement of
11 a material fact;

12 “(C) the applicant—

13 “(i) has failed to establish a system
14 for maintaining records, or has repeatedly
15 or deliberately failed to maintain records
16 or to make reports, required by an applica-
17 ble regulation under section 910;

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

21 “(iii) has not complied with the re-
22 quirements of section 906;

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

1 before the Secretary when the application was
2 approved, whether the methods used in, or the
3 facilities and controls used for, the manufac-
4 ture, processing, packing, or installation of the
5 tobacco product do not conform with the re-
6 quirements of section 907(e) and were not
7 brought into conformity with the requirements
8 within a reasonable time after receipt of written
9 notice from the Secretary of nonconformity;

10 “(E) on the basis of new information be-
11 fore the Secretary, evaluated, together with the
12 evidence before the Secretary when the applica-
13 tion was approved, whether the labeling of the
14 tobacco product, based on a fair evaluation of
15 all material facts, is false or misleading and
16 was not corrected within a reasonable time after
17 receipt of written notice from the Secretary of
18 the fact; or

19 “(F) on the basis of new information be-
20 fore the Secretary, evaluated, together with the
21 evidence before the Secretary when the applica-
22 tion was approved, whether the tobacco product
23 is shown to conform in all respects to a per-
24 formance standard that is in effect under sec-
25 tion 908, compliance with which was a condi-

1 tion to approval of the application, and whether
2 there is a lack of adequate information to jus-
3 tify the deviation from the standard.

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

11 “(3) TEMPORARY SUSPENSION.—

12 “(A) IN GENERAL.—If, after providing an
13 opportunity for an informal hearing, the Sec-
14 retary determines there is reasonable prob-
15 ability that the continuation of distribution of a
16 tobacco product under an approved application
17 would cause serious, adverse health con-
18 sequences or death, that is greater than ordi-
19 narily caused by tobacco products on the mar-
20 ket, the Secretary shall by order temporarily
21 suspend the approval of the application ap-
22 proved under this section.

23 “(B) WITHDRAWAL OF APPLICATION.—If
24 the Secretary issues such an order, the Sec-

1 retary shall proceed expeditiously under para-
2 graph (1) to withdraw the application.

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

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

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

11 **“SEC. 912. JUDICIAL REVIEW.**

12 “(a) DEFINITION OF RECORD.—In this section, the
13 term ‘record’ means—

14 “(1) all notices and other matter published in
15 the Federal Register with respect to a regulation or
16 order reviewed;

17 “(2) all information submitted to the Secretary
18 with respect to—

19 “(A) a regulation or order;

20 “(B) proceedings of any panel or advisory
21 committee with respect to the regulation or
22 order; and

23 “(C) any hearing held with respect to the
24 regulation or order; and

1 “(3) any other information identified by the
2 Secretary, in the administrative proceeding held with
3 respect to the regulation or order, as being relevant
4 to the regulation or order.

5 “(b) PETITION.—

6 “(1) IN GENERAL.—Not later than 30 days
7 after the date of promulgation of a regulation under
8 section 908 establishing, amending, or revoking a
9 performance standard for a tobacco product, or a
10 denial of an application for approval under section
11 911(c), any person adversely affected by the regula-
12 tion or order may file a petition with the United
13 States Court of Appeals for the District of Colum-
14 bia, or for the circuit in which the person resides or
15 has the person’s principal place of business, for judi-
16 cial review of the regulation or order.

17 “(2) COPY OF PETITION.—A copy of the peti-
18 tion shall be transmitted by the clerk of the court
19 to the Secretary or other officer designated by the
20 Secretary for that purpose.

21 “(3) RECORD OF PROCEEDINGS.—

22 “(A) FILING.—The Secretary shall file in
23 the court the record of the proceedings on
24 which the Secretary based the Secretary’s regu-
25 lation or order.

1 “(B) RATIONALE.—Each record or order
2 shall contain a statement of the reasons for the
3 issuance of the order and the basis, on the
4 record, for the issuance of the order.

5 “(c) ADDITIONAL FINDINGS BY SECRETARY.—

6 “(1) IN GENERAL.—The court may order the
7 Secretary to provide additional opportunity for the
8 oral presentation of data, views, or arguments and
9 for written submissions if the petitioner—

10 “(A) applies to the court for leave to ad-
11 duce additional data, views, or arguments re-
12 specting the regulation or order being reviewed;
13 and

14 “(B) demonstrates to the satisfaction of
15 the court that—

16 “(i) the additional data, views, or ar-
17 guments are material; and

18 “(ii) there were reasonable grounds
19 for the petitioner’s failure to adduce the
20 data, views, or arguments in the pro-
21 ceedings before the Secretary.

22 “(2) MODIFICATION.—The Secretary—

23 “(A) may modify the Secretary’s findings,
24 or make new findings by reason of the addi-
25 tional data, views, or arguments so taken; and

1 “(B) shall file with the court—

2 “(i) the modified or new findings;

3 “(ii) the Secretary’s recommendation,
4 if any, for the modification or setting aside
5 of the regulation or order being reviewed;
6 and

7 “(iii) the return of the additional
8 data, views, or arguments.

9 “(d) STANDARD OF REVIEW.—

10 “(1) IN GENERAL.—On the filing of the petition
11 under subsection (a) for judicial review of a regula-
12 tion or order, the court shall have jurisdiction—

13 “(A) to review the regulation or order in
14 accordance with chapter 7 of title 5, United
15 States Code; and

16 “(B) to grant appropriate relief, including
17 interim relief, as provided in that chapter.

18 “(2) STANDARD.—A regulation or order de-
19 scribed in paragraph (1) or (2) of subsection (a)
20 shall not be affirmed if the regulation or order is
21 found to be unsupported by substantial evidence on
22 the record taken as a whole.

23 “(e) FINALITY OF JUDGMENT.—The judgment of the
24 court affirming or setting aside, in whole or in part, any
25 regulation or order shall be final, subject to review by the

1 Supreme Court of the United States on certiorari or cer-
2 tification, as provided in section 1254 of title 28, United
3 States Code.

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

7 “(g) REGULATIONS AND ORDERS MUST RECITE
8 BASIS IN RECORD.—To facilitate judicial review under
9 this section or under any other provision of law or a regu-
10 lation or order issued under section 907, 908, 909, 910,
11 911, or 914, each such regulation or order shall contain
12 a statement of—

13 “(1) the reasons for the issuance of the regula-
14 tion or order; and

15 “(2) the basis, in the record of the proceedings
16 held in connection with the issuance of the regula-
17 tion or order, for the issuance of the regulation or
18 order.

19 **“SEC. 913. REDUCED EXPOSURE AND REDUCED RISK TO-**
20 **BACCO PRODUCTS.**

21 “(a) DEFINITIONS OF REDUCED EXPOSURE AND RE-
22 DUCED RISK TOBACCO PRODUCTS.—In this section, the
23 terms ‘reduced exposure tobacco product’ and ‘reduced
24 risk tobacco product’ mean a tobacco product designated
25 by the Secretary as a reduced exposure tobacco product

1 or a reduced risk tobacco product, respectively, under sub-
2 section (b).

3 “(b) DESIGNATION.—

4 “(1) IN GENERAL.—A product may be des-
5 ignated by the Secretary as a reduced exposure to-
6 bacco product or a reduced risk tobacco product if
7 the Secretary finds that the product is demonstrated
8 to significantly reduce harm to individuals caused by
9 a tobacco product in accordance with the standards
10 provided under subparagraph (B), based on an ap-
11 plication submitted by the manufacturer of the prod-
12 uct (or other responsible person) that—

13 “(A)(i) demonstrates, through appropriate
14 chemical and biological testing (including test-
15 ing on animals and short-term human testing),
16 that use of the product results in ingestion or
17 inhalation of a substantially lower yield of toxic
18 substances than use of another tobacco product
19 in the same or different category as the subject
20 tobacco product; or

21 “(ii) contains scientific evidence showing
22 that use of the product results in a substan-
23 tially lower potential risk to health in 1 or more
24 specific respects than use of another tobacco
25 product in the same or different category as the

1 proposed reduced exposure tobacco product or
2 the reduced risk product; and

3 “(B) if required by the Secretary, includes
4 studies of the long-term health effects of the
5 product.

6 “(2) CONSULTATION ON PROTOCOLS.—If stud-
7 ies are required under paragraph (1), the manufac-
8 turer may consult with the Secretary regarding pro-
9 tocols for conducting the studies.

