107TH CONGRESS
2D SESSION

S. 2764

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

IN THE SENATE OF THE UNITED STATES

JULY 19, 2002

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

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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 domestic and imported tobacco, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Tobacco Livelihood and Economic Assistance for Our Farmers Act of 2002''.

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

TITLE I—TERMINATION OF CURRENT TOBACCO PROGRAMS

SEC. 101. TERMINATION OF TOBACCO PRODUCTION ADJUSTMENT PROGRAMS.

(a) TOBACCO CONTROL.—The Act of April 25, 1936 (commonly known as the Tobacco Control Act; 7 U.S.C. 515 et seq.), is repealed.

(b) COMMODITY HANDLING ORDERS.—Section 8c(2)(A) of the Agricultural Adjustment Act (7 U.S.C. 608c(2)(A)), reenacted with amendments by the Agricultural Marketing Agreement Act of 1937, is amended by striking ''tobacco,''.

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

(1) in paragraph (2), by striking ''tobacco,''; and

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

(d) BURLEY TOBACCO IMPORT REVIEW.—Section 3 of Public Law 98–59 (7 U.S.C. 625) is repealed.

(e) DECLARATION OF POLICY.—Section 2 of the Agricultural Adjustment Act of 1938 (7 U.S.C. 1282) is amended by striking ''tobacco,''.

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

(1) in paragraph (3)—

(A) by striking subparagraph (C); and

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

(2) in paragraph (6)(A), by striking ''tobacco,'';

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

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

''Tobacco (other than Flue-cured), October 1–September 30;'';

(4) in paragraph (10)—

(A) by striking subparagraph (B); and

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

(5) in paragraph (11)(B), by striking ''and tobacco'';

(6) in paragraph (12), by striking ''tobacco,'';

(7) in paragraph (14)—

(A) in subparagraph (A), by striking ''(A)''; and

(B) by striking subparagraphs (B), (C), and (D);

(8) by striking paragraph (15);

(9) in paragraph (16)—

(A) by striking subparagraph (B); and

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

(10) by striking paragraph (17); and

(11) by redesignating paragraph (16) as paragraph (15).

(g) PARITY PAYMENTS.—Section 303 of the Agricultural Adjustment Act of 1938 (7 U.S.C. 1303) is amended in the first sentence by striking ''rice, or tobacco,'' and inserting ''or rice,''.

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

(i) ADMINISTRATIVE PROVISIONS.—Section 361 of the Agricultural Adjustment Act of 1938 (7 U.S.C. 1361) is amended by striking ''tobacco,''.

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

(1) in the first sentence of subsection (a), by striking ''rice, or tobacco'' and inserting ''or rice''; and

(2) in the first sentence of subsection (b), by striking ''rice, or tobacco'' and inserting ''or rice''.

(k) REPORTS AND RECORDS.—Section 373 of the Agricultural Adjustment Act of 1938 (7 U.S.C. 1373) is amended—

(1) by striking ''rice, or tobacco'' each place it appears in subsections (a) and (b) and inserting ''or rice''; and

(2) in subsection (a)—

(A) in the first sentence, by striking ''all persons engaged in the business of redrying, prizing, or stemming tobacco for producers,''; and

(B) in the last sentence, by striking ''$500;'' and all that follows through the period at the end of the sentence and inserting ''$500.''.

(l) REGULATIONS.—Section 375(a) of the Agricultural Adjustment Act of 1938 (7 U.S.C. 1375(a)) is amended by striking ''peanuts, or tobacco'' and inserting ''or peanuts''.

(m) EMINENT DOMAIN.—Section 378 of the Agricultural Adjustment Act of 1938 (7 U.S.C. 1378) is amended—

(1) in the first sentence of subsection (c), by striking ''cotton, and tobacco'' and inserting ''and cotton''; and

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

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

(1) in subsection (a)—

(A) by striking ''(a)''; and

(B) in paragraph (6), by striking '', but this clause (6) shall not be applicable in the case of burley tobacco''; and

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

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

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

(q) TRANSFER OF ALLOTMENTS.—Section 703 of the Food and Agriculture Act of 1965 (7 U.S.C. 1316) is repealed.

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

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

(t) LIABILITY.—The amendments made by this section shall not affect the liability of any person under any provision of law as in effect before the effective date under subsection (u).

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

SEC. 102. TERMINATION OF TOBACCO PRICE SUPPORT PROGRAM.

(a) PARITY PRICE SUPPORT.—Section 101 of the Agricultural Act of 1949 (7 U.S.C. 1441) is amended—

(1) in the first sentence of subsection (a), by striking ''tobacco (except as otherwise provided herein), corn,'' and inserting ''corn'';

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

(3) in subsection (d)(3)—

(A) by striking '', except tobacco,''; and

(B) by striking ''and no price support shall be made available for any crop of tobacco for which marketing quotas have been disapproved by producers;''; and

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

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

(c) DEFINITION OF BASIC AGRICULTURAL COMMODITY.—Section 408(c) of the Agricultural Act of 1949 (7 U.S.C. 1428(c)) is amended by striking ''tobacco,''.

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

(e) POWERS OF COMMODITY CREDIT CORPORATION.—Section 5 of the Commodity Credit Corporation Charter Act (15 U.S.C. 714c) is amended by inserting ''(other than tobacco)'' after ''agricultural commodities'' each place it appears.

(f) TRANSITION PROVISIONS.—

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

(2) TOBACCO STOCKS AND LOANS.—The Secretary of Agriculture shall promulgate regulations that require—

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

(B) the repayment of all tobacco price support loans or surrender of collateral by the associations not later than 1 year after the date of enactment of this Act.

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

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

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

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

(ii) if any funds remain, the Secretary shall transfer the funds to the Secretary of Health and Human Services for use in accordance with section 402.

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

SEC. 103. GEOGRAPHICAL RESTRICTIONS ON EXPANSION OF TOBACCO PRODUCTION.

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

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

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

(b) DEFINITIONS.—In this section:

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

(2) MARKETING YEAR.—The term ''marketing year'' means—

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

(B) in the case of each other kind of tobacco, October 1 through September 30.

(c) PENALTY APPLICABLE TO TOBACCO GROWN IN NONQUOTA COUNTIES AND STATES.—The marketing in the 2003 or subsequent marketing years of a kind of tobacco that was subject to a marketing quota in the 2002 marketing year shall be subject to a penalty equal to 100 percent of the total amount received for the marketing of the tobacco, unless the Secretary of Agriculture determines that the tobacco was grown in a county in which the kind of tobacco was grown pursuant to a marketing quota in the 2002 marketing year.

SEC. 104. CONTINUED AVAILABILITY OF FEDERAL CROP INSURANCE.

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

TITLE II—PAYMENTS TO TOBACCO QUOTA HOLDERS AND PRODUCERS

SEC. 201. DEFINITIONS.

In this title:

(1) ACTIVE PRODUCER OF QUOTA TOBACCO.—The term ''active producer of quota tobacco'' means a person that was the actual producer of tobacco marketed under a marketing quota for the 2001 tobacco marketing year, as determined by the Secretary.

