

108TH CONGRESS  
1ST SESSION

# H. R. 140

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

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## IN THE HOUSE OF REPRESENTATIVES

JANUARY 7, 2003

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

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## A BILL

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

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

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

2 (a) SHORT TITLE.—This Act may be cited as the  
 3 “Tobacco Livelihood and Economic Assistance for our  
 4 Farmers Act”.

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

- Sec. 1. Short title; table of contents.
- Sec. 2. Severability.

TITLE I—TERMINATION OF CURRENT TOBACCO PROGRAMS

- Sec. 101. Termination of marketing quota programs and repeal of related provisions.
- Sec. 102. Termination of tobacco price support loan and no net cost provisions and repeal of related provisions.
- Sec. 103. Geographical restrictions on expansion of tobacco production.
- Sec. 104. Continued availability of Federal crop insurance.

TITLE II—PAYMENTS TO TOBACCO QUOTA HOLDERS AND PRODUCERS

- Sec. 201. Definitions.
- Sec. 202. Payments to tobacco quota holders.
- Sec. 203. Transition payments for active producers of quota tobacco.

TITLE III—TOBACCO QUALITY BOARD

- Sec. 301. Establishment of Board.
- Sec. 302. Membership.
- Sec. 303. Duties.
- Sec. 304. Administrative provisions.

TITLE IV—TOBACCO PRODUCT MANUFACTURER AND IMPORTER USER FEES

- Sec. 401. User fee.
- Sec. 402. Allocation of user fees.

TITLE V—FDA REGULATION OF TOBACCO PRODUCTS

- Sec. 501. Findings.
- Sec. 502. Definitions.
- Sec. 503. Amendment of Federal Food, Drug, and Cosmetic Act.
- Sec. 504. Regulatory record.
- Sec. 505. Conforming and other amendments to general provisions.
- Sec. 506. Cigarette label and advertising warnings.
- Sec. 507. Authority to revise cigarette warning label statements.
- Sec. 508. Smokeless tobacco labels and advertising warnings.
- Sec. 509. Authority to revise smokeless tobacco product warning label statements.
- Sec. 510. Tar, nicotine, and other smoke constituent disclosure to the public.

Sec. 511. Regulation requirement.  
 Sec. 512. FTC jurisdiction not affected.

1 **SEC. 2. SEVERABILITY.**

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

8 **TITLE I—TERMINATION OF**  
 9 **CURRENT TOBACCO PROGRAMS**

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

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

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

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

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

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

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

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

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

11           (1) in paragraph (3)—

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

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

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

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

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

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

20           (4) in paragraph (10)—

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

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

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

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

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

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

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

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

12 (1) in subsection (a)—

13 (A) by striking the first sentence and in-  
14 serting the following new sentence: “This sub-  
15 section shall apply to warehousemen, proc-  
16 essors, and common carriers of corn, wheat,  
17 cotton, or rice, all ginners of cotton, and all  
18 persons engaged in the business of purchasing  
19 corn, wheat, cotton, or rice from producers.”;  
20 and

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

24 (2) in subsection (b), by striking “rice, or to-  
25 bacco” and inserting “or rice”.

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

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

8                 (1) in the first sentence of subsection (c) by  
9 striking “and tobacco”; and

10                (2) by striking subsection (f).

11           (n) BURLEY TOBACCO FARM RECONSTITUTION.—  
12 Section 379 of the Agricultural Adjustment Act of 1938  
13 (7 U.S.C. 1379) is amended—

14                 (1) in subsection (a)—

15                     (A) by striking “(a)”; and

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

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

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

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

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

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

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

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

15 (u) APPLICATION OF AMENDMENTS.—The amend-  
16 ments made by this section shall apply with respect to the  
17 2004 and subsequent tobacco crops.

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

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

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

1 (2) by striking subsection (c);

2 (3) in subsection (d)(3)—

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

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

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

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

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

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

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

24 (f) TRANSITION PROVISIONS.—

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

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

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

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

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

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

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

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

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

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

18        (g) APPLICATION OF AMENDMENTS.—This section  
19        and the amendments made by this section shall apply with  
20        respect to the 2004 and subsequent tobacco crops.

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

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

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

5 (b) PENALTY APPLICABLE TO TOBACCO GROWN IN  
6 NONQUOTA COUNTIES AND STATES.—The marketing of  
7 tobacco in the 2004 or subsequent marketing years, of a  
8 kind of tobacco that was subject to a marketing quota in  
9 the 2003 marketing year, shall be subject to a penalty  
10 equal to 100 percent of the total amount received on the  
11 marketing of the tobacco unless the tobacco was grown  
12 in any county in which such kind of tobacco was grown  
13 pursuant to a marketing quota in the 2003 marketing  
14 year.

15 (c) DEFINITIONS.—In this section:

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

19 (2) The term “marketing quota in the 2003  
20 marketing year” means a quota established for that  
21 year pursuant to part I of subtitle B of title III of  
22 the Agricultural Adjustment Act of 1938 (7 U.S.C.  
23 1311 et seq.) and related provisions, as in effect for  
24 that marketing year.

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

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

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

10 **SEC. 201. DEFINITIONS.**

11 In this title:

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

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

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

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

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

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

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

23          (c) **BASE QUOTA LEVEL.**—

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

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

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

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

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

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

5           (1) \$8 per pound; by

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

8           (e) TIME FOR PAYMENT.—The payments to eligible  
9 tobacco quota holders required under this section shall be  
10 made in five equal installments during fiscal years 2004,  
11 2005, 2006, 2007, and 2008.

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

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

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

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

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

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

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

26 (1) \$4 per pound; by



1 **SEC. 302. MEMBERSHIP.**

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

11 (b) **TERMS.**—

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

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

19 **SEC. 303. DUTIES.**

20 The Board shall be responsible for—

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

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

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

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

10 (4) investigating and communicating to the Sec-  
11 retary—

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

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

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

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

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

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

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

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

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

10 (a) IN GENERAL.—The Secretary of Health and  
11 Human Services shall assess an annual user fee, cal-  
12 culated in accordance with this section, upon each tobacco  
13 product manufacturer and tobacco product importer that  
14 sells tobacco products in domestic commerce in the United  
15 States. The assessments shall commence during calendar  
16 year 2004, based on domestic sales of tobacco products  
17 during fiscal year 2003.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

5 (1) USE OF CERTIFIED MANUFACTURER AND  
6 IMPORTER REPORTS.—The calculation of the volume  
7 of domestic sales of a class of tobacco product by a  
8 manufacturer or importer, and by all manufacturers  
9 and importers as a group, shall be made by the Sec-  
10 retary of Health and Human Services based on cer-  
11 tified reports submitted by such manufacturers and  
12 importers pursuant to subsection (f).

13 (2) MEASUREMENT METHODS.—For purposes  
14 of the Secretary's calculations under this subsection  
15 and the certifications under subsection (f), the vol-  
16 umes of domestic sales shall be measured as follows:

17 (A) With respect to cigarettes, in terms of  
18 the numbers of cigarettes sold.

19 (B) With respect to small cigars, the num-  
20 ber of cigars weighing not more than three  
21 pounds per thousand sold.

22 (C) With respect to large cigars, the num-  
23 ber of cigars weighing more than three pounds  
24 per thousand sold.

1 (D) With respect to other classes of to-  
2 bacco products, in terms of the number of  
3 pounds, or fraction thereof, of these tobacco  
4 products sold.

5 (f) CERTIFICATION OF VOLUME OF DOMESTIC  
6 SALES.—Every manufacturer and importer of tobacco  
7 products shall submit each year a certified report to the  
8 Secretary of Health and Human Services setting forth for  
9 each class of tobacco products the total, for the prior year,  
10 of such manufacturer's or importer's domestic sales to  
11 wholesalers and retailers and directly to consumers. These  
12 certified reports must be submitted to the Secretary not  
13 later than March 1 of the year after the year for which  
14 the certified report is being made.

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

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

23 (b) FUNDING FOR FDA REGULATION OF TOBACCO  
24 PRODUCTS.—The Secretary of Health and Human Serv-  
25 ices shall make 15 percent of the user fee amounts col-

1 lected pursuant to section 401 each year available to the  
2 Food and Drug Administration for the regulation of to-  
3 bacco products under chapter IX of the Federal Food,  
4 Drug, and Cosmetic Act.

5 (c) FUNDING FOR OTHER TOBACCO-RELATED PRO-  
6 GRAMS.—

7 (1) TITLE II EXPENDITURES.—The Secretary  
8 of Health and Human Services shall use the remain-  
9 ing 85 percent of the user fee amounts collected  
10 each year pursuant to section 401, and any amounts  
11 transferred to the Secretary by the Secretary of Ag-  
12 riculture pursuant to section 102(f)(3)(B)(ii), to re-  
13 imburse the Commodity Credit Corporation for the  
14 expenditures made by that agency under title II of  
15 this Act.