10 “(3) BASIS FOR FINDING.—

11 “(A) REDUCED EXPOSURE TOBACCO PROD-
12 UCTS.—The Secretary shall designate a tobacco
13 product as a reduced exposure tobacco product
14 if the Secretary determines, based on such in-
15 formation as may be submitted by the applicant
16 and other available information, that—

17 “(i) the product substantially reduces
18 exposure to 1 or more tobacco toxicants;
19 and

20 “(ii) independent scientific experts
21 have found or predict, through clinical or
22 epidemiological studies, a measurable re-
23 duction in the morbidity or mortality asso-
24 ciated with the use of the product com-
25 pared with the use of other tobacco prod-

1 ucts (whether in the same or a different
2 category) commercially marketed in the
3 United States.

4 “(B) REDUCED RISK TOBACCO PROD-
5 UCTS.—The Secretary shall designate a tobacco
6 product as a reduced risk tobacco product only
7 if the Secretary determines, based on such in-
8 formation as may be submitted by the applicant
9 and other available information, that—

10 “(i) the product meets the criteria es-
11 tablished under subparagraph (A); and

12 “(ii) there is sufficient evidence that
13 the product can reasonably be expected to
14 reduce the risk of 1 or more specific dis-
15 eases or other adverse health effects, as
16 compared with the use of other tobacco
17 products (whether in the same or a dif-
18 ferent category) commercially marketed in
19 the United States.

20 “(4) MARKETING REQUIREMENTS.—A tobacco
21 product may be marketed and labeled as a reduced
22 exposure tobacco product or a reduced risk tobacco
23 product if the tobacco product—

24 “(A) has been designated by the Secretary
25 under paragraph (1);

1 “(B) bears a label statement prescribed by
2 the Secretary concerning the product’s con-
3 tribution to reducing harm to health; and

4 “(C) complies with—

5 “(i) requirements prescribed by the
6 Secretary relating to marketing and adver-
7 tising of the product to ensure that neither
8 the marketing nor the labeling is false or
9 misleading; and

10 “(ii) other provisions of this chapter,
11 as prescribed by the Secretary.

12 “(c) REVOCATION OF DESIGNATION.—At any time
13 after the date on which a tobacco product is designated
14 as a reduced exposure tobacco product or a reduced risk
15 tobacco product under this section, the Secretary may,
16 after providing an opportunity for an informal hearing,
17 revoke the designation if the Secretary determines, based
18 on information not available at the time of the designa-
19 tion, that—

20 “(1) the finding made under subsection (b)(1)
21 is no longer valid; or

22 “(2) the product is being marketed in violation
23 of subsection (b)(3).

24 “(d) LIMITATION.—A tobacco product that is des-
25 ignated as a reduced exposure tobacco product or a re-

1 duced risk tobacco product that is in compliance with sub-
2 section (b) shall not be regulated as a drug or device.

3 “(e) DEVELOPMENT OF REDUCED EXPOSURE AND
4 RISK TOBACCO PRODUCT TECHNOLOGY.—A tobacco
5 product manufacturer shall provide written notice to the
6 Secretary on the development or acquisition by the manu-
7 facturer of any technology that would reduce exposure to
8 1 or more tobacco toxicants, or the risk of a tobacco prod-
9 uct to the health of the user, for which the manufacturer
10 is not seeking designation as a reduced exposure tobacco
11 product or a reduced risk tobacco product under this sec-
12 tion.

13 “(f) POSTMARKET SURVEILLANCE.—

14 “(1) DISCRETIONARY SURVEILLANCE.—The
15 Secretary may require a tobacco product manufac-
16 turer to conduct postmarket surveillance for a re-
17 duced exposure tobacco product or a reduced risk to-
18 bacco product of the manufacturer if the Secretary
19 determines that postmarket surveillance of the to-
20 bacco product is necessary to protect the public
21 health or is necessary to provide information regard-
22 ing the health risks and other safety issues involving
23 the tobacco product.

24 “(2) SURVEILLANCE APPROVAL.—

1 “(A) IN GENERAL.—Each tobacco product
2 manufacturer required to conduct a surveillance
3 of a reduced exposure tobacco product or a re-
4 duced risk tobacco product under paragraph (1)
5 shall, not later than 30 days after receiving no-
6 tice that the manufacturer is required to con-
7 duct the surveillance, submit, for the approval
8 of the Secretary, a protocol for the required
9 surveillance.

10 “(B) BASIS.—The Secretary, not later
11 than 60 days after the receipt of the protocol,
12 shall determine if—

13 “(i) the principal investigator pro-
14 posed to be used in the surveillance has
15 sufficient qualifications and experience to
16 conduct the surveillance; and

17 “(ii) the protocol will result in collec-
18 tion of useful data or other information
19 necessary to protect the public health.

20 “(C) REVIEW.—The Secretary may not ap-
21 prove such a protocol until the protocol has
22 been reviewed by an appropriately qualified sci-
23 entific and technical review committee estab-
24 lished by the Secretary.

1 **“SEC. 914. PRESERVATION OF STATE AND LOCAL AUTHOR-**
2 **ITY.**

3 “(a) ADDITIONAL REQUIREMENTS.—

4 “(1) IN GENERAL.—Except as provided in para-
5 graph (2), nothing in this Act prohibits a State or
6 political subdivision of a State from adopting or en-
7 forcing a requirement applicable to a tobacco prod-
8 uct that is in addition to, or more stringent than, re-
9 quirements established under this chapter.

10 “(2) PREEMPTION OF CERTAIN STATE AND
11 LOCAL REQUIREMENTS.—

12 “(A) IN GENERAL.—Except as provided in
13 subparagraph (B), no State or political subdivi-
14 sion of a State may establish or continue in ef-
15 fect with respect to a tobacco product any re-
16 quirement that is different from, or in addition
17 to, any requirement applicable under the provi-
18 sions of this chapter relating to performance
19 standards, premarket approval, adulteration,
20 misbranding, registration, labeling, good manu-
21 facturing standards, or reduced exposure to-
22 bacco products or reduced risk tobacco prod-
23 ucts.

24 “(B) SALE, DISTRIBUTION, OR USE.—Sub-
25 paragraph (A) does not apply to requirements
26 relating to the sale, use, or distribution of a to-

1 tobacco product, including requirements relating
 2 to the access to, and the advertising and pro-
 3 motion of, a tobacco product.

4 “(b) **PRODUCT LIABILITY.**—No provision of this
 5 chapter relating to a tobacco product modifies or otherwise
 6 affects any action or the liability of any person under the
 7 product liability law of any State.

8 **“SEC. 915. EQUAL TREATMENT OF RETAIL OUTLETS.**

9 “The Secretary shall promulgate regulations that re-
 10 quire that retail establishments for which the predominant
 11 business is the sale of tobacco products to comply with
 12 any advertising restrictions applicable to retail establish-
 13 ments accessible to individuals under the age of 18.

14 **“SEC. 916. ACCESS AND MARKETING RESTRICTIONS.**

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

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

20 “(2) **ADULT-ONLY FACILITY.**—

21 “(A) **IN GENERAL.**—The term ‘adult-only
 22 facility’ means a facility or restricted area
 23 (whether open-air or enclosed) where the oper-
 24 ator ensures or has a reasonable basis to believe
 25 (such as by checking identification as required

1 under State law, or by checking the identifica-
2 tion of any person appearing to be under the
3 age of 27) that only adults are present.

4 “(B) TEMPORARY ADULT-ONLY FACIL-
5 ITY.—A facility or restricted area need not be
6 permanently restricted to adults in order to
7 constitute an adult-only facility, if the operator
8 ensures or has a reasonable basis to believe that
9 only adults are present during the event or time
10 period in question.

11 “(3) BRAND NAME.—

12 “(A) IN GENERAL.—The term ‘brand
13 name’ means a brand name (alone or in con-
14 junction with any other word), trademark, logo,
15 symbol, motto, selling message, recognizable
16 pattern of colors, or any other indicia of prod-
17 uct identification identical or similar to, or
18 identifiable with, those used for any domestic
19 brand of tobacco products.

20 “(B) EXCLUSION.—The term ‘brand name’
21 shall not include the corporate name of any to-
22 bacco product manufacturer that does not, after
23 the date of enactment of the Tobacco Liveli-
24 hood and Economic Assistance for Our Farm-
25 ers Act of 2002, sell a brand of tobacco prod-

1 ucts in the United States that includes the cor-
2 porate name.

3 “(b) CIGARETTE AND SMOKELESS TOBACCO PROD-
4 UCT REQUIREMENTS.—

5 “(1) MINIMUM SALES AGE.—No retailer may
6 sell a tobacco product to any person younger than
7 18 years of age.