(2) QUOTA TOBACCO.—The term ''quota tobacco'' means a kind of tobacco that is subject to a farm marketing quota or farm acreage allotment for the 1999, 2000, 2001, and 2002 tobacco marketing years under a marketing quota or allotment program established under part I of subtitle B of title III of the Agricultural Adjustment Act of 1938 (7 U.S.C. 1281 et seq.) (as in effect before the amendment made by section 101(h)).

(3) SECRETARY.—The term ''Secretary'' means the Secretary of Agriculture.

(4) TOBACCO QUOTA HOLDER.—The term ''tobacco quota holder'' means an owner of a farm on January 1, 2002, for which a tobacco farm marketing quota or farm acreage allotment for quota tobacco was established with respect to the 2002 tobacco marketing year under a marketing quota program established under part I of subtitle B of title III of the Agricultural Adjustment Act of 1938 (7 U.S.C. 1281 et seq.) (as in effect before the amendment made by section 101(h)).

SEC. 202. PAYMENTS TO TOBACCO QUOTA HOLDERS.

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

(b) ELIGIBILITY.—

(1) IN GENERAL.—To be eligible to receive a payment under this section, a person shall submit to the Secretary an application containing such information as the Secretary may require to demonstrate

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

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

(c) BASE QUOTA LEVEL.—

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

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

(3) MARKETING QUOTAS OTHER THAN POUNDAGE QUOTAS.—For each kind of tobacco for which there is a marketing quota or allotment on an acreage basis, the base quota level for each tobacco quota holder shall be the quantity obtained by multiplying—

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

(B) the average county production yield per acre for the county in which the farm is located for the kind of tobacco for the 1998 marketing year.

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

(1) $8 per pound; by

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

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

(f) RESOLUTION OF DISPUTES.—Any dispute regarding the eligibility of a person to receive a payment under this section, or the amount of the payment, shall be resolved by the county committee established under section 8(b)(5) of the Soil Conservation and Domestic Allotment

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

(g) COMMODITY CREDIT CORPORATION.—The Secretary shall use the funds, facilities, and authorities of the Commodity Credit Corporation to carry out this section.

SEC. 203. TRANSITION PAYMENTS FOR ACTIVE PRODUCERS OF QUOTA TOBACCO.

(a) TRANSITION PAYMENTS REQUIRED.—The Secretary shall make transition payments under this section to eligible active producers of quota tobacco.

(b) ELIGIBILITY.—

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

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

(c) PRODUCTION BASE.—

(1) IN GENERAL.—The Secretary shall establish a production base applicable to each eligible active producer of quota tobacco, as determined under subsection (b).

(2) QUANTITY.—The production base of a producer shall be equal to the quantity, in pounds, of quota tobacco subject to the basic marketing quota produced and marketed by the producer under part I of subtitle B of title III of the Agricultural Adjustment Act of 1938 (7 U.S.C. 1281 et seq.) (as in effect before the amendment made by section 101(h)) for the 2001 marketing year.

(d) PAYMENT.—The Secretary shall make payments to each eligible active producer of quota tobacco, as determined under subsection (b), in an amount obtained by multiplying—

(1) $4 per pound; by

(2) the production base established for the active producer under subsection (c).

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

(f) RESOLUTION OF DISPUTES.—Any dispute regarding the eligibility of a person to receive a payment under this section, or the amount of the payment, shall be resolved by the county committee established under section 8(b)(5) of the Soil Conservation and Domestic Allotment

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

(g) COMMODITY CREDIT CORPORATION.—The Secretary shall use the funds, facilities, and authorities of the Commodity Credit Corporation to carry out this section.

TITLE III—TOBACCO QUALITY BOARD

SEC. 301. DEFINITIONS.

In this title:

(1) BOARD.—The term ''Board'' means the Tobacco Quality Board established under section 302.

(2) SECRETARY.—The term ''Secretary'' means the Secretary of Agriculture.

SEC. 302. ESTABLISHMENT OF BOARD.

(a) IN GENERAL.—The Secretary shall establish a permanent advisory board within the Department of Agriculture to be known as the Tobacco Quality Board.

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

(1) 5 members shall be appointed by the Secretary from nominations submitted by representatives of tobacco producers in the United States;

(2) 5 members shall be appointed by the Secretary from nominations submitted by representa-

tives of tobacco product manufacturers in the United States; and

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

(c) TERMS.—

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

(2) OTHER MEMBERS.—Other members of the Board shall serve for 2-year terms, except that of the members first appointed to the Board, 2 producer representatives and 2 manufacturer representatives shall have initial terms of 1 year, as determined by the Secretary.

SEC. 303. DUTIES.

The Board shall—

(1) determine and describe the physical characteristics of tobacco produced in the United States and unmanufactured tobacco imported into the United States;

(2) assemble and evaluate, in a systematic manner, concerns and problems with the quality of tobacco produced in the United States, expressed by domestic and foreign buyers and manufacturers of tobacco products;

(3) review data collected by Federal agencies on the physical and chemical integrity of tobacco produced in the United States and unmanufactured tobacco imported into the United States, to ensure that tobacco being used in domestically-manufactured tobacco products is of the highest quality and is free from prohibited physical and chemical agents;

(4) investigate and communicate to the Secretary—

(A) conditions with respect to the production of tobacco that discourage improvements in the quality of tobacco produced in the United States; and

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

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

SEC. 304. ADMINISTRATION.

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

(1) a staff that is—

(A) experienced in the sampling and analysis of unmanufactured tobacco; and

(B) capable of collecting data and monitoring tobacco production information; and

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

(b) COMMODITY CREDIT CORPORATION.—The Secretary shall use the funds, facilities, and authorities of the Commodity Credit Corporation to carry out this title.

TITLE IV—TOBACCO PRODUCT MANUFACTURER AND IMPORTER USER FEES

SEC. 401. USER FEE.

(a) IN GENERAL.—

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

(2) COMMENCEMENT.—The assessments shall commence during calendar year 2003, based on domestic sales of tobacco products during fiscal year 2003.

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

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

(2) for small cigar manufacturers and importers, $1,051,000;

(3) for large cigar manufacturers and importers, $164,274,000;

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

(5) for chewing tobacco manufacturers and importers, $2,275,000;

(6) for pipe tobacco manufacturers and importers, $1,505,000; and

(7) for roll-your-own tobacco manufacturers and importers, $3,231,000.

(c) DETERMINATION OF ANNUAL USER FEE FOR EACH CLASS OF TOBACCO PRODUCT.—The total user fee to be assessed on, and paid by, the manufacturers and importers of each class of tobacco product in each calendar year, as allocated pursuant to subsection (d), shall be the amount obtained by multiplying—

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

(2) a fraction—

(A) the numerator of which is the total volume of domestic sales of that class of tobacco

product during the fiscal year ending on September 30 of that calendar year; and

(B) the denominator of which is the total volume of domestic sales of that class of tobacco product during fiscal year 2003.

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

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

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

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

(B) the total user fee amount for the calendar year, as determined under subsection (c), for the class of tobacco product.