16 (2) OTHER TOBACCO-RELATED PROGRAM.—If  
17 amounts remain available for any year after making  
18 the reimbursement required under paragraph (1),  
19 the Secretary of Health and Human Services shall  
20 use the remaining amounts to fund any other pro-  
21 gram that relates to tobacco products.

## 22 **TITLE V—FDA REGULATION OF** 23 **TOBACCO PRODUCTS**

### 24 **SEC. 501. FINDINGS.**

25 The Congress finds the following:

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

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

9           (3) Nicotine is addictive.

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

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

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

21          (7) Federal and State governments have lacked  
22 the legal and regulatory authority and resources  
23 they need to address comprehensively the public  
24 health and societal problems caused by the use of to-  
25 bacco products.

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

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

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

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

21          (12) It is in the public interest for Congress to  
22          adopt comprehensive public health legislation be-  
23          cause of tobacco's unique position in the Nation's  
24          history and economy and the need to prevent the  
25          sale, distribution, marketing and advertising of to-

1       bacco products to persons under the minimum legal  
2       age to purchase such products.

3           (13) The public interest requires a timely, fair,  
4       equitable, and consistent result that will serve the  
5       public interest by restricting throughout the Nation  
6       the sale, distribution, marketing, and advertising of  
7       tobacco products only to persons of legal age to pur-  
8       chase such products.

9           (14) Public health authorities estimate that the  
10      benefits to the Nation of enacting Federal legislation  
11      to accomplish these goals would be significant in  
12      human and economic terms.

13          (15) Reducing the use of tobacco by minors by  
14      50 percent would prevent well over 60,000 early  
15      deaths each year and save up to \$43 billion each  
16      year in reduced medical costs, improved productivity,  
17      and the avoidance of premature deaths.

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

1           (17) Tobacco advertising increases the size of  
2           the tobacco market by increasing consumption of to-  
3           bacco products including increasing tobacco use by  
4           young people.

5           (18) Children are more influenced by tobacco  
6           advertising than adults and they smoke the most ad-  
7           vertised 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  
14          to prevent unrestricted tobacco advertising from un-  
15          dermining legislation prohibiting access to young  
16          people.

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 **SEC. 502. DEFINITIONS.**

21          (a) FEDERAL CIGARETTE LABELING AND ADVER-  
22          TISING ACT.—Section 3(1) of the Federal Cigarette La-  
23          beling and Advertising Act is amended—

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

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

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

5                   “(C) any tobacco product, in any form, in-  
6 cluding bidis and kreteks, if the tobacco in the  
7 product is heated or burned and is functional in  
8 the product, and the product, because of its ap-  
9 pearance, the type of tobacco used in the filler,  
10 or its packaging and labeling, is likely to be of-  
11 fered to, or purchased by, consumers as a ciga-  
12 rette or as roll-your-own tobacco.”.

13 (b) THIS TITLE.—In this title:

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

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

24           (3) CIGARETTE TOBACCO.—The term “cigarette  
25 tobacco” means any product that consists of loose

1 tobacco that is intended for use by consumers in a  
2 cigarette. Unless otherwise stated, the requirements  
3 for cigarettes shall also apply to cigarette tobacco.

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

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

11 (6) DISTRIBUTOR.—The term “distributor” as  
12 regards a tobacco product means any person who  
13 furthers the distribution of cigarette or smokeless to-  
14 bacco, whether domestic or imported, at any point  
15 from the original place of manufacture to the person  
16 who sells or distributes the product to individuals for  
17 personal consumption. Common carriers are not con-  
18 sidered distributors for purposes of this title.

19 (7) INGREDIENT.—The term “ingredient” in  
20 relation to cigarettes or smokeless tobacco products  
21 means any substance, chemical, or compound (other  
22 than tobacco, water, or reconstituted tobacco sheet  
23 made wholly from tobacco) added, or specified for  
24 addition, by the manufacturer to the tobacco, paper,  
25 or filter of a cigarette, or to the tobacco of a smoke-

1 less tobacco product, including flavorants, processing  
2 aids, casing sauces, preservatives, and combustion  
3 modifiers.

4 (8) MANUFACTURER.—The term “manufac-  
5 turer” means any person who manufactures tobacco  
6 products intended to be sold in the United States.  
7 The term “manufacturer” shall include an importer  
8 or other first purchaser for resale in the United  
9 States of tobacco products manufactured outside of  
10 the United States or tobacco products manufactured  
11 in the United States but not intended for sale in the  
12 United States.

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

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

23 (11) RETAILER.—The term “retailer” means  
24 any person who sells cigarettes or smokeless tobacco  
25 to individuals for personal consumption, or who op-

1 erates a facility where self-service displays of tobacco  
2 products are permitted.

3 (12) SECRETARY.—Except where the context  
4 otherwise requires, the term “Secretary” means the  
5 Secretary of Health and Human Services.

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

10 **SEC. 503. AMENDMENT OF FEDERAL FOOD, DRUG, AND**  
11 **COSMETIC ACT.**

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

15 “(nn) The term ‘tobacco product’ means any  
16 product made or derived from tobacco that is in-  
17 tended for human consumption, including any com-  
18 ponent, part, or accessory of a tobacco product (ex-  
19 cept for raw materials other than tobacco used in  
20 manufacturing a component, part, or accessory of a  
21 tobacco product).

22 “(ll) The definitions contained in section 502 of  
23 the Tobacco Livelihood and Economic Assistance for  
24 our Farmers Act of 2002 shall apply with respect to  
25 chapter IX.”.

1 (b) FDA AUTHORITY OVER TOBACCO PRODUCTS.—  
2 The Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
3 301 et seq.) is amended—

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

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

7 (3) by inserting after chapter VIII the fol-  
8 lowing:

9 **“CHAPTER IX—TOBACCO**  
10 **PRODUCTS**

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

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

15 “(1) such products are intended for use in the  
16 diagnosis, cure, mitigation, treatment, or prevention  
17 of disease (within the meaning of section  
18 201(g)(1)(B) or section 201(h)(2)); or

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

23 “(b) APPLICABILITY.—This chapter shall apply to all  
24 tobacco products subject to the provisions of part 897 of  
25 title 21, Code of Federal Regulations, and to any other

1 tobacco products that the Secretary by regulation deems  
2 to be subject to this chapter.

3 “(c) SCOPE.—

4 “(1) Nothing in this chapter shall be construed  
5 to affect the Secretary’s authority over, or the regu-  
6 lation of, products under this Act that are not to-  
7 bacco products under chapter V or any other chap-  
8 ter of this Act.

9 “(2) The provisions of this chapter shall not  
10 apply to tobacco leaf that is not in the possession of  
11 the manufacturer, or to the producers of tobacco  
12 leaf, including tobacco growers, tobacco warehouses,  
13 and tobacco grower cooperatives, nor shall any em-  
14 ployee of the Food and Drug Administration have  
15 any authority whatsoever to enter onto a farm  
16 owned by a producer of tobacco leaf without the  
17 written consent of such producer. Notwithstanding  
18 any other provision of this subparagraph, if a pro-  
19 ducer of tobacco leaf is also a tobacco product man-  
20 ufacturer or controlled by a tobacco product manu-  
21 facturer, the producer shall be subject to this chap-  
22 ter in the producer’s capacity as a manufacturer.  
23 Nothing in this chapter shall be construed to grant  
24 the Secretary authority to promulgate regulations on  
25 any matter that involves the production of tobacco

1 leaf or a producer thereof, other than activities by  
2 a manufacturer affecting production. For purposes  
3 of the preceding sentence, the term ‘controlled by’  
4 means a member of the same controlled group of  
5 corporations as that term is used in section 52(a) of  
6 the Internal Revenue Code of 1986, or under com-  
7 mon control within the meaning of the regulations  
8 promulgated under section 52(b) of such Code.

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

10 “A tobacco product shall be deemed to be adulterated  
11 if—

12 “(1) it consists in whole or in part of any filthy,  
13 putrid, or decomposed substance, or is otherwise  
14 contaminated by any poisonous or deleterious sub-  
15 stance that may render the product more injurious  
16 to health;

17 “(2) it has been prepared, packed, or held  
18 under insanitary conditions whereby it may have  
19 been contaminated with filth, or whereby it may  
20 have been rendered more injurious to health;

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

1           “(4) it is, or purports to be or is represented  
2 as, a tobacco product which is subject to a perform-  
3 ance standard established under section 907 unless  
4 such tobacco product is in all respects in conformity  
5 with such standard;

6           “(5) it is required by section 910(a) to have  
7 premarket approval, is not exempt under section  
8 906(f), and does not have an approved application in  
9 effect;

10           “(6) the methods used in, or the facilities or  
11 controls used for, its manufacture, packing or stor-  
12 age are not in conformity with applicable require-  
13 ments under section 906(e)(1) or an applicable con-  
14 dition prescribed by an order under section  
15 906(e)(2); or

16           “(7) it is a tobacco product for which an ex-  
17 emption has been granted under section 906(f) for  
18 investigational use and the person who was granted  
19 such exemption or any investigator who uses such  
20 tobacco product under such exemption fails to com-  
21 ply with a requirement prescribed by or under such  
22 section.