8 “(2) PROOF OF AGE.—

9 “(A) IN GENERAL.—Except as provided in
10 subparagraph (B), each retailer shall verify by
11 means of photographic identification containing
12 the bearer’s date of birth that no person pur-
13 chasing the product is younger than 18 years of
14 age.

15 “(B) MAXIMUM AGE.—No such verification
16 is required for any person over the age of 26.

17 “(3) ENFORCEMENT BY STATES.—

18 “(A) IN GENERAL.—The Secretary may
19 enter into an agreement with a State if—

20 “(i) the State has in effect a State
21 law that is at least as restrictive as this
22 subsection under which the State agrees to
23 enforce the State law in a manner reason-
24 ably designed to prevent the violation of
25 the State law; and

1 “(ii) the Secretary provides a grant to
2 the State for the purpose of enforcing the
3 State law.

4 “(B) AUTHORITY OF SECRETARY.—No ac-
5 tion taken by the Secretary under subparagraph
6 (A) limits the authority of the Secretary under
7 this subsection.

8 “(4) MAIL ORDER SALES.—Not later than 2
9 years after the date of enactment of the Tobacco
10 Livelihood and Economic Assistance for Our Farm-
11 ers Act of 2002, the Secretary shall submit to Con-
12 gress a report describing the extent, if any, to which
13 individuals younger than 18 years of age are obtain-
14 ing tobacco products through the mail.

15 “(c) MINIMUM PACKAGE SIZE REQUIREMENTS.—

16 “(1) MINIMUM NUMBER OF CIGARETTES.—No
17 manufacturer, distributor, or retailer may sell or
18 cause to be sold, or distribute or cause to be distrib-
19 uted, any cigarette package that contains fewer than
20 20 cigarettes.

21 “(2) OPENING TOBACCO PRODUCT PACKAGES.—

22 No retailer may break or otherwise open any tobacco
23 product package to sell or distribute individual ciga-
24 rettes or a number of unpackaged cigarettes that is
25 smaller than—

1 “(A) the quantity in the minimum ciga-
2 rette package size provided under paragraph
3 (1); or

4 “(B) any quantity of another tobacco prod-
5 uct that is smaller than the smallest package
6 distributed by the manufacturer for individual
7 consumer use.

8 “(d) PROHIBITION ON YOUTH ACCESS TO FREE
9 SAMPLES.—

10 “(1) DEFINITION OF FREE SAMPLE.—In this
11 subsection, the term ‘free sample’ does not include
12 a tobacco product that is provided to an adult in
13 connection with—

14 “(A) the purchase, exchange or redemption
15 for proof of purchase of any tobacco product
16 (including a free offer in connection with the
17 purchase of a tobacco product, such as a 2-for-
18 1 offer); or

19 “(B) the conducting of consumer testing or
20 evaluation of a tobacco product with persons
21 who certify that they are adults.

22 “(2) PROHIBITION.—No manufacturer, dis-
23 tributor, or retailer may distribute or cause to be
24 distributed any free sample of a tobacco product, ex-
25 cept in an adult-only facility.

1 “(e) VENDING MACHINES, SELF-SERVICE DISPLAYS,
2 MAIL-ORDER SALES, AND OTHER IMPERSONAL MODES
3 OF SALE.—

4 “(1) DEFINITION OF SELF-SERVICE DISPLAY.—

5 In this subsection, the term ‘self-service display’
6 means any display located in an area in which the
7 customer has access to the tobacco products without
8 the aid of a sales clerk.

9 “(2) REQUIREMENT.—Except as provided in
10 paragraph (3), a retailer may sell a tobacco
11 product—

12 “(A) only in a direct, face-to-face exchange
13 between the retailer and the consumer; and

14 “(B) not through a method of sale such as
15 a vending machine or self-service display.

16 “(3) PERMITTED METHODS.—The following
17 methods of sale of tobacco products shall be per-
18 mitted under this subsection:

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

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

24 “(f) PROHIBITION ON YOUTH TARGETING.

1 “(1) DEFINITION OF YOUTH.—In this sub-
2 section, the term ‘youth’ means any person or per-
3 sons under 18 years of age.

4 “(2) PROHIBITION.—No manufacturer, dis-
5 tributor, or retailer may take—

6 “(A) any action, directly or indirectly, to
7 target youth in the advertising, promotion, or
8 marketing of tobacco products; or

9 “(B) any action the primary purpose of
10 which is to initiate, maintain, or increase the
11 incidence of youth smoking.

12 “(g) PROHIBITION ON USE OF CARTOONS.—

13 “(1) DEFINITION OF CARTOON.—In this sub-
14 section:

15 “(A) IN GENERAL.—The term ‘cartoon’
16 means any drawing or other depiction of an ob-
17 ject, person, animal, or creature, or any similar
18 caricature, that satisfies any of the following
19 criteria:

20 “(i) The use of comically exaggerated
21 features.

22 “(ii) The attribution of human char-
23 acteristics to animals, plants, or other ob-
24 jects, or the similar use of
25 anthropomorphic technique.

1 “(iii) The attribution of unnatural or
2 extrahuman abilities, such as impervious-
3 ness to pain or injury, X-ray vision, tun-
4 neling at very high speeds, or trans-
5 formation.

6 “(B) INCLUSION.—The term ‘cartoon’ in-
7 cludes a drawing or other depiction of the char-
8 acter popularly known as ‘Joe Camel’.

9 “(C) EXCLUSIONS.—The term ‘cartoon’
10 does not include any drawing or other depiction
11 that, on July 1, 1998, was in use in the United
12 States in any manufacturer’s corporate logo or
13 in any manufacturer’s tobacco product pack-
14 aging.

15 “(2) PROHIBITION.—No manufacturer, dis-
16 tributor, or retailer may use or cause to be used any
17 cartoon in the advertising, promoting, packaging, or
18 labeling of tobacco products.

19 “(h) PROHIBITION ON OUTDOOR ADVERTISING.—

20 “(1) DEFINITIONS.—In this subsection:

21 “(A) OUTDOOR ADVERTISING.—

22 “(i) IN GENERAL.—The term ‘outdoor
23 advertising’ means advertising through—

24 “(I) billboards;

1 “(II) signs and placards in are-
2 nas, stadiums, shopping malls, and
3 video game arcades (regardless of
4 whether located in the open air or en-
5 closed); and

6 “(III) any other advertisements
7 placed—

8 “(aa) outdoors; or

9 “(bb) on the inside surface
10 of a window facing outward.

11 “(ii) EXCLUSIONS.—The term ‘out-
12 door advertising’ does not include—

13 “(I) an advertisement on the out-
14 side of a tobacco product manufac-
15 turing facility;

16 “(II) an individual advertisement
17 that—

18 “(aa) does not occupy an
19 area larger than 14 square feet;

20 “(bb) is not placed in such
21 proximity to any other such ad-
22 vertisement so as to create a sin-
23 gle mosaic-type advertisement
24 larger than 14 square feet;

1 “(cc) does not function sole-
2 ly as a segment of a larger adver-
3 tising unit or series; and

4 “(dd) is placed on the out-
5 side of any retail establishment
6 that sells tobacco products (other
7 than solely through a vending
8 machine), on the outside (but on
9 the property of) any such estab-
10 lishment, or on the inside surface
11 of a window facing outward in
12 any such establishment; or

13 “(III) an advertisement inside a
14 retail establishment that sells tobacco
15 products (other than solely through a
16 vending machine) that is not placed
17 on the inside surface of a window fac-
18 ing outward.

19 “(B) VIDEO GAME ARCADE.—The term
20 ‘video game arcade’ means an entertainment es-
21 tablishment primarily consisting of video games
22 (other than video games intended primarily for
23 use by persons 18 years of age or older) or pin-
24 ball machines.

1 “(2) PROHIBITION.—No manufacturer, dis-
2 tributor, or retailer may place or cause to be placed
3 any outdoor advertisement for tobacco products.

4 “(i) PROHIBITION ON TRANSIT ADVERTISEMENTS.—

5 “(1) DEFINITION OF TRANSIT ADVERTISESE-
6 MENT.—In this subsection:

7 “(A) IN GENERAL.—The term ‘transit ad-
8 vertisement’ means—

9 “(i) advertising on or within a private
10 or public vehicle; and

11 “(ii) an advertisement placed at, on,
12 or within any bus stop, taxi stand, trans-
13 portation waiting area, train station, air-
14 port, or any similar location.

15 “(B) EXCLUSION.—The term ‘transit ad-
16 vertisement’ does not include any advertisement
17 placed in, on, or outside the premises of any re-
18 tail establishment that sells tobacco products
19 (other than solely through a vending machine),
20 unless the individual advertisement—

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

23 “(ii) is placed in such proximity to
24 any other such advertisement so as to cre-

1 ate a single mosaic-type advertisement
2 larger than 14 square feet; or

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

5 “(2) PROHIBITION.—No manufacturer, dis-
6 tributor, or retailer may place or cause to be placed
7 any transit advertisement advertising tobacco prod-
8 ucts.