(e) DETERMINATION OF VOLUME OF DOMESTIC SALES.—

(1) IN GENERAL.—The calculation of the volume of domestic sales of a class of tobacco product by a manufacturer or importer, and by all manufacturers and importers as a group, shall be made by the Secretary of Health and Human Services based on certified reports submitted by the manufacturers and importers pursuant to subsection (f).

(2) MEASUREMENT.—For purposes of the calculations under this subsection and the certifications under subsection (f) by the Secretary of Health and Human Services, the volumes of domestic sales shall be measured by—

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

(B) in the case of each other class of tobacco products, such unit as is specified by regulation by the Secretary.

(f) CERTIFICATION OF VOLUME OF DOMESTIC SALES.—

(1) IN GENERAL.—Each manufacturer and importer of tobacco products shall submit for each year a certified report to the Secretary of Health and Human Services setting forth for each class of tobacco products marketed or imported the total, for the preceding year, of domestic sales of the tobacco products by the manufacturer and importer, respectively, to wholesalers and retailers and directly to consumers.

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

SEC. 402. ALLOCATION OF USER FEES.

(a) IN GENERAL.—The user fees collected pursuant to section 401 and any funds transferred to the Secretary of Health and Human Services by the Secretary of Agriculture pursuant to section 102(f)(3)(B)(ii) shall be available, without further appropriation, in accordance with, and for the purposes described in, this section, to remain available until expended.

(b) FUNDING FOR FDA REGULATION OF TOBACCO PRODUCTS.—The Secretary of Health and Human Services shall make 15 percent of the user fee amounts collected pursuant to section 401 for each year available to

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

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

(1) to reimburse the Commodity Credit Corporation for the expenditures made by the Commodity Credit Corporation under title II; and

(2) if any funds remain after carrying out paragraph (1), to fund any other program that relates to tobacco products.

TITLE V—FDA REGULATION OF TOBACCO PRODUCTS

SEC. 501. FINDINGS.

Congress finds that—

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

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

(3) nicotine is addictive;

(4) virtually all new users of tobacco products are under the minimum legal age to purchase tobacco products;

(5) tobacco advertising and marketing contribute significantly to the use of nicotine-containing tobacco products by adolescents;

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

(7) Federal and State governments have lacked the legal and regulatory authority and resources to address comprehensively the public health and societal problems caused by the use of tobacco products;

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

(9) under article I, section 8 of the Constitution, Congress is vested with the responsibility for regulating interstate commerce and commerce with Indian tribes;

(10) the sale, distribution, marketing, advertising, and use of tobacco products are activities in and substantially affect interstate commerce because tobacco products are sold, marketed, advertised, and distributed in interstate commerce on a nationwide basis;

(11) the sale, distribution, marketing, advertising, and use of tobacco products substantially affect interstate commerce through the health care and other costs attributable to the use of tobacco products;

(12) it is in the public interest for Congress to adopt comprehensive public health legislation because of—

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

(B) the need to prevent the sale, distribution, marketing and advertising of tobacco products to persons under the minimum legal age to purchase tobacco products;

(13) the public interest requires a timely, fair, equitable, and consistent result that will serve the public interest by restricting throughout the United States the sale, distribution, marketing, and advertising of tobacco products only to persons of legal age to purchase tobacco products;

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

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

(16)(A) advertising, marketing, and promotion of tobacco products have been especially directed to attract young persons to use tobacco products, resulting in increased use of tobacco products by youth; and

(B) past efforts to oversee those activities have not been successful in adequately preventing the increased use;

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

(18) children—

(A) are more influenced by tobacco advertising than adults; and

(B) smoke the most advertised brands;

(19) tobacco company documents indicate that young people are an important and often crucial segment of the tobacco market;

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

(21) restrictions on advertising are necessary to prevent unrestricted tobacco advertising from undermining legislation prohibiting access to young people; and

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

Subtitle A—FDA Jurisdiction Over Tobacco Products

SEC. 511. DEFINITION OF TOBACCO PRODUCT.

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

''(ll) TOBACCO PRODUCT.—

''(A) IN GENERAL.—The term 'tobacco product' means any product made or derived from tobacco that is intended for human consumption.

''(B) INCLUSIONS.—The term 'tobacco product' includes any component, part, or accessory of a tobacco product.

''(C) EXCLUSIONS.—The term 'tobacco product' does not include any raw material, other than tobacco, used in manufacturing a component, part, or accessory of a tobacco product.''.

SEC. 512. TOBACCO PRODUCTS.

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

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

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

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

"CHAPTER IX—TOBACCO PRODUCTS

"SEC. 901. DEFINITIONS.

''In this title:

''(1) BRAND.—The term 'brand' means a variety of tobacco product distinguished by the tobacco used, tar content, nicotine content, flavoring used, size, filtration, or packaging, logo, registered trademark or brand name, identifiable pattern of colors, or any combination of those attributes.

''(2) CIGARETTE.—The term 'cigarette' has the meaning given the term in section 3 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1332).

''(3) COMMERCE.—The term 'commerce' has the meaning given the term in section 3 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1332).

''(4) CONSTITUENT.—The term 'constituent' means, with respect to cigarettes, any element of mainstream or sidestream smoke.

''(5) DISTRIBUTOR.—

''(A) IN GENERAL.—The term 'distributor' means, with respect to a tobacco product, any person that furthers the distribution of cigarette or smokeless tobacco, whether domestic or

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

''(B) EXCLUSION.—The term 'distributor' does not include a common carrier.

''(6) INGREDIENT.—

''(A) IN GENERAL.—The term 'ingredient' means, with respect to cigarettes or smokeless tobacco products, any substance, chemical, or compound (other than tobacco, water, or reconstituted tobacco sheet made wholly from tobacco) added, or specified for addition, by a manufacturer to the tobacco, paper, or filter of a cigarette, or to the tobacco of a smokeless tobacco product.

''(B) INCLUSIONS.—The term 'ingredient' includes, with respect to cigarettes or smokeless tobacco products, flavorants, processing aids, casing sauces, preservatives, and combustion modifiers.

''(7) MANUFACTURER.—

''(A) IN GENERAL.—The term 'manufacturer' means any person that manufactures a

tobacco product intended to be sold in the United States.

''(B) INCLUSIONS.—The term ''manufacturer'' includes an importer, or other first purchaser for resale in the United States, of—

''(i) a tobacco product manufactured outside of the United States; or

''(ii a tobacco product manufactured in the United States but not intended for sale in the United States.

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

''(9) PACKAGE.—The term 'package' means—

''(A) a pack, box, carton, or container of any kind; or

''(B) if no other container is used, any wrapping (including cellophane) in which cigarettes or smokeless tobacco is offered for sale, sold, or otherwise distributed to consumers.

''(10) RETAILER.—The term 'retailer' means any person that—

''(A) sells cigarettes or smokeless tobacco to individuals for personal consumption; or

''(B) operates a facility at which self-service displays of tobacco products are permitted.