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

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

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

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

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

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

11 except that under subparagraph (B) of this para-  
12 graph reasonable variations shall be permitted, and  
13 exemptions as to small packages shall be established,  
14 by regulations prescribed by the Secretary;

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

23           “(4) if it has an established name, unless its  
24 label bears, to the exclusion of any other nonpropri-  
25 etary name, its established name prominently print-

1 ed in type as required by the Secretary by regula-  
2 tion;

3 “(5) if the Secretary has issued regulations re-  
4 quiring that its labeling bear adequate directions for  
5 use, or adequate warnings against use by children,  
6 that are necessary for the protection of users unless  
7 its labeling conforms in all respects to such regula-  
8 tions;

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

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

21 “(A) its advertising is false or misleading  
22 in any particular; or

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

1           “(8) unless, in the case of any tobacco product  
2 distributed or offered for sale in any State, the man-  
3 ufacturer, packer, or distributor thereof includes in  
4 all advertisements and other descriptive printed mat-  
5 ter issued or caused to be issued by the manufac-  
6 turer, packer, or distributor with respect to that to-  
7 bacco product—

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

11           “(B) a brief statement of—

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

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

1           “(9) unless, in the case of any tobacco product  
2 distributed or offered for sale in any State, the man-  
3 ufacturer, packer, or distributor thereof includes in  
4 all advertisements the information required by sec-  
5 tion 916(c);

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

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

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

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

15           “(b) PRIOR APPROVAL OF STATEMENTS ON  
16 LABEL.—The Secretary may, by regulation, require prior  
17 approval of statements made on the label of a tobacco  
18 product. No regulation issued under this subsection may  
19 require prior approval by the Secretary of the content of  
20 any advertisement and no advertisement of a tobacco  
21 product, published after the date of enactment of this  
22 chapter shall, with respect to the matters specified in this  
23 section or covered by regulations issued hereunder, be sub-  
24 ject to the provisions of sections 12 through 15 of the Fed-  
25 eral Trade Commission Act (15 U.S.C. 52 through 55).

1 This subsection does not apply to any printed matter  
2 which the Secretary determines to be labeling as defined  
3 in section 201(m).

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

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

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

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

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

1 components, and tobacco additives, described in  
2 paragraph (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 thereof) that  
7 relate to the issue of whether a reduction in risk to  
8 health from tobacco products can occur upon the  
9 employment of technology available or known to the  
10 manufacturer.

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

14 An importer of a tobacco product not manufactured in the  
15 United States shall supply the information required of a  
16 tobacco product manufacturer under this subsection.

17 “(b) ANNUAL SUBMISSION.—A tobacco product man-  
18 ufacturer or importer that is required to submit informa-  
19 tion under subsection (a) shall update such information  
20 on an annual basis under a schedule determined by the  
21 Secretary.

22 “(c) TIME FOR SUBMISSION.—

23 “(1) NEW PRODUCTS.—At least 90 days prior  
24 to the delivery for introduction into interstate com-  
25 merce of a tobacco product not on the market on the

1 date of enactment of this chapter, the manufacturer  
2 of such product shall provide the information re-  
3 quired under subsection (a) and such product shall  
4 be subject to the annual submission under sub-  
5 section (b).

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

16 **“SEC. 905. ANNUAL REGISTRATION.**

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

18 “(1) consistent with the provisions of section  
19 901(c)(2), the term ‘manufacture, preparation,  
20 compounding, or processing’ shall include repack-  
21 aging or otherwise changing the container, wrapper,  
22 or labeling of any tobacco product package in fur-  
23 therance of the distribution of the tobacco product  
24 from the original place of manufacture to the person

1 who makes final delivery or sale to the ultimate con-  
2 sumer or user; and

3 “(2) the term ‘name’ shall include in the case  
4 of a partnership the name of each partner and, in  
5 the case of a corporation, the name of each cor-  
6 porate officer and director, and the State of incorpo-  
7 ration.

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

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

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

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

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

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

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

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

17       “(i) REGISTRATION INFORMATION.—

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

1 products filed by that person with the Secretary  
2 under this paragraph or paragraph (2) before such  
3 time of registration. Such list shall be prepared in  
4 such form and manner as the Secretary may pre-  
5 scribe and shall be accompanied by—

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

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

21 “(C) if the registrant filing a list has de-  
22 termined that a tobacco product contained in  
23 such list is not subject to a performance stand-  
24 ard established under section 907, a brief state-  
25 ment of the basis upon which the registrant

1           made such determination if the Secretary re-  
2           quests such a statement with respect to that  
3           particular tobacco product.

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

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

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

1           discontinuance, and the identity of its estab-  
2           lished name.

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

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

19          “(j) REPORT PRECEDING INTRODUCTION OF CER-  
20          TAIN SUBSTANTIALLY EQUIVALENT PRODUCTS INTO  
21          INTERSTATE COMMERCE.—Each person who is required  
22          to register under this section and who proposes to begin  
23          the introduction or delivery for introduction into interstate  
24          commerce for commercial distribution of a tobacco product  
25          intended for human use that was not commercially mar-

1 keted (other than for test marketing) in the United States  
2 as of the date of enactment of this chapter, as defined  
3 by the Secretary by regulation shall, at least 90 days be-  
4 fore making such introduction or delivery, report to the  
5 Secretary (in such form and manner as the Secretary shall  
6 by regulation prescribe)—

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

14           “(2) action taken by such person to comply  
15          with the requirements under section 907 that are  
16          applicable to the tobacco product.

17 **“SEC. 906. GENERAL PROVISIONS RESPECTING CONTROL**  
18 **OF TOBACCO PRODUCTS.**

19           “(a) IN GENERAL.—Any requirement established by  
20 or under section 902, 903, 905, or 909 applicable to a  
21 tobacco product shall apply to such tobacco product until  
22 the applicability of the requirement to the tobacco product  
23 has been changed by action taken under section 907, sec-  
24 tion 910, or subsection (d) of this section, and any re-  
25 quirement established by or under section 902, 903, 905,

1 or 909 which is inconsistent with a requirement imposed  
2 on such tobacco product under section 907, section 910,  
3 or subsection (d) of this section shall not apply to such  
4 tobacco product.

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

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

16               “(2) the period within which interested persons  
17       may present their comments on the notice or find-  
18       ings (including the need thereof) orally or in writing,  
19       which period shall be at least 60 days but may not  
20       exceed 90 days unless the time is extended by the  
21       Secretary by a notice published in the Federal Reg-  
22       ister stating good cause therefor.

23       “(c) LIMITED CONFIDENTIALITY OF INFORMA-  
24 TION.—Any information reported to or otherwise obtained  
25 by the Secretary or the Secretary’s representative under

1 section 904, 905, 907, 908, 909, 910, 912, or 704, or  
2 under subsection (e) or (f) of this section, which is exempt  
3 from disclosure under subsection (a) of section 552 of title  
4 5, United States Code, by reason of subsection (b)(4) of  
5 that section shall be considered confidential and shall not  
6 be disclosed, except that the information may be disclosed  
7 to other officers or employees concerned with carrying out  
8 this chapter, or when relevant in any proceeding under  
9 this chapter.

10 “(d) RESTRICTIONS.—

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

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

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

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

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

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

1 “(B) The Secretary shall—

2 “(i) before promulgating any regula-  
3 tion under subparagraph (A), afford an ad-  
4 visory committee an opportunity to submit  
5 recommendations with respect to the regu-  
6 lation proposed to be promulgated;

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

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

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

1           “(2) EXEMPTIONS; VARIANCES.—

2           “(A) Any person subject to any require-  
3           ment prescribed under paragraph (1) may peti-  
4           tion the Secretary for a permanent or tem-  
5           porary exemption or variance from such re-  
6           quirement. Such a petition shall be submitted  
7           to the Secretary in such form and manner as  
8           the Secretary shall prescribe and shall—

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

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

24          “(iii) contain such other information  
25          as the Secretary shall prescribe.