9 “(j) PROHIBITION ON ADVERTISING IN YOUTH-ORI-
10 ENTED PUBLICATIONS.—

11 “(1) DEFINITION OF YOUTH-ORIENTED PUBLI-
12 CATION.—In this subsection, the term ‘youth-ori-
13 ented publication’ means a newspaper, magazine, pe-
14 riodical, or other publication—

15 “(A) at least 15 percent of the total read-
16 ership of which is comprised of readers younger
17 than 18 years of age, as measured by com-
18 petent and reliable survey evidence; or

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

22 “(2) PROHIBITION.—No manufacturer, dis-
23 tributor, or retailer shall advertise a tobacco product
24 in any youth-oriented publication, regardless of

1 whether the publication has periodic or limited dis-
2 tribution.

3 “(k) PROHIBITION ON TOBACCO PRODUCT BRAND
4 NAME SPONSORSHIPS.—

5 “(1) IN GENERAL.—No manufacturer, dis-
6 tributor, or retailer may sponsor or cause to be
7 sponsored any athletic, musical, artistic, or other so-
8 cial or cultural event, or any entry or team in any
9 event, using the brand name (alone or in conjunction
10 with any other word), logo, symbol, motto, selling
11 message, recognizable color or pattern of colors, or
12 any other indicia of product identification identical
13 or similar to, or identifiable with, that used for any
14 brand of cigarettes or smokeless tobacco.

15 “(2) EXCEPTIONS.—Nothing in this subsection
16 prevents a manufacturer, distributor, or retailer
17 from sponsoring or causing to be sponsored any ath-
18 letic, musical, artistic, or other social or cultural
19 event, or team or entry, in the name of the corpora-
20 tion that manufactures the tobacco product, if—

21 “(A) both the corporate name and the cor-
22 poration were registered and in use in the
23 United States before January 1, 2001; and

24 “(B) the corporate name does not include
25 any brand name (alone or in conjunction with

1 any other word), logo, symbol, motto, selling
2 message, recognizable color or pattern of colors,
3 or any other indicia of product identification
4 identical or similar to, or identifiable with, that
5 used for any brand of cigarettes or smokeless
6 tobacco.

7 “(3) ADULT-ONLY FACILITIES.—This sub-
8 section shall not apply to any event sponsored in an
9 adult-only facility.

10 “(1) PROHIBITION ON TOBACCO BRAND NAME MER-
11 CHANDISE.—

12 “(1) IN GENERAL.—No manufacturer may mar-
13 ket, distribute, offer, sell, license or cause to be mar-
14 keted, distributed, offered, sold, or licensed (includ-
15 ing by catalog or direct mail), any apparel or other
16 merchandise that bears the brand name of a tobacco
17 product, other than items the sole function of which
18 is to advertise tobacco products or written or elec-
19 tronic publications.

20 “(2) EXCEPTIONS.—Nothing in this subsection
21 shall—

22 “(A) prohibit the distribution to any man-
23 ufacturer’s employee who is an adult of any
24 item described in paragraph (1) that is in-
25 tended for the personal use of the employee;

1 “(B) require any manufacturer to retrieve,
2 collect, or otherwise recover any item that, be-
3 fore the date of enactment of the Tobacco Live-
4 lihood and Economic Assistance for Our Farm-
5 ers Act of 2002, was marketed, distributed, of-
6 fered, sold, licensed, or caused to be marketed,
7 distributed, offered, sold, or licensed by the
8 manufacturer;

9 “(C) apply to coupons or other items used
10 by adults solely in connection with the purchase
11 of tobacco products; or

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

16 “(m) PROHIBITION ON GIFTS TO UNDERAGE PER-
17 SONS BASED ON PROOFS OF PURCHASE.—

18 “(1) IN GENERAL.—No manufacturer, dis-
19 tributor, or retailer may provide or cause to be pro-
20 vided to any person, without sufficient proof that the
21 person is an adult, any item in exchange for the pur-
22 chase of tobacco products, or the furnishing of cred-
23 its, proofs-of-purchase, or coupons with respect to
24 such a purchase.

25 “(2) PROOF OF AGE.—

1 “(A) IN GENERAL.—For purposes of para-
2 graph (1), a driver’s license or other govern-
3 ment-issued identification (or legible photocopy
4 of the license or identification), the validity of
5 which is certified by the person to whom the
6 item is provided, shall by itself be deemed to be
7 a sufficient form of proof of age.

8 “(B) RETAILERS.—In the case of items
9 provided (or to be redeemed) at retail establish-
10 ments, a manufacturer shall be entitled to rely
11 on verification of proof of age by the retailer,
12 if the retailer is required to obtain verification
13 under applicable Federal, State, or local law.

14 “(n) PROHIBITION ON NON-TOBACCO PRODUCT
15 BRAND NAMES.—

16 “(1) DEFINITION OF OTHER VALUABLE CON-
17 sideration.—In this subsection, the term ‘other
18 valuable consideration’ does not include an agree-
19 ment between 2 entities that enter into an agree-
20 ment for the sole purpose of avoiding infringement
21 claims.

22 “(2) PROHIBITION.—Except as provided in
23 paragraph (3), no manufacturer may, pursuant to
24 any agreement requiring the payment of money or

1 other valuable consideration, use or cause to be used
2 as a brand name of any tobacco product—

3 “(A) any nationally recognized or nation-
4 ally established brand name or trade name of
5 any non-tobacco item or service; or

6 “(B) any nationally recognized or nation-
7 ally established sports team, entertainment
8 group, or individual celebrity.

9 “(3) NONAPPLICABILITY.—Paragraph (2) shall
10 not apply to any tobacco product brand name in ex-
11 istence as of July 1, 1998.

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

14 “(1) IN GENERAL.—No manufacturer may li-
15 cense or otherwise expressly authorize any third
16 party to use or advertise any brand name of a to-
17 bacco product in a manner prohibited by this chap-
18 ter if used or advertised by the manufacturer itself.

19 “(2) EXCEPTIONS.—Nothing in this subsection
20 requires any manufacturer to retrieve, collect, or
21 otherwise recover any item that, before the date of
22 enactment of the Tobacco Livelihood and Economic
23 Assistance for Our Farmers Act of 2002, was mar-
24 keted, distributed, offered, sold, licensed, or caused

1 to be marketed, distributed, offered, sold, or licensed
2 by the manufacturer.

3 “(p) PROHIBITION ON PRODUCT PLACEMENT IN
4 CERTAIN MEDIA.—

5 “(1) IN GENERAL.—Except as provided in para-
6 graph (2), no manufacturer may make, or cause to
7 be made, any payment or other consideration to any
8 other person or entity to use, display, make ref-
9 erence to, or use as a prop any tobacco product, to-
10 bacco product package, advertisement for a tobacco
11 product, or any other item bearing a brand name in
12 any motion picture, television show, theatrical pro-
13 duction or other live performance, live or recorded
14 performance of music, commercial film or video, or
15 video game (collectively referred to in this subsection
16 as ‘media’).

17 “(2) EXCEPTIONS.—Paragraph (1) shall not
18 apply to—

19 “(A) media the audience or viewers of
20 which are within an adult-only facility, if the
21 media are not visible to persons outside the
22 adult-only facility;

23 “(B) media not intended for distribution or
24 display to the public; or

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

7 “(q) EFFECTIVE DATES.—

8 “(1) IN GENERAL.—Except as provided in para-
9 graph (2), this section shall apply beginning on the
10 date that is 180 days after the date of enactment of
11 the Tobacco Livelihood and Economic Assistance for
12 Our Farmers Act of 2002.

13 “(2) VENDING MACHINES; SPONSORSHIPS.—
14 Subsections (e) and (k) shall apply beginning on the
15 date that is 1 year after the date of enactment of
16 that Act.

17 **“SEC. 917. MANDATORY DISCLOSURES.**

18 “(a) DISCLOSURE OF INGREDIENTS TO THE
19 PUBLIC.—

20 “(1) IN GENERAL.—Not later than 1 year after
21 the date of enactment of the Tobacco Livelihood and
22 Economic Assistance for Our Farmers Act of 2002,
23 except as otherwise provided in this subsection, the
24 Secretary shall promulgate regulations requiring the
25 disclosure to the public on a brand-by-brand basis of

1 the common or usual name of each ingredient of a
2 tobacco product in descending order of predomi-
3 nance by weight.