''(11) SMOKELESS TOBACCO.—The term 'smokeless tobacco' means any product that—

''(A) consists of cut, ground, powdered, or leaf tobacco; and

''(B) is intended to be placed in the oral or nasal cavity.

''SEC. 902. FDA JURISDICTION OVER TOBACCO PRODUCTS.

''(a) IN GENERAL.—A tobacco product shall be regulated by the Secretary under this chapter and shall not be subject to the provisions of chapter V, except to the extent that—

''(1) the tobacco product is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease (within the meaning of section 201(g)(1)(B) or 201(h)(2)); or

''(2) a health claim is made for the tobacco product under section 201(g)(1)(C) or 201(h)(3), except that this paragraph shall not apply to a reduced exposure tobacco product or a reduced risk tobacco product covered by section 913.

''(b) APPLICABILITY.—This chapter shall apply to—

''(1) all tobacco products subject to part 897 of title 21, Code of Federal Regulations and any successor regulations; and

''(2) any other tobacco product that the Secretary by regulation determines to be subject to this chapter.

''(c) SCOPE.—

''(1) OTHER PRODUCTS.—Nothing in this chapter affects the authority of the Secretary over, or the regulation of, products under this Act that are not tobacco products under chapter V or any other chapter of this Act.

''(2) LEAF TOBACCO.—

''(A) DEFINITION OF CONTROLLED BY.—In this paragraph, the term 'controlled by' means, when used with respect to a tobacco product manufacturer, that the tobacco product manufacturer—

''(i) is a member of the same controlled group of corporations (as that term is used in section 52(a) of the Internal Revenue Code of 1986); or

''(ii) is under common control (within the meaning of the regulations promulgated under section 52(b) of that Code).

"(B) NONAPPLICABILITY.—This chapter shall not apply to—

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

"(ii) a producer of leaf tobacco, including a tobacco grower, tobacco warehouse, and tobacco grower cooperative.

"(C) ENTRY ONTO FARMS.—An officer or employee of the Food and Drug Administration shall not have any authority to enter onto a farm owned by a producer of leaf tobacco without the written consent of the producer.

"(D) DUAL CAPACITY AS LEAF TOBACCO PRODUCER AND MANUFACTURER.—Notwithstanding any other provision of this subparagraph, if a producer of leaf tobacco is also a tobacco product manufacturer or is controlled by a tobacco product manufacturer, the producer shall be subject to this chapter in the producer's capacity as a manufacturer.

"(E) REGULATIONS ON LEAF TOBACCO PRODUCTION.—Nothing in this chapter grants the Secretary authority to promulgate regulations on any matter that involves the production of leaf tobacco or a producer of leaf to-

bacco, other than activities by a manufacturer affecting production.

"SEC. 903. ADULTERATED TOBACCO PRODUCTS.

"(a) CONTAMINATED SUBSTANCES.—A tobacco product shall be deemed adulterated if the tobacco product—

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

"(2) is otherwise contaminated by any poisonous or deleterious substance that may render the tobacco product more injurious to health.

"(b) UNSANITARY CONDITIONS.—A tobacco product shall be deemed adulterated if the tobacco product has been prepared, packed, or held under unsanitary conditions under which the tobacco product may have been contaminated with filth, or under which the tobacco product may have been rendered more injurious to health.

"(c) CONTAINERS.—A tobacco product shall be deemed adulterated if the container of the tobacco product is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents more injurious to health.

"(d) PERFORMANCE STANDARDS.—A tobacco product shall be deemed adulterated if the tobacco product is, purports to be, or is represented as a tobacco product that is subject to a performance standard established under

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

''(e) PREMARKET APPROVAL.—A tobacco product shall be deemed adulterated if the tobacco product—

''(1) is required by section 911(b) to have premarket approval;

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

''(3) does not have an approved application in effect.

''(f) MANUFACTURING PRACTICES.—A tobacco product shall be deemed adulterated if the methods used in, or the facilities or controls used for, the manufacture, packing, or storage of the tobacco product are not in conformity with applicable requirements under section 907(e)(1) or an applicable condition prescribed by an order under section 907(e)(2).

''(g) INVESTIGATIONAL USE.—A tobacco product shall be deemed adulterated if—

''(1) the tobacco product is a tobacco product for which an exemption has been granted under section 907(f) for investigational use; and

''(2) the person that is granted the exemption or any investigator that uses the tobacco product under the exemption fails to comply with a requirement prescribed by or under section 907(f).

''(h) IMPORTED CIGARETTES.—A tobacco product shall be deemed adulterated if the tobacco product is imported, or offered for import, into the United States in violation of section 5754 of the Internal Revenue Code of 1986 or title VIII of the Tariff Act of 1930 (19 U.S.C. 1681 et seq.).

''SEC. 904. MISBRANDED TOBACCO PRODUCTS.

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

''(b) MISLABELED PACKAGES.—

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

''(A) the name and place of business of the tobacco product manufacturer, packer, or distributor; and

''(B) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.

''(2) ADMINISTRATION.—In carrying out paragraph (1)(B), the Secretary shall (by regulation)—

''(A) permit reasonable variations; and

''(B) establish exemptions for small packages.

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

''(d) ESTABLISHED NAME.—A tobacco product shall be deemed misbranded if—

''(1) the tobacco product has an established name; and

''(2) the label of the tobacco product does not bear, to the exclusion of any other nonproprietary name, the established name of the tobacco product prominently printed in type, as required by the Secretary by regulation.

''(e) DIRECTIONS.—A tobacco product shall be deemed misbranded if the Secretary has promulgated regulations requiring that the labeling of the tobacco product bear adequate directions for use, or adequate warnings against use by children, that are necessary for the protec-

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

''(f) PROCESSING.—A tobacco product shall be deemed misbranded if—

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

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

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

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

''(g) FALSE ADVERTISING.—In the case of any tobacco product distributed or offered for sale in any State, a tobacco product shall be deemed misbranded if—

''(1) the advertising of the tobacco product is false or misleading; or

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

''(h) REQUIRED STATEMENTS.—In the case of any tobacco product distributed or offered for sale in any State, a tobacco product shall be deemed misbranded unless the manufacturer, packer, or distributor of the tobacco product includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to the tobacco product—

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

''(2) a brief description of—

''(A) the uses of the tobacco product and relevant warnings, precautions, side effects, and contraindications; and

''(B) in the case of specific tobacco products made subject to a finding by the Secretary after notice and opportunity for comment that the action is necessary to protect the public health, a full description of the components of the tobacco product or the formula showing quantitatively each ingredient of the tobacco product, to the extent required in regulations which shall be promulgated by the Secretary after an opportunity for a hearing.

''(i) MANDATORY DISCLAIMERS.—In the case of any tobacco product distributed or offered for sale in any State, a tobacco product shall be deemed misbranded unless the manufacturer, packer, or distributor of the tobacco product includes in all advertisements the information required by section 917(c).

''(j) PERFORMANCE STANDARDS.—A tobacco product shall be deemed misbranded if the tobacco product is a tobacco product subject to a performance standard established under section 908, unless the tobacco product bears such labeling as may be prescribed in the performance standard.