1           “(B) The Secretary may refer to an advisory  
2           committee any petition submitted under  
3           subparagraph (A). The advisory committee  
4           shall report its recommendations to the Secretary  
5           with respect to a petition referred to it  
6           within 60 days after the date of the petition’s  
7           referral. Within 60 days after—

8                   “(i) the date the petition was submitted  
9                   to the Secretary under subparagraph  
10                  graph (A); or

11                  “(ii) the day after the petition was referred  
12                  to an advisory committee,  
13                  whichever occurs later, the Secretary shall by  
14                  order either deny the petition or approve it.

15           “(C) The Secretary may approve—

16                   “(i) a petition for an exemption for a  
17                   tobacco product from a requirement if the  
18                   Secretary determines that compliance with  
19                   such requirement is not required to assure  
20                   that the tobacco product will be in compliance  
21                   with this chapter; and

22                   “(ii) a petition for a variance for a tobacco  
23                   product from a requirement if the  
24                   Secretary determines that the methods to  
25                   be used in, and the facilities and controls

1 to be used for, the manufacture, packing,  
2 and storage of the tobacco product in lieu  
3 of the methods, controls, and facilities pre-  
4 scribed by the requirement are sufficient to  
5 assure that the tobacco product will be in  
6 compliance with this chapter.

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

16 “(E) After the issuance of an order under  
17 subparagraph (B) respecting a petition, the pe-  
18 titioner shall have an opportunity for an infor-  
19 mal hearing on such order.

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

24 “(g) RESEARCH AND DEVELOPMENT.—The Sec-  
25 retary may enter into contracts for research, testing, and

1 demonstrations respecting tobacco products and may ob-  
2 tain tobacco products for research, testing, and dem-  
3 onstration purposes without regard to section 3324(a) and  
4 (b) of title 31, United States Code, and section 5 of title  
5 41, United States Code.

6 **“SEC. 907. PERFORMANCE STANDARDS.**

7 “(a) IN GENERAL.—

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

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

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

22 “(2) CONTENT OF PERFORMANCE STAND-  
23 ARDS.—A performance standard established under  
24 this section for a tobacco product—

1           “(A) shall include provisions to provide  
2 performance that is appropriate for the protec-  
3 tion of the public health, including provisions,  
4 where appropriate—

5           “(i) for the reduction of nicotine  
6 yields of the product;

7           “(ii) for the reduction or elimination  
8 of other harmful constituents or harmful  
9 components of the product; or

10          “(iii) relating to any other require-  
11 ment under (B);

12          “(B) shall, where necessary to be appro-  
13 priate for the protection of the public health,  
14 include—

15          “(i) provisions respecting the con-  
16 struction, components, ingredients, and  
17 properties of the tobacco product;

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

21          “(iii) provisions for the measurement  
22 of the performance characteristics of the  
23 tobacco product; and

24          “(iv) provisions requiring that the re-  
25 sults of each or of certain of the tests of

1           the tobacco product required to be made  
2           under clause (ii) show that the tobacco  
3           product is in conformity with the portions  
4           of the standard for which the test or tests  
5           were required; and

6           “(C) shall not render the tobacco product  
7           unacceptable for adult consumption.

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

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

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

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

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

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

9           “(b) ESTABLISHMENT OF STANDARDS.—

10           “(1) NOTICE.—

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

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

19           “(i) set forth a finding with sup-  
20           porting justification that the performance  
21           standard is appropriate for the protection  
22           of the public health;

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

1 the performance standard is intended to  
2 reduce or eliminate; and

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

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

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

1 standard would be appropriate for the protec-  
2 tion of the public health.

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

5 “(2) PROMULGATION.—

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

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

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

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

1 date is necessary for the protection of the pub-  
2 lic health. Such date or dates shall be estab-  
3 lished so as to minimize, consistent with the  
4 public health, economic loss to, and disruption  
5 or dislocation of, domestic and international  
6 trade.

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

10 “(A) eliminating all cigarettes, all smoke-  
11 less tobacco products, or any similar class of to-  
12 bacco products, or

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

15 Congress expressly reserves to itself the power to  
16 make such a decision.

17 “(4) AMENDMENT; REVOCATION.—

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

24 “(B) The Secretary may declare a pro-  
25 posed amendment of a performance standard to

1           be effective on and after its publication in the  
2           Federal Register and until the effective date of  
3           any final action taken on such amendment if  
4           the Secretary determines that making it so ef-  
5           fective is in the public interest.

6           “(5) REFERENCE TO ADVISORY COMMITTEE.—

7           The Secretary—

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

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

17           refer such proposed regulation to an advisory com-  
18           mittee, for a report and recommendation with re-  
19           spect to any matter involved in the proposed regula-  
20           tion which requires the exercise of scientific judg-  
21           ment. If a proposed regulation is referred under this  
22           subparagraph to the advisory committee, the Sec-  
23           retary shall provide the advisory committee with the  
24           data and information on which such proposed regu-  
25           lation is based. The advisory committee shall, within

1 60 days after the referral of a proposed regulation  
2 and after independent study of the data and infor-  
3 mation furnished to it by the Secretary and other  
4 data and information before it, submit to the Sec-  
5 retary a report and recommendation respecting such  
6 regulation, together with all underlying data and in-  
7 formation and a statement of the reason or basis  
8 for the recommendation. A copy of such report and  
9 recommendation shall be made public by the Sec-  
10 retary.

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

12 “(a) NOTIFICATION.—If the Secretary determines  
13 that—

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

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

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

11 “(b) NO EXEMPTION FROM OTHER LIABILITY.—  
12 Compliance with an order issued under this section shall  
13 not relieve any person from liability under Federal or  
14 State law.

15 “(c) RECALL AUTHORITY.—

16 “(1) IN GENERAL.—If the Secretary finds that  
17 there is a reasonable probability that a tobacco prod-  
18 uct contains a manufacturing or other defect not or-  
19 dinarily contained in tobacco products on the market  
20 that would cause serious, adverse health con-  
21 sequences or death, the Secretary shall issue an  
22 order requiring the appropriate person (including  
23 the manufacturers, importers, distributors, or retail-  
24 ers of the tobacco product) to immediately cease dis-  
25 tribution of such tobacco product. The order shall

1 provide the person subject to the order with an op-  
2 portunity for an informal hearing, to be held not  
3 later than 10 days after the date of the issuance  
4 of the order, on the actions required by the order  
5 and on whether the order should be amended to re-  
6 quire a recall of such tobacco product. If, after pro-  
7 viding an opportunity for such a hearing, the Sec-  
8 retary determines that inadequate grounds exist to  
9 support the actions required by the order, the Sec-  
10 retary shall vacate the order.

11 “(2) AMENDMENT OF ORDER TO REQUIRE RE-  
12 CALL.—

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

24 “(B) An amended order under subpara-  
25 graph (A)—

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

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

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

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

15                  **“SEC. 909. RECORDS AND REPORTS ON TOBACCO PROD-**  
16                  **UCTS.**

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

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

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

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

20           “(4) when prescribing the procedure for making  
21          requests for reports or information, shall require  
22          that each request made under such regulations for  
23          submission of a report or information to the Sec-  
24          retary state the reason or purpose for such request

1 and identify to the fullest extent practicable such re-  
2 port or information;

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

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

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

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

23 (1) Except as provided in paragraph (3), the  
24 Secretary shall by regulation require a tobacco prod-  
25 uct manufacturer or importer of a tobacco product

1 to report promptly to the Secretary any corrective  
2 action taken or removal from the market of a to-  
3 bacco product undertaken by such manufacturer or  
4 importer if the removal or correction was under-  
5 taken—

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

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

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

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

21 **“SEC. 910. PREMARKET REVIEW OF CERTAIN TOBACCO**  
22 **PRODUCTS.**

23 “(a) IN GENERAL.—

24 “(1) PREMARKET APPROVAL REQUIRED.—Ap-  
25 proval under this section of an application for pre-

1 market approval for any tobacco product, other than  
2 a reduced risk product under section 912, that is not  
3 commercially marketed (other than for test mar-  
4 keting) in the United States as of the date of this  
5 chapter's enactment, is required unless the manufac-  
6 turer has submitted a report under section 905(j),  
7 and the Secretary has not suspended the distribution  
8 of such product under this paragraph. Within 90  
9 days of the submission of a report under section  
10 905(j), the Secretary may by order suspend the dis-  
11 tribution of the tobacco product that is the subject  
12 of that report if the Secretary determines that there  
13 is a reasonable likelihood that the tobacco product is  
14 not substantially equivalent to a tobacco product  
15 commercially marketed (other than for test mar-  
16 keting) in the United States as of the date of this  
17 chapter's enactment, that is in compliance with the  
18 requirements of this Act. If the Secretary fails to  
19 issue an order within this 90-day period, then the  
20 tobacco product that is the subject of that report  
21 shall be deemed to be substantially equivalent to a  
22 predicate tobacco product. The issuance of an order  
23 under this paragraph shall constitute final agency  
24 action for purposes of section 702 of title 5, the  
25 United States Code; provided, that the Secretary

1       may rescind or modify an order issued under this  
2       paragraph at any time.