4 “(2) SPICES, FLAVORINGS, AND COLORINGS.—A
5 manufacturer may elect to designate spices,
6 flavorings, and colorings under paragraph (1) with-
7 out naming each spice, flavoring, or coloring.

8 “(3) OTHER LAWS.—Any ingredient that has
9 been disclosed to the public pursuant to any other
10 law (including regulations) with respect to a par-
11 ticular brand may be required to be disclosed for the
12 brand pursuant to this subsection.

13 “(4) INCIDENTAL ADDITIVES.—The regulations
14 required by this subsection shall provide that inci-
15 dental additives that are present in a tobacco prod-
16 uct at insignificant levels and that do not have any
17 technical or functional effect in the finished tobacco
18 product shall be exempt from disclosure.

19 “(5) SMALL QUANTITIES.—The requirement of
20 this subsection to disclose ingredients in descending
21 order of predominance shall not apply to ingredients
22 in quantities of 2 percent or less by weight if a list-
23 ing of the ingredients is placed at the end of the in-
24 gredients statement following an appropriate quanti-

1 fying statement, such as ‘contains ____ percent or
2 less of ____’, or ‘less than ____ percent of ____’.

3 “(6) MEANS OF DISCLOSURE.—

4 “(A) IN GENERAL.—Except as provided in
5 subparagraph (B), any disclosure required pur-
6 suant to this subsection may be required by ap-
7 propriate means.

8 “(B) LISTING OF INGREDIENTS.—Notwith-
9 standing any other provision of this Act, the
10 Secretary shall not require the listing of any in-
11 gredient of a tobacco product on any package
12 or in any advertisement.

13 “(b) DISCLOSURE OF PERCENTAGE OF DOMESTIC
14 AND FOREIGN TOBACCO.—Not later than 1 year after the
15 date of enactment of the Tobacco Livelihood and Eco-
16 nomic Assistance for Our Farmers Act of 2002, the Sec-
17 retary shall promulgate regulations that require that each
18 package of a tobacco product disclose, with respect to the
19 tobacco contained in that brand—

20 “(1) the percentage of tobacco that is domestic
21 tobacco; and

22 “(2) the percentage of tobacco that is foreign
23 tobacco.

24 “(c) MANDATORY DISCLAIMER.—

1 “(1) IN GENERAL.—Except as otherwise pro-
2 vided in this subsection, any tobacco product adver-
3 tising that includes a term classifying a brand of to-
4 bacco product according to the tar yield or the yield
5 of the brand to consumers of any substance, includ-
6 ing terms such as ‘light’ or ‘low tar’, shall also in-
7 clude the following disclaimer: ‘[Brand] not shown
8 to be less hazardous than other [type of tobacco
9 product]’.

10 “(2) FILTERED.—This section shall apply to
11 the use of the terms ‘filtered’ or ‘filter’.

12 “(3) TOBACCO PRODUCT PACKAGES.—A dis-
13 claimer described in paragraph (1) shall not be re-
14 quired on any tobacco product package.

15 “(4) USE OF TERMS.—Not later than 1 year
16 after the date of enactment of the Tobacco Liveli-
17 hood and Economic Assistance for Our Farmers Act
18 of 2002, the Secretary shall promulgate regulations
19 relating to the use of the terms described in para-
20 graph (1) to ensure that the terms are not false or
21 misleading.

22 “(5) REDUCED EXPOSURE AND REDUCED RISK
23 TOBACCO PRODUCTS.—The Secretary may modify or
24 waive any requirement under this subsection with re-
25 spect to any product that has been designated by the

1 Secretary as a reduced exposure tobacco product or
2 a reduced risk tobacco product under section 913.

3 **“SEC. 918. REGULATORY RECORD.**

4 “(a) IN GENERAL.—Notwithstanding subchapter II
5 of chapter 5 of title 5, United States Code, in promul-
6 gating regulations under this chapter, the record devel-
7 oped and used by the Secretary for the purposes of pro-
8 mulgating subparts (B) and (D) of the regulations relat-
9 ing to the sale, distribution, and use of tobacco products
10 on or about August 28, 1996, as reflected in articles IV
11 and VI of the preamble to the 1996 Food and Drug Ad-
12 ministration Tobacco Rule (including public comments,
13 Food and Drug Administration documents, and any other
14 information generated or compiled for purposes of promul-
15 gating the regulations), shall be deemed to have the same
16 legal status as if the record had been developed under a
17 rulemaking proceeding conducted pursuant to section
18 907(d)(1).

19 “(b) OTHER RESPECTS.—In all other respects (in-
20 cluding the issue of whether the regulations conform to
21 section 907(d)(1)), the procedural requirements of this
22 chapter and subchapter II of chapter 5, and chapter 7,
23 of title 5, United States Code (commonly known as the
24 ‘Administrative Procedure Act’) shall apply to this chap-
25 ter.

1 **“SEC. 919. REGULATION REQUIREMENT.**

2 “(a) TESTING, REPORTING, AND DISCLOSURE.—Not
3 later than 2 years after the date of enactment of the To-
4 bacco Livelihood and Economic Assistance for Our Farm-
5 ers Act of 2002, the Secretary, acting through the Com-
6 missioner of Food and Drugs, shall promulgate regula-
7 tions under this Act that meet the requirements of sub-
8 section (b).

9 “(b) CONTENTS OF RULES.—

10 “(1) IN GENERAL.—The rules promulgated
11 under subsection (a) shall require the testing, re-
12 porting, and disclosure of tobacco product smoke
13 constituents and ingredients that the Secretary de-
14 termines should be disclosed to the public in order
15 to protect the public health.

16 “(2) CONSTITUENTS.—The constituents shall
17 include tar, nicotine, carbon monoxide, and such
18 other smoke constituents or ingredients as the Sec-
19 retary may determine to be appropriate.

20 “(3) ADMINISTRATION.—The rules may require
21 that tobacco product manufacturers, packagers, or
22 importers make—

23 “(A) the disclosures relating to tar and
24 nicotine through labels or advertising; and

25 “(B) the disclosures regarding other smoke
26 constituents or ingredients that the Secretary

1 determines are necessary to protect the public
2 health.

3 “(c) AUTHORITY.—The Secretary, acting through the
4 Commissioner of Food and Drugs, shall have authority to
5 conduct or to require the testing, reporting, or disclosure
6 of tobacco product smoke constituents.”.

7 **SEC. 513. CONFORMING AND TECHNICAL AMENDMENTS.**

8 (a) PROHIBITED ACTS.—Section 301 of the Federal
9 Food, Drug, and Cosmetic Act (21 U.S.C. 331) is
10 amended—

11 (1) in subsections (a), (b), (c), (g), (h), and (k),
12 by inserting “tobacco product,” after “device,” each
13 place it appears;

14 (2) in subsection (e), by striking “515(f), or
15 519” and inserting “515(f), 519, or 910”;

16 (3) in subsection (j), by striking “708, or 721”
17 and inserting “708, 721, 904, 905, 906, 907, 908,
18 909, 910, 911, or 913”;

19 (4) by striking subsection (p) and inserting the
20 following:

21 “(p) The failure—

22 “(1) to register in accordance with section 510
23 or 906;

24 “(2) to provide any information required by sec-
25 tion 510(j), 510(k), 906(i), or 906(j); or

1 “(3) to provide a notice required by section
2 510(j)(2) or 906(j)(2).”;

3 (5) in subsection (q)—

4 (A) by striking paragraph (1) and insert-
5 ing the following:

6 “(1) The failure or refusal—

7 “(A) to comply with any requirement prescribed
8 under section 518, 520(g), 907(f), or 909;

9 “(B) to furnish any notification or other mate-
10 rial or information required by or under section 519,
11 520(g), 905, 907(f), or 910; or

12 “(C) to comply with a requirement under sec-
13 tion 522.”; and

14 (B) in paragraph (2), by striking “device,”
15 and inserting “device or tobacco product,”;

16 (6) in subsection (r), by inserting “or tobacco
17 product” after “device” each place it appears; and

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

19 “(bb) The sale of a tobacco product in violation of
20 a no-tobacco-sale order issued under section 303(g)(3).”.

21 (b) PENALTIES.—Section 303(g) of the Federal
22 Food, Drug, and Cosmetic Act (21 U.S.C. 333(g)) is
23 amended—

24 (1) by striking “(g)(1)(A) Except” and insert-
25 ing the following:

1 “(g) CIVIL PENALTIES.—

2 “(1) IN GENERAL.—

3 “(A) PENALTY.—Except”;

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

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

8 (4) by inserting after paragraph (2) the fol-
9 lowing:

10 “(3) NO-TOBACCO-SALE ORDERS.—

11 “(A) IN GENERAL.—If the Secretary finds
12 that a person has committed repeated violations
13 of restrictions promulgated under section
14 906(d) at a particular retail outlet, the Sec-
15 retary may impose a no-tobacco-sale order on
16 the person prohibiting the sale of tobacco prod-
17 ucts in the outlet.