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

''(1) to comply with any requirement prescribed under section 905 or 909; or

''(2) to furnish any material or information required by or under section 910.

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

''(1) the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1331 et seq.); or

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

''(m) PRIOR APPROVAL OF STATEMENTS ON LABEL.—

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

''(2) ADVERTISEMENT CONTENT.—In the case of matters specified in this section or covered by regulations promulgated under this section—

''(A) no regulation promulgated under this subsection may require prior approval by the Secretary of the content of any advertisement; and

''(B) no advertisement of a tobacco product, published after the date of enactment of the Tobacco Livelihood and Economic Assistance for Our Farmers Act of 2002, shall be subject to sections 12 through 15 of the Federal Trade Commission Act (15 U.S.C. 52 through 55).

''(3) LABELING.—This subsection does not apply to any printed matter that the Secretary determines to be labeling (as defined in section 201).

"SEC. 905. SUBMISSION OF HEALTH INFORMATION TO THE SECRETARY.

''(a) REQUIREMENT.—Not later than 180 days after the date of enactment of the Tobacco Livelihood and Economic Assistance for Our Farmers Act of 2002, each tobacco product manufacturer or importer of tobacco products, or their agents, shall submit to the Secretary the following information:

''(1) A listing of all tobacco ingredients, substances, and compounds that are, as of that date, added by the manufacturer to the tobacco, paper, filter, or other component of each tobacco product by brand and by quantity in each brand and subbrand.

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

''(3) All documents (including underlying scientific information) relating to research activities and research findings conducted, supported, or possessed by the manufacturer (or agents) on the health, behavioral, or physiological effects of tobacco products, their constituents, ingredients, and compo-

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

''(4) All documents (including underlying scientific information) relating to research activities, and research findings, conducted, supported, or possessed by the manufacturer (or agents) that relate to the issue of whether a reduction in risk to health from tobacco products can occur on the employment of technology available or known to the manufacturer.

''(5) All documents (including underlying scientific information) relating to marketing research involving the use of tobacco products.

''(b) ANNUAL SUBMISSION OF INFORMATION.—A tobacco product manufacturer or importer that is required to submit information under subsection (a) shall update the information on an annual basis in accordance with a schedule determined by the Secretary.

''(c) TIME FOR SUBMISSION.—

''(1) NEW PRODUCTS.—At least 90 days prior to the delivery for introduction into interstate commerce of a tobacco product not on the market on the date of enactment of the Tobacco Livelihood and Economic Assistance for Our Farmers Act of 2002—

''(A) the manufacturer of the tobacco product shall provide the information required under subsection (a); and

''(B) the tobacco product shall be subject to the annual submission requirement under subsection (b).

''(2) MODIFICATION OF EXISTING PRODUCTS.—Not later than 60 days after the date of an action described in this paragraph, a tobacco product manufacturer shall advise the Secretary of the action in writing, and reference the action in submissions made under subsection (b), if the manufacturer—

''(A) adds to the tobacco product a new tobacco additive;

''(B) increases or decreases the quantity of an existing tobacco additive or the nicotine content, delivery, or form; or

''(C) eliminates a tobacco additive from the tobacco product.

''SEC. 906. ANNUAL REGISTRATION.

''(a) DEFINITIONS.—In this section:

''(1) MANUFACTURE, PREPARATION, COMPOUNDING, OR PROCESSING.—The term 'manufacture, preparation, compounding, or processing' includes (consistent with section 902(c)(2)) repack-

aging or otherwise changing the container, wrapper, or labeling of any tobacco product package in furtherance of the distribution of the tobacco product from the original place of manufacture of the tobacco product to the place of business of the person that makes final delivery or sale to the ultimate consumer or user.

''(2) NAME.—The term 'name' includes—

''(A) in the case of a partnership, the name of each partner; and

''(B) in the case of a corporation—

''(i) the name of each corporate officer and director; and

''(ii) the State of incorporation.

''(b) REGISTRATION BY OWNERS AND OPERATORS.—On or before December 31 of each year, each person that owns or operates any establishment in any State engaged in the manufacture, preparation, compounding, or processing of 1 or more tobacco products shall register with the Secretary the name, places of business, and all such establishments of the person.

''(c) REGISTRATION OF NEW OWNERS AND OPERATORS.—On first engaging in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products in an establishment owned or operated

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

''(d) REGISTRATION OF ADDED ESTABLISHMENTS.—Each person required to register under subsection (b) or (c) shall immediately register with the Secretary any additional establishment that person owns or operates in any State and at which the person begins the manufacture, preparation, compounding, or processing of 1 or more tobacco products.

''(e) UNIFORM PRODUCT IDENTIFICATION SYSTEM.—The Secretary may by regulation—

''(1) prescribe a uniform system for the identification of tobacco products; and

''(2) require that persons that are required to list the tobacco products under subsection (i) shall list the tobacco products in accordance with the system.

''(f) PUBLIC ACCESS TO REGISTRATION INFORMATION.—On request, the Secretary shall make available for inspection any registration filed under this section.

''(g) BIENNIAL INSPECTION OF REGISTERED ESTABLISHMENTS.—

''(1) IN GENERAL.—Each establishment in any State registered with the Secretary under this section shall be subject to inspection under section 704.

''(2) ADMINISTRATION.—Each such establishment engaged in the manufacture, compounding, or processing of a tobacco product or tobacco products shall be so inspected by 1 or more officers or employees duly designated by the Secretary—

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

''(B) at least once in every successive 2-year period thereafter.

''(h) FOREIGN ESTABLISHMENTS.—

''(1) REGISTRATION.—Any establishment within any foreign country engaged in the manufacture of a tobacco product that is imported, or offered for import, into the United States shall register with the Secretary the name and place of business of the establishment and the name of the United States agent for the establishment.

''(2) REGISTRATION INFORMATION.—Any establishment required to be registered under paragraph (1) shall—

''(A) provide to the Secretary the information required by subsection (i); and

''(B) comply with any other requirement of this section that is applicable to domestic manufacturers.

''(3) INSPECTIONS.—Any establishment required to be registered under paragraph (1) shall—

''(A) be subject to inspection under section 704; and

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

''(i) the 2-year period beginning on the date of the registration of the establishment under paragraph (1); and

''(ii) each 2-year period thereafter.

''(4) COOPERATIVE AGREEMENTS.—The Secretary may enter into cooperative agreements with officials of foreign countries to ensure that adequate and effective means are available for purposes of determining, from time to time, whether tobacco products manufactured by an establishment required to be registered under paragraph (1), if imported or offered for import into the United States, shall be refused admission under section 801(a).