3           “(2) SUBSTANTIALLY EQUIVALENT DEFINED.—

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

10           “(i) has the same characteristics as  
11       the predicate tobacco product; or

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

1           “(B) For purposes of subparagraph (A),  
2           the term ‘characteristics’ means the materials,  
3           ingredients, design, composition, heating source,  
4           or other features of a tobacco product.

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

11          “(3) HEALTH INFORMATION.—

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

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

1 to another tobacco product. The communication  
2 that such product is a reduced risk product  
3 may comply with requirements prescribed by  
4 the Secretary relating to such communication,  
5 and the Secretary may require prior approval  
6 of the communication, in each case in accord-  
7 ance with section 912.

8 “(b) APPLICATION.—

9 “(1) CONTENTS.—An application for premarket  
10 approval shall contain—

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

18 “(B) a full statement of the components,  
19 ingredients, and properties, and of the principle  
20 or principles of operation, of such tobacco prod-  
21 uct;

22 “(C) a full description of the methods used  
23 in, and the facilities and controls used for, the  
24 manufacture, processing, and, when relevant,

1           packing and installation of, such tobacco prod-  
2           uct;

3           “(D) an identifying reference to any per-  
4           formance standard under section 907 which  
5           would be applicable to any aspect of such to-  
6           bacco product, and either adequate information  
7           to show that such aspect of such tobacco prod-  
8           uct fully meets such performance standard or  
9           adequate information to justify any deviation  
10          from such standard;

11          “(E) such samples of such tobacco product  
12          and of components thereof as the Secretary  
13          may reasonably require;

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

16          “(G) such other information relevant to  
17          the subject matter of the application as the Sec-  
18          retary may require.

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

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

24                 “(B) shall, upon the request of an appli-  
25                 cant,

1 refer such application to an advisory committee and  
2 for submission (within such period as the Secretary  
3 may establish) of a report and recommendation re-  
4 specting approval of the application, together with  
5 all underlying data and the reasons or basis for the  
6 recommendation.

7 “(c) ACTION ON APPLICATION.—

8 “(1) DEADLINE.—

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

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

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

1           “(B) An order approving an application for  
2           a tobacco product may require as a condition to  
3           such approval that the sale and distribution of  
4           the tobacco product be restricted but only to  
5           the extent that the sale and distribution of a  
6           tobacco product may be restricted under a regu-  
7           lation under section 906(d).

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

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

19                 “(B) the methods used in, or the facilities  
20                 or controls used for, the manufacture, proc-  
21                 essing, or packing of such tobacco product do  
22                 not conform to the requirements of section  
23                 906(e);

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

4           “(D) such tobacco product is not shown to  
5           conform in all respects to a performance stand-  
6           ard in effect under section 907, compliance with  
7           which is a condition to approval of the applica-  
8           tion, and there is a lack of adequate informa-  
9           tion to justify the deviation from such standard.

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

18          “(4) BASIS FOR ACTION.—

19                 “(A) For purposes of paragraph (2)(A),  
20                 whether permitting a tobacco product to be  
21                 marketed would be appropriate for the protec-  
22                 tion of the public health shall, when appro-  
23                 priate, be determined on the basis of well-con-  
24                 trolled investigations, which may include one or  
25                 more clinical investigations by experts qualified

1 by training and experience to evaluate the to-  
2 bacco product.

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

11 “(d) WITHDRAWAL AND TEMPORARY SUSPENSION.—

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

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

22 “(B) that the application contained or was  
23 accompanied by an untrue statement of a mate-  
24 rial fact;

25 “(C) that the applicant—

1           “(i) has failed to establish a system  
2           for maintaining records, or has repeatedly  
3           or deliberately failed to maintain records  
4           or to make reports, required by an applica-  
5           ble regulation under section 909;

6           “(ii) has refused to permit access to,  
7           or copying or verification of, such records  
8           as required by section 704; or

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

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

23          “(E) on the basis of new information be-  
24          fore the Secretary, evaluated together with the  
25          evidence before the Secretary when the applica-

1           tion was approved, that the labeling of such to-  
2           bacco product, based on a fair evaluation of all  
3           material facts, is false or misleading in any par-  
4           ticular and was not corrected within a reason-  
5           able time after receipt of written notice from  
6           the Secretary of such fact; or

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

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

24          “(3) TEMPORARY SUSPENSION.—If, after pro-  
25          viding an opportunity for an informal hearing, the

1 Secretary determines there is reasonable probability  
2 that the continuation of distribution of a tobacco  
3 product under an approved application would cause  
4 serious, adverse health consequences or death, that  
5 is greater than ordinarily caused by tobacco prod-  
6 ucts on the market, the Secretary shall by order  
7 temporarily suspend the approval of the application  
8 approved under this section. If the Secretary issues  
9 such an order, the Secretary shall proceed expedi-  
10 tiously under paragraph (1) to withdraw such appli-  
11 cation.

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

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

16 “(2) by mailing the order by registered mail or  
17 certified mail addressed to the applicant at the ap-  
18 plicant’s last known address in the records of the  
19 Secretary.

20 **“SEC. 911. JUDICIAL REVIEW.**

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

22 “(1) the promulgation of a regulation under  
23 section 907 establishing, amending, or revoking a  
24 performance standard for a tobacco product; or

1           “(2) a denial of an application for approval  
2           under section 910(c),  
3 any person adversely affected by such regulation or order  
4 may file a petition with the United States Court of Ap-  
5 peals for the District of Columbia or for the circuit where-  
6 in such person resides or has his principal place of busi-  
7 ness for judicial review of such regulation or order. A copy  
8 of the petition shall be transmitted by the clerk of the  
9 court to the Secretary or other officer designated by the  
10 Secretary for that purpose. The Secretary shall file in the  
11 court the record of the proceedings on which the Secretary  
12 based the Secretary’s regulation or order and each record  
13 or order shall contain a statement of the reasons for its  
14 issuance and the basis, on the record, for its issuance. For  
15 purposes of this section, the term ‘record’ means all no-  
16 tices and other matter published in the Federal Register  
17 with respect to the regulation or order reviewed, all infor-  
18 mation submitted to the Secretary with respect to such  
19 regulation or order, proceedings of any panel or advisory  
20 committee with respect to such regulation or order, any  
21 hearing held with respect to such regulation or order, and  
22 any other information identified by the Secretary, in the  
23 administrative proceeding held with respect to such regu-  
24 lation or order, as being relevant to such regulation or  
25 order.

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

19           “(c) STANDARD OF REVIEW.—Upon the filing of the  
20    petition under subsection (a) of this section for judicial  
21    review of a regulation or order, the court shall have juris-  
22    diction to review the regulation or order in accordance  
23    with chapter 7 of title 5, United States Code, and to grant  
24    appropriate relief, including interim relief, as provided in  
25    such chapter. A regulation or order described in paragraph

1 (1) or (2) of subsection (a) of this section shall not be  
2 affirmed if it is found to be unsupported by substantial  
3 evidence on the record taken as a whole.

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

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

13 “(f) REGULATIONS AND ORDERS MUST RECITE  
14 BASIS IN RECORD.—To facilitate judicial review under  
15 this section or under any other provision of law of a regu-  
16 lation or order issued under section 906, 907, 908, 909,  
17 910, or 913, each such regulation or order shall contain  
18 a statement of the reasons for its issuance and the basis,  
19 in the record of the proceedings held in connection with  
20 its issuance, for its issuance.

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

22 “(a) REQUIREMENTS.—

23 “(1) IN GENERAL.—For purposes of this sec-  
24 tion, the term ‘reduced risk tobacco product’ means

1 a tobacco product designated by the Secretary under  
2 paragraph (2).

3 “(2) DESIGNATION.—

4 “(A) IN GENERAL.—A product may be  
5 designated by the Secretary as a reduced risk  
6 tobacco product if the Secretary finds that the  
7 product is demonstrated to significantly reduce  
8 harm to individuals caused by a tobacco prod-  
9 uct and is otherwise appropriate to protect pub-  
10 lic health, based on an application submitted by  
11 the manufacturer of the product (or other re-  
12 sponsible person) that—

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

21 “(II) contains scientific evidence  
22 showing that use of such product results in  
23 a substantially lower potential risk to  
24 health in one or more specific respects  
25 than use of another tobacco product in the

1 same or different category as the proposed  
2 reduced risk product; and

3 “(ii) if required by the Secretary, in-  
4 cludes studies of the long-term health ef-  
5 fects of the product.