18 “(B) CIVIL PENALTIES.—A no-tobacco-sale
19 order may be imposed with a civil penalty under
20 paragraph (1).”;

21 (5) in paragraph (4) (as redesignated by para-
22 graph (3))—

23 (A) in subparagraph (A)—

24 (i) in the first sentence, by striking
25 “assessed” the first place it appears and

1 inserting “assessed, or a no-tobacco-sale
2 order may be imposed,”; and

3 (ii) in the second sentence, by striking
4 “penalty” and inserting “penalty, or on
5 whom a no-tobacco-order is to be im-
6 posed,”;

7 (B) in subparagraph (B)—

8 (i) by striking “(B) In” and inserting
9 the following:

10 “(B) ADMINISTRATION.—

11 “(i) FACTORS.—In”

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

15 (iii) by adding at the end the fol-
16 lowing:

17 “(ii) NO-TOBACCO-SALE ORDERS.—A
18 no-tobacco-sale order permanently prohib-
19 iting an individual retail outlet from selling
20 tobacco products shall include provisions
21 that allow the outlet, after a specified pe-
22 riod of time, to request that the Secretary
23 compromise, modify, or terminate the
24 order.”; and

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

1 “(D) COMPROMISE, MODIFICATION, OR
2 TERMINATION OF NO-TOBACCO-SALE ORDERS.—
3 The Secretary may compromise, modify, or ter-
4 minate, with or without conditions, any no-to-
5 bacco-sale order.”;

6 (6) in paragraph (5) (as redesignated by para-
7 graph (3))—

8 (A) in the first sentence—

9 (i) by striking “(3)(A)” and inserting
10 “(4)(A)”;

11 (ii) by inserting “or the imposition of
12 a no-tobacco-sale order” after “penalty”
13 the first 2 places it appears; and

14 (B) in the second sentence, by inserting
15 before the period at the end the following: “, or
16 on which the no-tobacco-sale order was im-
17 posed, as the case may be”;

18 (7) in paragraph (6) (as redesignated by para-
19 graph (3)), by striking “paragraph (4)” each place
20 it appears and inserting “paragraph (5)”.

21 (c) SEIZURE.—Section 304 of the Federal Food,
22 Drug, and Cosmetic Act (21 U.S.C. 334) is amended—

23 (1) in subsection (a)(2)—

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

1 (B) by inserting before the period at the
2 end the following: “, and (E) Any adulterated
3 or misbranded tobacco product”;

4 (2) in the first sentence of subsection (d)(1), by
5 inserting “tobacco product,” after “device,”; and

6 (3) in subsection (g), by inserting “or tobacco
7 product” after “device” each place it appears.

8 (d) EXAMINATIONS AND INVESTIGATIONS.—Section
9 702(a) of the Federal Food, Drug, and Cosmetic Act (21
10 U.S.C. 372(a)) is amended—

11 (1) by striking the section heading through “(a)
12 The Secretary” and inserting the following:

13 **“SEC. 702. EXAMINATIONS AND INVESTIGATIONS.**

14 **“(a) IN GENERAL.—**

15 **“(1) AUTHORITY.—The Secretary”;** and

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

17 **“(2) TOBACCO PRODUCTS.—In the case of a to-**
18 **bacco product, to the maximum extent practicable,**
19 **the Secretary shall contract with States in accord-**
20 **ance with paragraph (1) to carry out inspections of**
21 **retailers in connection with the enforcement of this**
22 **Act.”.**

23 (e) RECORDS OF INTERSTATE SHIPMENT.—Section
24 703 of the Federal Food, Drug, and Cosmetic Act (21
25 U.S.C. 373) is amended—

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

3 (2) by inserting “tobacco product,” after “de-
4 vice,” each place it appears.

5 (f) FACTORY INSPECTION.—Section 704 of the Fed-
6 eral Food, Drug, and Cosmetic Act (21 U.S.C. 374) is
7 amended—

8 (1) in subsection (a)(1), by inserting “tobacco
9 products,” after “devices,” each place it appears;
10 and

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

13 (g) PUBLICITY.—Section 705(b) of the Federal Food,
14 Drug, and Cosmetic Act (21 U.S.C. 375(b)) is amended
15 in the first sentence by inserting “tobacco products,” after
16 “devices,”.

17 (h) PRESUMPTION.—Section 709 of the Federal
18 Food, Drug, and Cosmetic Act (21 U.S. C. 379) is amend-
19 ed by inserting “tobacco product,” after “device,”.

20 (i) IMPORTS AND EXPORTS.—Section 801 of the Fed-
21 eral Food, Drug, and Cosmetic Act (21 U.S.C. 381) is
22 amended—

23 (1) in subsection (a)—

24 (A) in the first sentence, by inserting “to-
25 bacco products,” after “devices,”;

1 (B) in the second sentence, by striking
2 “subsection (i) of section 510” and inserting
3 “section 510(i) or 906(j)”; and

4 (C) by striking “drugs or devices” each
5 place it appears and inserting “drugs, devices,
6 or tobacco products”; and

7 (2) in subsection (e)(1), by inserting “tobacco
8 product,” after “device,”.

9 (j) FOOD AND DRUG ADMINISTRATION.—Section
10 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic
11 Act (as redesignated by section 512(2)) is amended by
12 striking “and devices” and inserting “devices, and tobacco
13 products”.

14 (k) EFFECTIVE DATE FOR NO-TOBACCO-SALE
15 ORDER AMENDMENTS.—The amendments made by sub-
16 section (a), other than the amendment to section 301(b)
17 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
18 331(b)) made by subsection (a)(1), shall take effect only
19 on the promulgation of final regulations by the Secretary
20 of Health and Human Services—

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

1 lations of particular requirements over a specified
2 period of time that constitute a repeated violation;

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

5 (3) providing that a person may not be charged
6 with repeated violations at a particular retail outlet
7 unless the Secretary has provided notice of previous
8 violations at the outlet;

9 (4) establishing a period of time during which,
10 if there are no violations by a particular retail out-
11 let, the outlet will not be considered to have been the
12 site of repeated violations when the next violation oc-
13 curs; and

14 (5) providing that good faith reliance on false
15 identification does not constitute a violation of any
16 minimum age requirement for the sale of tobacco
17 products.

18 **Subtitle B—Cigarette Labeling and** 19 **Advertising**

20 **SEC. 521. DEFINITION OF CIGARETTE.**

21 Section 3(1) of the Federal Cigarette Labeling and
22 Advertising Act (15 U.S.C. 1332) is amended—

23 (1) in subparagraph (A), by striking “and” at
24 the end;

1 (2) in subparagraph (B), by striking the period
2 at the end and inserting “; and”; and

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

4 “(C) any tobacco product, in any form (in-
5 cluding Bidi and Kretek cigarettes), if—

6 “(i) the tobacco in the product—

7 “(I) is heated or burned; and

8 “(II) is functional in the product;

9 and

10 “(ii) the product, because of the ap-
11 pearance of the product, the type of to-
12 bacco used in the filler, or the packaging
13 and labeling of the product, is likely to be
14 offered to, or purchased by, consumers as
15 a cigarette or as roll-your-own tobacco.”.

16 **SEC. 522. CIGARETTE LABEL AND ADVERTISING WARNINGS.**

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

20 **“SEC. 4. LABELING.**

21 “(a) LABEL REQUIREMENTS.—

22 “(1) IN GENERAL.—It shall be unlawful for any
23 person to manufacture, package, or import for sale
24 or distribution within the United States any ciga-
25 rettes the package of which fails to bear, in accord-

1 ance with the requirements of this section, 1 of the
2 following labels:

3 “WARNING: Cigarettes are addictive.

4 “WARNING: Tobacco smoke can harm your
5 children.

6 “WARNING: Cigarettes cause fatal lung dis-
7 ease.

8 “WARNING: Cigarettes cause cancer.

9 “WARNING: Cigarettes cause strokes and
10 heart disease.

11 “WARNING: Smoking during pregnancy can
12 harm your baby.

13 “WARNING: Smoking can kill you.

14 “WARNING: Tobacco smoke causes fatal lung
15 disease in non-smokers.

16 “WARNING: Quitting smoking now greatly re-
17 duces serious risks to your health.