''(i) REGISTRATION INFORMATION.—

''(1) PRODUCT LIST.—Each person that registers with the Secretary under subsection (b), (c), or (d) shall, at the time of registration under any of those subsections, file with the Secretary a list of all tobacco products that—

''(A) are being manufactured, prepared, compounded, or processed by the person for commercial distribution; and

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

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

''(A) in the case of a tobacco product contained in the applicable list with respect to which a performance standard has been established under section 908 or that is subject to section 911—

''(i) a reference to the authority for the marketing of the tobacco product; and

''(ii) a copy of all labeling for the tobacco product;

''(B) in the case of any other tobacco product contained in an applicable list—

''(i) a copy of all consumer information and other labeling for the tobacco product;

''(ii) a representative sampling of advertisements for the tobacco product; and

''(iii) on request made by the Secretary for good cause, a copy of all advertisements for a particular tobacco product; and

''(C) if the registrant filing a list has determined that a tobacco product contained in the list is not subject to a performance standard established under section 908, a brief statement of the basis on which the registrant made the determination, if the Secretary requests such a statement with respect to the particular tobacco product.

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

''(A)(i) A list of each tobacco product introduced by the registrant for commercial distribution that has not been included in any list previously filed by the person with the Secretary under this subparagraph or paragraph (1).

''(ii) A list under this subparagraph shall list a tobacco product by the established name of the tobacco product and shall be accompanied by the other information required by paragraphs (1) and (2).

''(B) If, since the date the registrant last made a report under this paragraph, the person has discontinued the manufacture, preparation, compounding, or processing for commercial distribution of a tobacco product included in a list filed under subparagraph (A) or paragraph (1)—

''(i) notice of the discontinuance;

''(ii) the date of the discontinuance; and

''(iii) the identity of the established name of the tobacco product.

''(C) If, since the date the registrant reported under subparagraph (B), a notice of dis-

continuance that person has resumed the manufacture, preparation, compounding, or processing for commercial distribution of the tobacco product with respect to which a notice of discontinuance was reported, notice of the resumption, the date of the resumption, the identity of the tobacco product by established name, and other information required by paragraphs (1) and (2), unless the registrant has previously reported the resumption to the Secretary under this subparagraph.

''(D) Any material change in any information previously submitted under this paragraph or paragraph (1).

''(j) REPORT PRECEDING INTRODUCTION OF CERTAIN SUBSTANTIALLY EQUIVALENT PRODUCTS INTO INTERSTATE COMMERCE.—Each person that is required to register under this section and that proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a tobacco product intended for human use that was not commercially marketed in the United States as of the date of enactment of the Tobacco Livelihood and Economic Assistance for Our Farmers Act of 2002 (as defined by the Secretary by regulation) shall, at least 90 days before making the

introduction or delivery, report to the Secretary (in such form and manner as the Secretary shall by regulation prescribe)—

''(1) the basis for the person's determination that the tobacco product is substantially equivalent (as defined in section 911) to a tobacco product commercially marketed in the United States as of the date of enactment of the Tobacco Livelihood and Economic Assistance for Our Farmers Act of 2002 that is in compliance with the requirements of this Act; and

''(2) action taken by the person to comply with the requirements under section 908 that are applicable to the tobacco product.

''SEC. 907. GENERAL PROVISIONS CONCERNING CONTROL OF TOBACCO PRODUCTS.

''(a) IN GENERAL.—

''(1) APPLICABLE REQUIREMENTS.—Any requirement established by or under section 903, 904, 906, or 910 that is applicable to a tobacco product shall apply to the tobacco product until the applicability of the requirement to the tobacco product has been changed by action taken under section 908, section 911, or subsection (d).

''(2) INAPPLICABLE REQUIREMENTS.—Any requirement established by or under section 903, 904, 906, or 910 that is inconsistent with a requirement imposed on the tobacco product under section 908, section 911, or subsection (d) shall not apply to the tobacco product.

''(b) INFORMATION ON PUBLIC ACCESS AND COMMENT.—

''(1) APPLICATION.—This subsection applies to—

''(A) each notice of proposed rulemaking under this section or section 908, 909, 910, or 911;

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

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

''(2) INFORMATION.—Each notice and publication described in paragraph (1) shall set forth—

''(A) the manner in which interested persons may examine data and other information on which the notice or findings are based; and

''(B) the period within which interested persons may present their comments on the notice or findings (including the need for the notice or findings) orally or in writing, which period shall be not less than 60 days, and not more than 90 days, unless the period is extended by the Secretary by a notice published in the Federal Register stating good cause for the extension.

''(c) LIMITED CONFIDENTIALITY OF INFORMATION.—

''(1) IN GENERAL.—Except as provided in paragraph (2), any information reported to or otherwise obtained by the Secretary or the Secretary's representative under section 704, 905, 906, 908, 909, 910, 911, or 913, or under subsection (e) or (f), that is exempt from disclosure under section 552(a) of title 5, United States Code, by reason of section 552(b)(4) of that title shall be considered confidential and shall not be disclosed.

''(2) EXCEPTIONS.—Information described in paragraph (1) may be disclosed—

''(A) to other officers or employees that are carrying out this chapter; or

''(B) when relevant in any proceeding under this chapter.

''(d) RESTRICTIONS.—

''(1) IN GENERAL.—The Secretary may by regulation require that a tobacco product be restricted to sale or distribution on such conditions (including restrictions on the access to, and the advertising and promotion of, the tobacco product) as the Secretary may prescribe in the regulation if the Secretary determines that the regulation would be appropriate for the prevention of, or decrease in, the use of tobacco products by children under the age at which tobacco products may be legally purchased.

''(2) PRESCRIPTIONS.—No condition under paragraph (1) may require that the sale or distribution of a tobacco product be limited to the written or oral authorization of a practitioner licensed by law to prescribe medical products.

''(3) LABELS.—The label of a tobacco product shall bear such appropriate statements of the restrictions required by a regulation under subsection (a) as the Secretary may by regulation prescribe.

''(4) FACE-TO-FACE TRANSACTIONS.—No restriction under paragraph (1) may prohibit the sale

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

''(e) GOOD MANUFACTURING PRACTICES.—

''(1) METHODS, FACILITIES, AND CONTROLS.—

''(A) IN GENERAL.—The Secretary may, in accordance with subparagraph (B), prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, pre-production design validation (including a process to assess the performance of a tobacco product), and packing, and storage of a tobacco product conform to current good manufacturing practice for an agricultural product, as prescribed in the regulations, to ensure that the public health is protected and that the tobacco product is in compliance with this chapter.

''(B) ADMINISTRATION.—The Secretary shall—

''(i) before promulgating any regulation under subparagraph (A), afford an advisory committee an opportunity to submit recommendations with respect to the regulation proposed to be promulgated;

''(ii) before promulgating any regulation under subparagraph (A), afford opportunity for an oral hearing;

''(iii) provide the advisory committee a reasonable time to make the recommendation of the advisory committee with respect to a proposed regulation under subparagraph (A); and

''(iv) in establishing the effective date of a regulation promulgated under this subsection—

''(I) take into account the differences in—

''(aa) the manner in which the different types of tobacco products have historically been produced;

''(bb) the financial resources of the different tobacco product manufacturers; and

''(cc) the state of their existing manufacturing facilities; and

''(II) provide for a reasonable period of time for the manufacturers to

conform to good manufacturing practices.