6 If such studies are required, the manufacturer  
7 may consult with the Secretary regarding proto-  
8 cols for conducting the studies.

9 “(B) BASIS FOR FINDING.—In making the  
10 finding under subparagraph (A), the Secretary  
11 shall take into account—

12 “(i) the risks and benefits to the pop-  
13 ulation as a whole, including both users of  
14 tobacco products and non-users of tobacco  
15 products;

16 “(ii) the increased or decreased likeli-  
17 hood that existing users of tobacco prod-  
18 ucts will stop using such products includ-  
19 ing reduced risk tobacco products;

20 “(iii) the increased or decreased likeli-  
21 hood that those who do not use tobacco  
22 products will start to use such products,  
23 including reduced risk tobacco products;  
24 and

1                   “(iv) the risks and benefits to con-  
2                   sumers from the use of a reduced risk to-  
3                   bacco product as compared to the use of  
4                   products approved under chapter V to re-  
5                   duce exposure to tobacco.

6                   “(3) **MARKETING REQUIREMENTS.**—A tobacco  
7                   product may be marketed and labeled as a reduced  
8                   risk tobacco product if it—

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

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

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

1           the Secretary may require prior approval of the  
2           communication.

3           “(b) REVOCATION OF DESIGNATION.—At any time  
4 after the date on which a tobacco product is designated  
5 as a reduced risk tobacco product under this section the  
6 Secretary may, after providing an opportunity for an in-  
7 formal hearing, revoke such designation if the Secretary  
8 determines, based on information not available at the time  
9 of the designation, that—

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

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

14           “(c) LIMITATION.—A tobacco product that is des-  
15 ignated as a reduced risk tobacco product that is in com-  
16 pliance with subsection (a) shall not be regulated as a  
17 drug or device.

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

1 “(e) POSTMARKET SURVEILLANCE.—

2 “(1) DISCRETIONARY SURVEILLANCE.—The  
3 Secretary may require a tobacco product manufac-  
4 turer to conduct postmarket surveillance for reduced  
5 risk a tobacco product of the manufacturer if the  
6 Secretary determines that postmarket surveillance of  
7 the tobacco product is necessary to protect the pub-  
8 lic health or is necessary to provide information re-  
9 garding the health risks and other safety issues in-  
10 volving the tobacco product.

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

1 an appropriately qualified scientific and technical re-  
2 view committee established by the Secretary.

3 **“SEC. 913. PRESERVATION OF STATE AND LOCAL AUTHOR-**  
4 **ITY.**

5 “(a) ADDITIONAL REQUIREMENTS.—

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

13 “(2) PREEMPTION OF CERTAIN STATE AND  
14 LOCAL REQUIREMENTS.—

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

1           “(B) Subparagraph (A) does not apply to  
2 requirements relating to the sale, use, or dis-  
3 tribution of a tobacco product including require-  
4 ments related to the access to, and the adver-  
5 tising and promotion of, a tobacco product.

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

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

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

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

18           “(a) **DEFINITIONS.**—For purposes of this section, the  
19 following definitions apply:

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

24           “(2) **ADULT-ONLY FACILITY.**—The term ‘adult-  
25 only facility’ means a facility or restricted area

1 (whether open-air or enclosed) where the operator  
2 ensures or has a reasonable basis to believe (such as  
3 by checking identification as required under state  
4 law, or by checking the identification of any person  
5 appearing to be under the age of 27) that only  
6 adults are present. A facility or restricted area need  
7 not be permanently restricted to adults in order to  
8 constitute an adult-only facility, provided that the  
9 operator ensures or has a reasonable basis to believe  
10 that only adults are present during the event or time  
11 period in question.

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

24 “(b) CIGARETTE AND SMOKELESS TOBACCO PROD-  
25 UCT REQUIREMENTS.—

1           “(1) MINIMUM SALES AGE.—No retailer may  
2           sell a tobacco product to any person younger than  
3           18 years of age.

4           “(2) PROOF OF AGE.—

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

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

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

24           “(4) MAIL ORDER SALES.—After two years  
25           from the date of enactment of this chapter, the Sec-

1       retary shall transmit to Congress a report describing  
2       the extent, if any, to which individuals younger than  
3       18 years of age are obtaining tobacco products  
4       through the mail.

5       “(c) MINIMUM PACKAGE SIZE REQUIREMENTS.—

6             “(1) No manufacturer, distributor, or retailer  
7       may sell or cause to be sold, or distribute or cause  
8       to be distributed, any cigarette package that con-  
9       tains fewer than 20 cigarettes.

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

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

19            “(1) No manufacturer, distributor, or retailer  
20       may distribute or cause to be distributed any free  
21       samples of tobacco products, except in an adult-only  
22       facility.

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

1           “(A) the purchase, exchange or redemption  
2           for proof of purchase of any tobacco products  
3           (including, but not limited to, a free offer in  
4           connection with the purchase of tobacco prod-  
5           ucts, such as a ‘two-for-one’ offer), or

6           “(B) the conducting of consumer testing or  
7           evaluation of tobacco products with persons who  
8           certify that they are adults.

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

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

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

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

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

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

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

13          “(g) BAN ON USE OF CARTOONS.—

14                 “(1) No manufacturer, distributor, or retailer  
15                 may use or cause to be used any cartoon in the ad-  
16                 vertising, promoting, packaging, or labeling of to-  
17                 bacco products.

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

22                         “(A) The use of comically exaggerated fea-  
23                         tures;

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

4           “(C) The attribution of unnatural or  
5           extrahuman abilities, such as imperviousness to  
6           pain or injury, X-ray vision, tunneling at very  
7           high speeds, or transformation.

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

13          “(h) ELIMINATION OF OUTDOOR ADVERTISING.—

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

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

19                   “(A) billboards;

20                   “(B) signs and placards in arenas, sta-  
21                   diums, shopping malls, and video game arcades  
22                   (whether any of the foregoing are open air or  
23                   enclosed); and

24                   “(C) any other advertisements placed—

25                           “(i) outdoors, or

1                   “(ii) on the inside surface of a window  
2                   facing outward.

3                   “(D) The term ‘outdoor advertising’ does  
4                   not mean—

5                   “(i) an advertisement on the outside  
6                   of a tobacco product manufacturing facil-  
7                   ity;

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

23                  “(iii) an advertisement inside a retail  
24                  establishment that sells tobacco products  
25                  (other than solely through a vending ma-

1                   chine) that is not placed on the inside sur-  
2                   face of a window facing outward.

3                   “(3) For purposes of this subsection, the term  
4                   ‘video game arcade’ means an entertainment estab-  
5                   lishment primarily consisting of video games (other  
6                   than video games intended primarily for use by per-  
7                   sons 18 years of age or older) and/or pinball ma-  
8                   chines.

9                   “(i) ELIMINATION OF TRANSIT ADVERTISEMENTS.—

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

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

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

1           “(A) occupies an area larger than 14  
2 square feet;

3           “(B) is placed in such proximity to any  
4 other such advertisement so as to create a sin-  
5 gle ‘mosaic’-type advertisement larger than 14  
6 square feet; or

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

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

11           “(1) No manufacturer, distributor, or retailer  
12 shall advertise a tobacco product in any youth-ori-  
13 ented publication (whether periodic or limited dis-  
14 tribution).

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

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

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

1       “(k) BAN ON TOBACCO PRODUCT BRAND NAME  
2 SPONSORSHIPS.—

3           “(1) No manufacturer, distributor, or retailer  
4 may sponsor or cause to be sponsored any athletic,  
5 musical, artistic, or other social or cultural event, or  
6 any entry or team in any event, in the brand name  
7 (alone or in conjunction with any other word), logo,  
8 symbol, motto, selling message, recognizable color or  
9 pattern of colors, or any other indicia of product  
10 identification identical or similar to, or identifiable  
11 with, those used for any brand of cigarettes or  
12 smokeless tobacco.

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

1       tion identical or similar to, or identifiable with, those  
2       used for any brand of cigarettes or smokeless to-  
3       bacco.

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

6       “(1) BAN ON TOBACCO BRAND NAME MERCHAN-  
7       DISE.—

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

16           “(2) Nothing in this subsection shall—

17           “(A) prohibit the distribution to any man-  
18      ufacturer’s employee who is an adult of any  
19      item described above that is intended for the  
20      personal use of such an employee;

21           “(B) require any manufacturer to retrieve,  
22      collect or otherwise recover any item that prior  
23      to the enactment of this chapter was marketed,  
24      distributed, offered, sold, licensed, or caused to

1 be marketed, distributed, offered, sold, or li-  
2 censed by such manufacturer;

3 “(C) apply to coupons or other items used  
4 by adults solely in connection with the purchase  
5 of tobacco products; or

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

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

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

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

24 “(B) In the case of items provided (or to be re-  
25 deemed) at retail establishments, a manufacturer

1 shall be entitled to rely on verification of proof of  
2 age by the retailer, where such retailer is required  
3 to obtain verification under applicable Federal, State  
4 or local law.