18 “(2) FORMAT.—

19 “(A) LOCATION.—Each label statement re-
20 quired by paragraph (1) shall be located in the
21 upper portion of the front and rear panels of
22 the package, directly on the package under-
23 neath the cellophane or other clear wrapping.

24 “(B) PERCENTAGE OF PANELS.—Except
25 as provided in subparagraph (C), each label

1 statement shall comprise at least the top 25
2 percent of the front and rear panels of the
3 package.

4 “(C) TEXT.—

5 “(i) IN GENERAL.—Except as pro-
6 vided in clause (ii), the word ‘WARNING’
7 shall appear in capital letters and all text
8 shall be in conspicuous and legible 17-point
9 type.

10 “(ii) SMALLER TYPE SIZE.—If the
11 text of the label statement would occupy
12 more than 70 percent of the area of a
13 panel, the text may be in a smaller con-
14 spicuous and legible type size, if at least
15 60 percent of the area of the panel is occu-
16 pied by required text.

17 “(iii) CONTRAST.—The text shall be
18 black on a white background, or white on
19 a black background, in a manner that con-
20 trasts, by typography, layout, or color,
21 with all other printed material on the
22 package, in an alternating fashion under
23 the plan submitted under subsection
24 (b)(4).

25 “(D) FLIP-TOP BOXES.—

1 “(i) IN GENERAL.—For any cigarette
2 brand package manufactured or distributed
3 before January 1, 2000, that employs a
4 flip-top style (if the packaging was used
5 for that brand in commerce before June
6 21, 1997), the label statement required by
7 paragraph (1) shall be located on the flip-
8 top area of the package, even if the area
9 is less than 25 percent of the area of the
10 front panel.

11 “(ii) PACKAGES.—Except as provided
12 in clause (i), the provisions of this sub-
13 section shall apply to the package.

14 “(3) FOREIGN DISTRIBUTION.—This subsection
15 does not apply to a tobacco product manufacturer or
16 distributor of cigarettes that does not manufacture,
17 package, or import cigarettes for sale or distribution
18 within the United States.

19 “(4) TAR, NICOTINE, AND OTHER SMOKE CON-
20 STITUENT DISCLOSURE TO THE PUBLIC.—

21 “(A) IN GENERAL.—The Secretary shall,
22 by a rulemaking conducted under section 553 of
23 title 5, United States Code, determine (in the
24 Secretary’s sole discretion) whether cigarette
25 and other tobacco product manufacturers shall

1 be required to include in the area of each ciga-
2 rette advertisement specified by subsection (b),
3 or on the package label, or both, the tar and
4 nicotine yields of the advertised or packaged
5 brand.

6 “(B) METHOD.—Any such disclosure
7 shall—

8 “(i) be in accordance with the meth-
9 odology established under the regulations;

10 “(ii) conform to the type size require-
11 ments of subsection (b); and

12 “(iii) appear within the area specified
13 in subsection (b).

14 “(C) CONSISTENCY WITH FTC REPORTING RE-
15 QUIREMENTS.—Any differences between the require-
16 ments established by the Secretary under subpara-
17 graph (A) and tar and nicotine yield reporting re-
18 quirements established by the Federal Trade Com-
19 mission shall be resolved by a memorandum of un-
20 derstanding between the Secretary and the Federal
21 Trade Commission.

22 “(D) SMOKE CONSTITUENTS.—

23 “(i) IN GENERAL.—In addition to the dis-
24 closures required by subparagraph (A), the Sec-
25 retary may, under a rulemaking conducted

1 under section 553 of title 5, United States
2 Code, prescribe disclosure requirements regard-
3 ing the level of any cigarette or other tobacco
4 product smoke constituent.

5 “(ii) CONDITIONS.—Any disclosure under
6 this subparagraph may be required if the Sec-
7 retary determines that disclosure would—

8 “(I) be of benefit to the public health;
9 or

10 “(II) otherwise increase consumer
11 awareness of the health consequences of
12 the use of tobacco products.

13 “(iii) FACE OF CIGARETTE PACKAGE OR
14 ADVERTISEMENT.—No disclosure shall be re-
15 quired under this subparagraph on the face of
16 any cigarette package or advertisement.

17 “(iv) OTHER MEANS.—Nothing in this sec-
18 tion prohibits the Secretary from requiring dis-
19 closure under this subparagraph through a cig-
20 arette or other tobacco product package or ad-
21 vertisement insert, or by any other means,
22 under the Federal Food, Drug, and Cosmetic
23 Act (21 U.S.C. 301 et seq.).

24 “(b) ADVERTISING REQUIREMENTS.—

1 “(1) IN GENERAL.—It shall be unlawful for any
2 tobacco product manufacturer, importer, distributor,
3 or retailer of cigarettes to advertise or cause to be
4 advertised within the United States any cigarette
5 unless the advertising for the cigarette bears, in ac-
6 cordance with this section, 1 of the labels specified
7 in subsection (a)(1).

8 “(2) FORMAT.—

9 “(A) IN GENERAL.—Each label statement
10 required by subsection (a) in cigarette adver-
11 tising shall comply with the standards set forth
12 in this paragraph.

13 “(B) PRESS AND POSTER ADVERTISE-
14 MENTS.—In the case of a press or poster adver-
15 tisement, each such statement and (if applica-
16 ble) any required statement relating to tar, nic-
17 otine, or other constituent yield shall—

18 “(i) comprise at least 20 percent of
19 the area of the advertisement; and

20 “(ii) appear in a conspicuous and
21 prominent format and location at the top
22 of each advertisement within the border
23 area.

24 “(C) REVISION OF TYPE SIZES.—The Sec-
25 retary may revise the required type sizes in the

1 border area in such manner as the Secretary
2 determines appropriate.

3 “(D) TEXT.—

4 “(i) IN GENERAL.—The word
5 ‘WARNING’ shall appear in capital let-
6 ters, and each label statement shall appear
7 in conspicuous and legible type.

8 “(ii) CONTRAST.—The text of the
9 label statement shall be black if the back-
10 ground is white and white if the back-
11 ground is black, under the plan submitted
12 under paragraph (4).

13 “(E) BORDER.—The label statement shall
14 be enclosed by a rectangular border that is—

15 “(i) the same color as the letters of
16 the statement; and

17 “(ii) the width of the first downstroke
18 of the capital ‘W’ of the word ‘WARNING’
19 in the label statement.

20 “(F) TYPEFACE.—The text of the label
21 statement shall be in a typeface pro rata to the
22 following requirements:

23 “(i) 45-point type for a whole-page
24 broadsheet newspaper advertisement.

1 “(ii) 39-point type for a half-page
2 broadsheet newspaper advertisement.

3 “(iii) 39-point type for a whole-page
4 tabloid newspaper advertisement.

5 “(iv) 27-point type for a half-page
6 tabloid newspaper advertisement.

7 “(v) 31.5-point type for a double page
8 spread magazine or whole-page magazine
9 advertisement.

10 “(vi) 22.5-point type for a 28-centi-
11 meter-by-3-column advertisement.

12 “(vii) 15-point type for a 20-centi-
13 meter-by-2-column advertisement.

14 “(G) LANGUAGE.—

15 “(i) IN GENERAL.—Except as pro-
16 vided in clauses (ii) and (iii), the label
17 statements shall be in English.

18 “(ii) NON-ENGLISH PUBLICATIONS.—
19 In the case of an advertisement that ap-
20 pears in a newspaper, magazine, periodical,
21 or other publication that is not in English,
22 the statement shall appear in the predomi-
23 nant language of the publication.

24 “(iii) NON-ENGLISH ADVERTISE-
25 MENTS.—In the case of any other adver-

1 tisement that is not in English, the state-
2 ment shall appear in the same language as
3 that principally used in the advertisement.

4 “(3) ADJUSTMENTS BY SECRETARY.—

5 “(A) IN GENERAL.—The Secretary may,
6 through a rulemaking under section 553 of title
7 5, United States Code—

8 “(i) adjust the format and type sizes
9 for the label statements required by this
10 subsection;

11 “(ii) adjust the text, format, and type
12 sizes of any required tar, nicotine yield, or
13 other constituent disclosures; or

14 “(iii) establish the text, format, and
15 type sizes for any other disclosures re-
16 quired under the Federal Food, Drug, and
17 Cosmetic Act (21 U.S.C. 301 et seq.).

18 “(B) LOCATION.—

19 “(i) IN GENERAL.—The text of any
20 such label statements or disclosures ad-
21 justed under this paragraph shall be re-
22 quired to appear only within the 20 per-
23 cent area of cigarette advertisements re-
24 quired under paragraph (2).