''(2) EXEMPTIONS; VARIANCES.—

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

''(B) CONTENT.—The petition shall be submitted to the Secretary in such form and manner as the Secretary shall prescribe and shall—

''(i) in the case of a petition for an exemption from a requirement, set forth the basis for the petitioner's determination that compliance with the requirement is not required to ensure that the tobacco product will be in compliance with this chapter;

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

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

"(iii) contain such other information as the Secretary shall prescribe.

"(C) ADVISORY COMMITTEE.—

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

"(ii) RECOMMENDATIONS.—The advisory committee shall report the recommendations of the advisory committee to the Secretary with respect to a petition referred to the advisory committee within 60 days after the date of the petition's referral.

"(iii) DEADLINE FOR APPROVAL OR DENIAL.—The Secretary shall by order either approve or deny the petition not later than 60 days after the later of—

"(I) the date on which the petition was submitted to the Secretary under subparagraph (A); or

"(II) the day after the date on which the petition was referred to an advisory committee.

''(D) GROUNDS FOR APPROVAL.—The Secretary may approve—

''(i) a petition for an exemption for a tobacco product from a requirement if the Secretary determines that compliance with the requirement is not required to ensure that the tobacco product will be in compliance with this chapter; and

''(ii) a petition for a variance for a tobacco product from a requirement if the Secretary determines that the methods to be used in, and the facilities and controls to be used for, the manufacture, packing, and storage of the tobacco product in lieu of the methods, controls, and facilities prescribed by the requirement are sufficient to ensure that the tobacco product will be in compliance with this chapter.

''(E) CONDITIONS.—An order of the Secretary approving a petition for a variance shall prescribe such conditions respecting the methods used in, and the facilities and controls used for, the manufacture, packing, and storage of the tobacco product to be granted the variance under the petition as may be necessary to en-

sure that the tobacco product will be in compliance with this chapter.

''(F) HEARING.—After the issuance of an order under subparagraph (C) with respect to a petition, the petitioner shall have an opportunity for an informal hearing on the order.

''(f) EXEMPTION FOR INVESTIGATIONAL USE.—The Secretary may exempt tobacco products intended for investigational use from this chapter under such conditions as the Secretary may prescribe by regulation.

''(g) RESEARCH AND DEVELOPMENT.—The Secretary may enter into contracts for research, testing, and demonstrations with respect to tobacco products, and may obtain tobacco products for research, testing, and demonstration purposes, without regard to section 3324(a) and (b) of title 31, United States Code, and section 5 of title 41, United States Code.

''SEC. 908. PERFORMANCE STANDARDS.

''(a) IN GENERAL.—

''(1) FINDING.—

''(A) REQUIREMENT.—The Secretary may adopt a performance standard for a tobacco product if the Secretary finds that the performance standard is appropriate for the protection of the public health.

''(B) BASIS.—The finding shall be determined with respect to the risks and benefits to the population as a whole, including users and non-users of the tobacco product, and taking into account—

''(i) the increased or decreased likelihood that existing users of tobacco products will stop using tobacco products; and

''(ii) the increased or decreased likelihood that those individuals who do not use tobacco products will start using tobacco products.

''(2) CONTENT OF PERFORMANCE STANDARDS.—A performance standard established under this section for a tobacco product—

''(A) shall include provisions to provide performance that is appropriate for the protection of the public health, including provisions, where appropriate—

''(i) for the reduction of nicotine yields of the tobacco product;

''(ii) for the reduction or elimination of other harmful constituents or harmful components of the tobacco product; or

"(iii) relating to any other requirement under subparagraph (B);

"(B) shall, if necessary for the protection of public health, include—

"(i) provisions respecting the construction, components, ingredients, and properties of the tobacco product;

"(ii) provisions for the testing (on a sample basis or, if necessary, on an individual basis) of the tobacco product;

"(iii) provisions for the measurement of the performance characteristics of the tobacco product; and

"(iv) provisions requiring that the results of each or of certain of the tests of the tobacco product required to be made under clause (ii) demonstrate that the tobacco product is in conformity with the portions of the standard for which the test or tests were required; and

"(C) shall not render the tobacco product unacceptable for adult consumption.

"(3) PERIODIC REEVALUATION OF PERFORMANCE STANDARDS.—

''(A) IN GENERAL.—The Secretary shall provide for periodic evaluation of performance standards established under this section to determine whether the standards should be changed to reflect new medical, scientific, or other technological data.

''(B) TESTER.—The Secretary may provide for testing under paragraph (2) by any person.

''(4) INVOLVEMENT OF OTHER AGENCIES; INFORMED PERSONS.—In carrying out duties under this section, the Secretary shall, to the maximum extent practicable—

''(A) use available personnel, facilities, and other technical support of other Federal agencies;

''(B) consult with other Federal agencies concerned with standard-setting and other nationally or internationally recognized standard-setting entities; and

''(C) invite appropriate participation, through joint or other conferences, workshops, or other means, by informed persons representative of scientific, professional, industry, or con-

sumer organizations who, in the Secretary's judgment, can make a significant contribution.

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

''(1) NOTICE.—

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

''(B) ESTABLISHMENT OR AMENDMENT.—A notice of proposed rulemaking for the establishment or amendment of a performance standard for a tobacco product shall—

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

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

''(iii) invite interested persons to submit an existing performance standard for the tobacco product, including a draft or

proposed performance standard, for consideration by the Secretary.

''(C) REVOCATION.—A notice of proposed rulemaking for the revocation of a performance standard shall set forth a finding with supporting justification that the performance standard is no longer necessary for the protection of the public health.

''(D) ADMINISTRATION.—The Secretary shall—

''(i) consider all information submitted in connection with a proposed standard, including information concerning the countervailing effects of the performance standard on the health of adolescent tobacco users, adult tobacco users, or nontobacco users, such as the creation of a significant demand for contraband or other tobacco products that do not meet the requirements of this chapter and the significance of the demand; and

''(ii) issue the standard, if the Secretary determines that the standard would be appropriate for the protection of the public health.

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

''(2) PROMULGATION.—

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

''(i) promulgate a regulation establishing a performance standard and publish in the Federal Register findings on the matters referred to in paragraph (1); or

''(ii) publish a notice terminating the proceeding for the development of the standard, together with the reasons for the termination.

''(B) EFFECTIVE DATE.—

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

or more dates on which the standard takes effect.

''(ii) EARLIEST EFFECTIVE DATE.—No such regulation may take effect before the date that is 1 year after the date of the publication of the regulation unless the Secretary determines that an earlier effective date is necessary for the protection of the public health.

''(iii) BASIS.—The 1 or more effective dates shall be established so as to minimize, consistent with the public health, economic loss to, and disruption or dislocation of, domestic and international trade.

''(3) POWERS RESERVED TO CONGRESS.—Congress expressly reserves the power to make a decision establishing a performance standard—

''(A) eliminating all cigarettes, all smokeless tobacco products, or any similar class of tobacco products; or

''(B) requiring the reduction of nicotine yields of a tobacco product to zero.