5 “(n) BAN ON NON-TOBACCO PRODUCT BRAND  
6 NAMES.—

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

16 “(2) Paragraph (1) shall not apply to any to-  
17 bacco product brand name in existence as of July 1,  
18 1998.

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

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

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

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

11       “(p) BAR ON PRODUCT PLACEMENT IN CERTAIN  
12 MEDIA.—

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

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

1           “(A) media where the audience or viewers  
2           are within an adult-only facility (provided such  
3           media are not visible to persons outside such  
4           adult-only facility);

5           “(B) media not intended for distribution or  
6           display to the public; or

7           “(C) instructional media concerning non-  
8           conventional tobacco products or tobacco prod-  
9           ucts designated as reduced risk viewed only by  
10          or provided only to consumers who are adults.

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

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

20          **“SEC. 916. MANDATORY DISCLOSURES.**

21          “(a) DISCLOSURE OF INGREDIENTS TO THE PUB-  
22          LIC.—

23                  “(1) Not later than 12 months after the effec-  
24          tive date of this section, the Secretary shall promul-  
25          gate regulations requiring the disclosure to the pub-

1       lic on a brand-by-brand basis of the common or  
2       usual name of each ingredient of a tobacco product  
3       in descending order of predominance by weight, ex-  
4       cept that spices, flavorings, and colorings may at the  
5       manufacturer’s election be designated as spices,  
6       flavorings, and colorings without naming each. Any  
7       ingredient that has been disclosed to the public pur-  
8       suant to any other law or regulation with respect to  
9       a particular brand may be required to be disclosed  
10      for such brand pursuant to this subsection.

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

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

1           “(4) Any disclosure required pursuant to this  
2 subsection may be required by appropriate means,  
3 except that, notwithstanding any other provision of  
4 this Act, the Secretary shall not require the listing  
5 of any ingredient on any package or in any adver-  
6 tisement.

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

13           “(1) the percentage of tobacco that is domestic  
14 tobacco; and

15           “(2) the percentage of tobacco that is foreign  
16 tobacco.

17           “(c) MANDATORY DISCLAIMER.—

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

25           This section shall not be deemed to apply to the use

1 of the terms ‘filtered’ or ‘filter’. In no event shall  
2 any such disclaimer be required on any tobacco  
3 product package.

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

9 “(3) The Secretary may modify or waive any  
10 requirement under this subsection with respect to  
11 any product that has been designated by the Sec-  
12 retary as a reduced risk product under section  
13 912.”.

14 **SEC. 504. REGULATORY RECORD.**

15 Notwithstanding the provisions of subchapter II of  
16 chapter 5 of title 5, United States Code, in promulgating  
17 regulations under this chapter, the record developed and  
18 utilized by the Secretary for the purposes of promulgating  
19 subparts (B) and (D) of the regulations relating to the  
20 sale, distribution, and use of tobacco products on or about  
21 August 28, 1996, as reflected in articles IV and VI of the  
22 preamble to the 1996 Food and Drug Administration To-  
23 bacco Rule (including public comments, Food and Drug  
24 Administration documents, and any other information  
25 generated or compiled for purposes of promulgating such

1 regulations), shall be deemed to have the same legal status  
2 as if such record had been developed under a rulemaking  
3 proceeding conducted pursuant to section 906(d)(1). In all  
4 other respects, including with respect to the issue of  
5 whether such regulations conform to section 906(d)(1),  
6 the procedural requirements of this chapter and the Ad-  
7 ministration Procedure Act will apply.

8 **SEC. 505. CONFORMING AND OTHER AMENDMENTS TO GEN-**  
9 **ERAL PROVISIONS.**

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

17 (b) SECTION 301.—Section 301 (21 U.S.C. 331) is  
18 amended—

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

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

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

1           (4) in subsection (e), by striking “515(f), or  
2           519” and inserting “515(f), 519, or 909”;

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

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

7           (7) in subsection (j), by striking “708, or 721”  
8           and inserting “708, 721, 903, 904, 905, 906, 907,  
9           908, 909, 910, or 912”;

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

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

14          “(p) The failure to register in accordance with section  
15          510 or 905, the failure to provide any information re-  
16          quired by section 510(j), 510(k), 905(i), or 905(j), or the  
17          failure to provide a notice required by section 510(j)(2)  
18          or 905(j)(2).”;

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

21          “(1) The failure or refusal—

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

1           “(B) to furnish any notification or other mate-  
2           rial or information required by or under section 519,  
3           520(g), 904, 906(f), or 909; or

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

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

8           (12) in subsection (r), by inserting “or tobacco  
9           product” after “device” each time that it appears;  
10          and

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

12          “(aa) The sale of tobacco products in violation  
13          of a no-tobacco-sale order issued under section  
14          303(f).”.

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

17                 (1) by striking the subsection heading and in-  
18                 serting the following:

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

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

23                 (3) by redesignating paragraphs (3), (4), and  
24                 (5) as paragraphs (4), (5), and (6), respectively;

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

3           “(3) If the Secretary finds that a person has  
4           committed repeated violations of restrictions promul-  
5           gated under section 906(d) at a particular retail out-  
6           let then the Secretary may impose a no-tobacco-sale  
7           order on that person prohibiting the sale of tobacco  
8           products in that outlet. A no-tobacco-sale order may  
9           be imposed with a civil penalty under paragraph  
10          (1).”;

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

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

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

19          (6) in subparagraph (B) of paragraph (4), as so  
20          redesignated—

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

24                 (B) by adding at the end the following: “A  
25                 no-tobacco-sale order permanently prohibiting

1 an individual retail outlet from selling tobacco  
2 products shall include provisions that allow the  
3 outlet, after a specified period of time, to re-  
4 quest that the Secretary compromise, modify,  
5 or terminate the order.”;

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

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

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

12 (A) by striking “(3)(A)” and inserting  
13 “(4)(A)”;

14 (B) by inserting “or the imposition of a  
15 no-tobacco-sale order” after “penalty” the first  
16 2 places it appears;

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

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

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

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

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

5                   “(E) Any adulterated or misbranded to-  
6 bacco product.”;

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

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

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

14       (e) SECTION 702.—Section 702(a) (21 U.S.C.  
15 372(a)) is amended—

16           (1) by inserting “(A)” after “(1)”; and

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

18                   “(B) For a tobacco product, to the extent feasible,  
19 the Secretary shall contract with the States in accordance  
20 with subparagraph (A) to carry out inspections of retailers  
21 in connection with the enforcement of this Act.”.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

11          (l) EFFECTIVE DATE FOR NO-TOBACCO-SALE  
12          ORDER AMENDMENTS.—The amendments made by sub-  
13          section (c), other than the amendment made by paragraph  
14          (2) thereof, shall take effect only upon the promulgation  
15          of final regulations by the Secretary—

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

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

24               (3) providing that a person may not be charged  
25               with repeated violations at a particular retail outlet

1 unless the Secretary has provided notice of previous  
2 violations at that outlet;

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

8 (5) providing that good faith reliance on false  
9 identification does not constitute a violation of any  
10 minimum age requirement for the sale of tobacco  
11 products.

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

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

16 **“SEC. 4. LABELING.**

17 **“(a) LABEL REQUIREMENTS.—**

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

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

1 “WARNING: Tobacco smoke can harm your chil-  
2 dren”

3 “WARNING: Cigarettes cause fatal lung disease”

4 “WARNING: Cigarettes cause cancer”

5 “WARNING: Cigarettes cause strokes and heart  
6 disease”

7 “WARNING: Smoking during pregnancy can harm  
8 your baby”

9 “WARNING: Smoking can kill you”

10 “WARNING: Tobacco smoke causes fatal lung dis-  
11 ease in non-smokers”

12 “WARNING: Quitting smoking now greatly reduces  
13 serious risks to your health”

14 “(2) PLACEMENT; TYPOGRAPHY; ETC.—

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

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

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

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

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

4 “(b) ADVERTISING REQUIREMENTS.—

5 “(1) IN GENERAL.—It shall be unlawful for any  
6 tobacco product manufacturer, importer, distributor,  
7 or retailer of cigarettes to advertise or cause to be  
8 advertised within the United States any cigarette  
9 unless its advertising bears, in accordance with the  
10 requirements of this section, one of the labels speci-  
11 fied in subsection (a) of this section.