1 “(ii) REGULATIONS.—The Secretary
2 shall promulgate regulations that provide
3 for adjustments in the format and type
4 sizes of any text required to appear in the
5 20 percent area to ensure that the total
6 text required to appear by law will fit with-
7 in the area.

8 “(4) MARKETING REQUIREMENTS.—

9 “(A) IN GENERAL.—The label statements
10 specified in subsection (a)(1) shall be randomly
11 displayed—

12 “(i) in each 12-month period, in as
13 equal a number of times as is practicable
14 on each brand of the product; and

15 “(ii) in all areas of the United States
16 in which the product is marketed in ac-
17 cordance with a plan submitted by the to-
18 bacco product manufacturer, importer, dis-
19 tributor, or retailer and approved by the
20 Secretary.

21 “(B) QUARTERLY ROTATION.—The label
22 statements specified in subsection (a)(1) shall
23 be rotated quarterly in alternating sequence in
24 advertisements for each brand of cigarettes in
25 accordance with a plan submitted by the to-

1 bacco product manufacturer, importer, dis-
2 tributor, or retailer to, and approved by, the
3 Secretary.

4 “(C) APPROVAL OF PLAN.—The Secretary
5 shall review each plan submitted under sub-
6 paragraph (B) and approve the plan if the
7 plan—

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

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

17 “(c) CHANGE IN REQUIRED STATEMENTS.—The Sec-
18 retary may, by a rulemaking conducted under section 553
19 of title 5, United States Code, adjust the format, type size,
20 and text of any of the warning label statements required
21 by this section (subject to the limitation on proportional
22 size of the warning contained in subsections (a)(2) and
23 (b)(2)), or establish the format, type size, and text of any
24 other disclosures required under the Federal Food, Drug,
25 and Cosmetic Act (21 U.S.C. 301 et seq.), if the Secretary

1 finds that such a change would promote greater public un-
 2 derstanding of the risks associated with the use of ciga-
 3 rettes or smokeless tobacco products.”.

4 **Subtitle C—Smokeless Tobacco** 5 **Labels and Advertising Warnings**

6 **SEC. 531. SMOKELESS TOBACCO LABELS AND ADVERTISING** 7 **WARNINGS.**

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

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

12 “(a) GENERAL RULE.—

13 “(1) LABELS.—It shall be unlawful for any per-
 14 son to manufacture, package, or import for sale or
 15 distribution within the United States any smokeless
 16 tobacco product unless the product package bears, in
 17 accordance with the requirements of this Act, 1 of
 18 the following labels:

19 “WARNING: This product can cause mouth
 20 cancer.

21 “WARNING: This product can cause gum dis-
 22 ease and tooth loss.

23 “WARNING: This product is not a safe alter-
 24 native to cigarettes.

25 “WARNING: Smokeless tobacco is addictive.

1 “(2) FORMAT.—

2 “(A) LOCATION.—Each label statement re-
3 quired by paragraph (1) shall be located on the
4 2 principal display panels of the package.

5 “(B) PERCENT OF PANEL.—Each label
6 statement shall comprise at least 25 percent of
7 each display panel.

8 “(C) TEXT.—

9 “(i) IN GENERAL.—Except as pro-
10 vided in clause (ii), under the plan sub-
11 mitted under subsection (b)(3), each label
12 statement shall be—

13 “(I) in 17-point conspicuous and
14 legible type; and

15 “(II) in black text on a white
16 background, or white text on a black
17 background, in a manner that con-
18 trasts by typography, layout, or color,
19 with all other printed material on the
20 package, in an alternating fashion.

21 “(ii) SMALLER TYPE.—If the text of a
22 label statement would occupy more than
23 70 percent of the warning area of a pack-
24 age, the text may appear in a smaller type

1 size, if least 60 percent of the warning
2 area is occupied by the label statement.

3 “(3) CONCURRENT INTRODUCTION.—The label
4 statements required by paragraph (1) shall be intro-
5 duced by each tobacco product manufacturer, pack-
6 ager, importer, distributor, or retailer of smokeless
7 tobacco products concurrently into the distribution
8 chain of the products.

9 “(4) FOREIGN DISTRIBUTION.—This subsection
10 does not apply to a tobacco product manufacturer or
11 distributor of any smokeless tobacco product that
12 does not manufacture, package, or import smokeless
13 tobacco products for sale or distribution within the
14 United States.

15 “(b) REQUIRED LABELS.—

16 “(1) IN GENERAL.—It shall be unlawful for any
17 tobacco product manufacturer, packager, importer,
18 distributor, or retailer of smokeless tobacco products
19 to advertise or cause to be advertised within the
20 United States any smokeless tobacco product unless
21 the advertising for the product bears, in accordance
22 with this section, 1 of the labels specified in sub-
23 section (a)(1).

24 “(2) STANDARDS.—

1 “(A) IN GENERAL.—Each label statement
2 required by subsection (a) in smokeless tobacco
3 advertising shall comply with the standards set
4 forth in this paragraph.

5 “(B) PRESS AND POSTER ADVERTISE-
6 MENTS.—For press and poster advertisements,
7 each such statement and (where applicable) any
8 required statement relating to tar, nicotine, or
9 other constituent yield shall—

10 “(i) comprise at least 20 percent of
11 the area of the advertisement, and the
12 warning area shall be delineated by a di-
13 viding line of contrasting color from the
14 advertisement; and

15 “(ii) the word ‘WARNING’ shall ap-
16 pear in capital letters and each label state-
17 ment shall appear in conspicuous and leg-
18 ible type.

19 “(C) TEXT.—The text of the label state-
20 ment shall be black on a white background, or
21 white on a black background, in an alternating
22 fashion under the plan submitted under para-
23 graph (3).

24 “(3) MARKETING REQUIREMENTS.—

1 “(A) IN GENERAL.—The label statements
2 specified in paragraph (1) shall be randomly
3 displayed—

4 “(i) in each 12-month period, in as
5 equal a number of times as is practicable
6 on each brand of the product; and

7 “(ii) in all areas of the United States
8 in which the product is marketed in ac-
9 cordance with a plan submitted by the to-
10 bacco product manufacturer, importer, dis-
11 tributor, or retailer and approved by the
12 Secretary.

13 “(B) QUARTERLY ROTATION.—The label
14 statements specified in paragraph (1) shall be
15 rotated quarterly in alternating sequence in ad-
16 vertisements for each brand of smokeless to-
17 bacco product in accordance with a plan sub-
18 mitted by the tobacco product manufacturer,
19 importer, distributor, or retailer to, and ap-
20 proved by, the Secretary.

21 “(C) APPROVAL OF PLAN.—The Secretary
22 shall review each plan submitted under sub-
23 paragraph (B) and approve the plan if the plan,
24 as determined by the Secretary—

1 “(i) will provide for the equal distribu-
2 tion and display on packaging and the ro-
3 tation required in advertising under this
4 subsection; and

5 “(ii) ensures that all of the labels re-
6 quired under this section will be displayed
7 by the tobacco product manufacturer, im-
8 porter, distributor, or retailer at the same
9 time.

10 “(c) TELEVISION AND RADIO ADVERTISING.—It is
11 unlawful to advertise smokeless tobacco on any medium
12 of electronic communications subject to the jurisdiction of
13 the Federal Communications Commission.

14 “(d) AUTHORITY TO REVISE WARNING LABEL
15 STATEMENTS.—The Secretary may, by a rulemaking con-
16 ducted under section 553 of title 5, United States Code,
17 adjust the format, type size, and text of any of the warn-
18 ing label statements required by this section (subject to
19 the limitations on proportional size of the warning re-
20 quired under this section), or establish the format, type
21 size, and text of any other disclosures required under the
22 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301
23 et seq.), if the Secretary finds that such a change would
24 promote greater public understanding of the risks associ-
25 ated with the use of smokeless tobacco products.”.

1 **Subtitle D—Administration**

2 **SEC. 541. FTC JURISDICTION NOT AFFECTED.**

3 (a) IN GENERAL.—Except as otherwise expressly
4 provided in this Act or an amendment made by this Act,
5 nothing in this Act or an amendment made by this Act
6 limits or diminishes the authority of the Federal Trade
7 Commission to enforce the laws under the jurisdiction of
8 the Commission with respect to the advertising, sale, or
9 distribution of tobacco products.

10 (b) ENFORCEMENT BY FTC.—Any advertising that
11 violates this Act or an amendment made by this Act shall
12 be considered—

13 (1) an unfair or deceptive act or practice under
14 section 5(a) of the Federal Trade Commission Act
15 (15 U.S.C. 45(a)); and

16 (2) a violation of a rule promulgated under sec-
17 tion 18 of that Act (15 U.S.C. 57a).

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