12 “(2) TYPOGRAPHY, ETC.—Each label statement  
13 required by subsection (a) of this section in cigarette  
14 advertising shall comply with the standards set forth  
15 in this paragraph. For press and poster advertise-  
16 ments, each such statement and (where applicable)  
17 any required statement relating to tar, nicotine, or  
18 other constituent yield shall comprise at least 20  
19 percent of the area of the advertisement and shall  
20 appear in a conspicuous and prominent format and  
21 location at the top of each advertisement within the  
22 trim area. The Secretary may revise the required  
23 type sizes in such area in such manner as the Sec-  
24 retary determines appropriate. The word “WARN-  
25 ING” shall appear in capital letters, and each label

1 statement shall appear in conspicuous and legible  
2 type. The text of the label statement shall be black  
3 if the background is white and white if the back-  
4 ground is black, under the plan submitted under  
5 paragraph (4) of this subsection. The label state-  
6 ments shall be enclosed by a rectangular border that  
7 is the same color as the letters of the statements  
8 and that is the width of the first downstroke of the  
9 capital “W” of the word “WARNING” in the label  
10 statements. The text of such label statements shall  
11 be in a typeface pro rata to the following require-  
12 ments: 45-point type for a whole-page broadsheet  
13 newspaper advertisement; 39-point type for a half-  
14 page broadsheet newspaper advertisement; 39-point  
15 type for a whole-page tabloid newspaper advertise-  
16 ment; 27-point type for a half-page tabloid news-  
17 paper advertisement; 31.5-point type for a double  
18 page spread magazine or whole-page magazine ad-  
19 vertisement; 22.5-point type for a 28 centimeter by  
20 3 column advertisement; and 15-point type for a 20  
21 centimeter by 2 column advertisement. The label  
22 statements shall be in English, except that in the  
23 case of—

24 “(A) an advertisement that appears in a  
25 newspaper, magazine, periodical, or other publi-

1 cation that is not in English, the statements  
2 shall appear in the predominant language of the  
3 publication; and

4 “(B) in the case of any other advertise-  
5 ment that is not in English, the statements  
6 shall appear in the same language as that prin-  
7 cipally used in the advertisement.

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

1 “(4) MARKETING REQUIREMENTS.—

2 “(A) The label statements specified in sub-  
3 section (a)(1) shall be randomly displayed in  
4 each 12-month period, in as equal a number of  
5 times as is possible on each brand of the prod-  
6 uct and be randomly distributed in all areas of  
7 the United States in which the product is mar-  
8 keted in accordance with a plan submitted by  
9 the tobacco product manufacturer, importer,  
10 distributor, or retailer and approved by the Sec-  
11 retary.

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

19 “(C) The Secretary shall review each plan  
20 submitted under subparagraph (B) and approve  
21 it if the plan—

22 “(i) will provide for the equal distribu-  
23 tion and display on packaging and the ro-  
24 tation required in advertising under this  
25 subsection; and

1                   “(ii) assures that all of the labels re-  
2                   quired under this section will be displayed  
3                   by the tobacco product manufacturer, im-  
4                   porter, distributor, or retailer at the same  
5                   time.”.

6 **SEC. 507. AUTHORITY TO REVISE CIGARETTE WARNING**  
7                   **LABEL STATEMENTS.**

8                   Section 4 of the Federal Cigarette Labeling and Ad-  
9                   vertising Act (15 U.S.C. 1333), as amended by section  
10                  506, is further amended by adding at the end the fol-  
11                  lowing:

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

1 **SEC. 508. SMOKELESS TOBACCO LABELS AND ADVERTISING**  
2 **WARNINGS.**

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

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

7 **“(a) GENERAL RULE.—**

8 **“(1) It shall be unlawful for any person to man-**  
9 **ufacture, package, or import for sale or distribution**  
10 **within the United States any smokeless tobacco**  
11 **product unless the product package bears, in accord-**  
12 **ance with the requirements of this Act, one of the**  
13 **following labels:**

14 **“WARNING: This product can cause mouth cancer”**

15 **“WARNING: This product can cause gum disease**  
16 **and tooth loss”**

17 **“WARNING: This product is not a safe alternative**  
18 **to cigarettes”**

19 **“WARNING: Smokeless tobacco is addictive”**

20 **“(2) Each label statement required by para-**  
21 **graph (1) shall be—**

22 **“(A) located on the 2 principal display**  
23 **panels of the package, and each label statement**  
24 **shall comprise at least 25 percent of each such**  
25 **display panel; and**

1           “(B) in 17-point conspicuous and legible  
2           type and in black text on a white background,  
3           or white text on a black background, in a man-  
4           ner that contrasts by typography, layout, or  
5           color, with all other printed material on the  
6           package, in an alternating fashion under the  
7           plan submitted under subsection (b)(3), except  
8           that if the text of a label statement would oc-  
9           cupy more than 70 percent of the area specified  
10          by subparagraph (A), such text may appear in  
11          a smaller type size, so long as at least 60 per-  
12          cent of such warning area is occupied by the  
13          label statement.

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

19          “(4) The provisions of this subsection do not  
20          apply to a tobacco product manufacturer or dis-  
21          tributor of any smokeless tobacco product that does  
22          not manufacture, package, or import smokeless to-  
23          bacco products for sale or distribution within the  
24          United States.

25          “(b) REQUIRED LABELS.—

1           “(1) It shall be unlawful for any tobacco prod-  
2           uct manufacturer, packager, importer, distributor, or  
3           retailer of smokeless tobacco products to advertise or  
4           cause to be advertised within the United States any  
5           smokeless tobacco product unless its advertising  
6           bears, in accordance with the requirements of this  
7           section, one of the labels specified in subsection (a).

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

15                 “(A) comprise at least 20 percent of the  
16                 area of the advertisement, and the warning area  
17                 shall be delineated by a dividing line of con-  
18                 trasting color from the advertisement; and

19                 “(B) the word “WARNING” shall appear  
20                 in capital letters and each label statement shall  
21                 appear in conspicuous and legible type. The text  
22                 of the label statement shall be black on a white  
23                 background, or white on a black background, in  
24                 an alternating fashion under the plan submitted  
25                 under paragraph (3).

1           “(3)(A) The label statements specified in sub-  
2           section (a)(1) shall be randomly displayed in each  
3           12-month period, in as equal a number of times as  
4           is possible on each brand of the product and be ran-  
5           domly distributed in all areas of the United States  
6           in which the product is marketed in accordance with  
7           a plan submitted by the tobacco product manufac-  
8           turer, importer, distributor, or retailer and approved  
9           by the Secretary.

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

17           “(C) The Secretary shall review each plan sub-  
18           mitted under subparagraph (B) and approve it if the  
19           plan—

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

23                   “(ii) assures that all of the labels required  
24                   under this section will be displayed by the to-

1           bacco product manufacturer, importer, dis-  
2           tributor, or retailer at the same time.

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

7 **SEC. 509. AUTHORITY TO REVISE SMOKELESS TOBACCO**  
8                                   **PRODUCT WARNING LABEL STATEMENTS.**

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

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

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

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

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

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

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

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

21 **SEC. 511. REGULATION REQUIREMENT.**

22       (a) TESTING, REPORTING, AND DISCLOSURE.—Not  
23      later than 24 months after the date of enactment of this  
24      Act, the Secretary, through the Commissioner of Food and  
25      Drugs, shall promulgate regulations under the Federal

1 Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)  
2 that meet the requirements of subsection (b) of this sec-  
3 tion.

4 (b) CONTENTS OF RULES.—The rules promulgated  
5 under subsection (a) shall require the testing, reporting,  
6 and disclosure of tobacco product smoke constituents and  
7 ingredients that the Secretary determines should be dis-  
8 closed to the public in order to protect the public health.  
9 Such constituents shall include tar, nicotine, carbon mon-  
10 oxide, and such other smoke constituents or ingredients  
11 as the Secretary may determine to be appropriate. The  
12 rule may require that tobacco product manufacturers,  
13 packagers, or importers make such disclosures relating to  
14 tar and nicotine through labels or advertising, and make  
15 such disclosures regarding other smoke constituents or in-  
16 gredients as the Secretary determines are necessary to  
17 protect the public health.

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

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

23 (a) IN GENERAL.—Except where expressly provided  
24 in this Act, nothing in this Act shall be construed as lim-  
25 iting or diminishing the authority of the Federal Trade

1 Commission to enforce the laws under its jurisdiction with  
2 respect to the advertising, sale, or distribution of tobacco  
3 products.

4 (b) ENFORCEMENT BY FTC.—Any advertising that  
5 violates this Act is an unfair or deceptive act or practice  
6 under section 5(a) of the Federal Trade Commission Act  
7 (15 U.S.C. 45(a)) and shall be considered a violation of  
8 a rule promulgated under section 18 of that Act (15  
9 U.S.C. 57a).

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