''(4) AMENDMENT; REVOCATION.—

''(A) IN GENERAL.—On the Secretary's own initiative or on petition of an interested

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

''(B) INTERIM EFFECTIVENESS.—The Secretary may declare a proposed amendment of a performance standard to be effective on and after the publication of the amendment in the Federal Register and until the effective date of any final action taken on the amendment, if the Secretary determines that making it so effective is in the public interest.

''(5) REFERENCE TO ADVISORY COMMITTEE.—

''(A) IN GENERAL.—In the case of a proposed regulation for the establishment, amendment, or revocation of a performance standard, the Secretary—

''(i) on the Secretary's own initiative, may refer to an advisory committee, for a report and recommendation, any matter involved in the proposed regulation that requires the exercise of scientific judgment; and

''(ii) on the request of an interested person that demonstrates good cause for

referral and that is made before the expiration of the period for submission of comments on a proposed regulation, shall refer to an advisory committee, for a report and recommendation, any matter described in clause (i).

''(B) INFORMATION.—If a proposed regulation is referred to the advisory committee under this paragraph, the Secretary shall provide the advisory committee with the data and information on which the proposed regulation is based.

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

''(i) conduct an independent study of the data and information furnished to the advisory committee by the Secretary and other data and information before the advisory committee; and

''(ii) submit to the Secretary a report and recommendation with respect to the proposed regulation, together with all underlying data and information and a state-

ment of the reason or basis for the recommendation.

''(D) COPY.—A copy of the report and recommendation shall be made public by the Secretary.

''SEC. 909. NOTIFICATION AND OTHER REMEDIES.

''(a) NOTIFICATION.—

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

''(A) a tobacco product that is introduced or delivered for introduction into interstate commerce for commercial distribution presents a risk of substantial harm to the public health that exceeds the risks posed by similar tobacco products marketed before the date of enactment of the Tobacco Livelihood and Economic Assistance for Our Farmers Act of 2002; and

''(B)(i) notification under this subsection is necessary to eliminate the unreasonable risk of the harm; and

''(ii) no more practicable means is available under the provisions of this chapter (other than this section) to eliminate the risk.

''(2) ORDER.—If the Secretary makes a determination described in paragraph (2), the Secretary may issue such order as may be necessary to ensure that adequate notification is provided in an appropriate form, by the persons and means best suited under the circumstances involved, to all persons that should properly receive the notification in order to eliminate the risk.

''(3) MEANS.—The Secretary may order notification by any appropriate means, including public service announcements.

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

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

''(c) RECALL AUTHORITY.—

''(1) IN GENERAL.—If the Secretary finds that there is a reasonable probability that a tobacco product contains a manufacturing or other defect not ordinarily contained in tobacco products on the market that would cause serious, adverse health con-

sequences or death, the Secretary shall issue an order requiring the appropriate person (including the manufacturers, importers, distributors, or retailers of the tobacco product) to immediately cease distribution of the tobacco product.

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

''(3) VACATION OF ORDER.—If, after providing an opportunity for such a hearing, the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

''(4) AMENDMENT OF ORDER TO REQUIRE RECALL.—

''(A) IN GENERAL.—Except as provided in subparagraph (C), if, after providing an opportunity for an informal hearing under paragraph (1), the Secretary determines that the order should be amended to include a recall of the tobacco product with respect to which the order

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

''(B) TIMETABLE.—The Secretary shall specify a timetable during which the tobacco product recall will occur and shall require periodic reports to the Secretary describing the progress of the recall.

''(C) CONTENTS.—An amended order under subparagraph (A)—

''(i) shall not include recall of a tobacco product from individuals; and

''(ii) shall provide for notice to persons subject to the risks associated with the use of the tobacco product.

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

''(E) NOTIFICATION BY SECRETARY.—If a significant number of persons described in subparagraph (D) cannot be identified, the Secretary shall notify the persons under section 705(b).

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

"SEC. 910. RECORDS AND REPORTS ON TOBACCO PRODUCTS.

''(a) IN GENERAL.—Each person that is a tobacco product manufacturer or importer of a tobacco product shall establish and maintain such records, make such reports, and provide such information as the Secretary may by regulation reasonably require to ensure that the tobacco product is not adulterated or misbranded and to otherwise protect public health.

''(b) ADMINISTRATION.—Regulations promulgated under subsection (a)—

''(1) may require a tobacco product manufacturer or importer to report to the Secretary in any case in which the manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that 1 of the marketed tobacco products of the manufacturer or importer may have caused or contributed to a serious, unexpected adverse experience associated with the use of the product or any significant increase in the frequency of a serious, expected adverse product experience;

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

''(3) shall not impose requirements that are unduly burdensome to a tobacco product manufacturer or importer, taking into account the cost of complying with the requirements and the need for the protection of the public health and the implementation of this chapter;

''(4) when prescribing the procedure for making requests for reports or information, shall require that each request made under the regulations for submission of a report or information to the Secretary state the reason or purpose for the request and identify, to the maximum extent practicable, the report or information;

''(5) when requiring submission of a report or information to the Secretary, shall state the reason or purpose for the submission of the report or information and identify to the maximum extent practicable the report or information; and

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

''(A) to protect the medical welfare of an individual;

''(B) to determine risks to public health of a tobacco product; or

''(C) to verify a record, report, or information submitted under this chapter.

''(c) MEDICAL ETHICS AND PATIENT INTERESTS.—

''(1) IN GENERAL.—In promulgating regulations under this section, the Secretary shall have due regard for the professional ethics of the medical profession and the interests of patients.

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

''(d) REPORTS OF REMOVALS AND CORRECTIONS.—

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

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

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

''(2) RECORD.—A tobacco product manufacturer or importer of a tobacco product that undertakes a corrective action or removal from the market of a tobacco product that is not required to be reported under this subsection shall keep a record of the correction or removal.

''(3) PREVIOUS REPORT.—No report of the corrective action or removal of a tobacco product may be required under paragraph (1) if a report of the corrective action or removal is required and has been submitted under subsection (a).

''SEC. 911. PREMARKET REVIEW OF CERTAIN TOBACCO PRODUCTS.

''(a) DEFINITION OF SUBSTANTIALLY EQUIVALENT.—

''(1) IN GENERAL.—In this section and section 906(j), the term 'substantially equivalent' or 'substantial equivalence' mean, with respect to the tobacco product being compared to the predicate to-

bacco product, that the Secretary by order has determined that—

"(A) the tobacco product has the same characteristics as the predicate tobacco product; or

"(B) the tobacco product has different characteristics, and the information for the tobacco product submitted contains information, including clinical data if considered necessary by the Secretary, that demonstrates that it is not appropriate to regulate the product under the applicable section because the product could not reasonably be expected to increase the health risks to consumers compared to a conventional tobacco product that is commercially marketed in the United States and that is in compliance with the requirements of this Act.

"(2) DEFINITION OF CHARACTERISTICS.—In subparagraph (A), the term 'characteristics' means the materials, ingredients, design, composition, heating source, or other features of a tobacco product.

"(3) INAPPLICABLE TOBACCO PRODUCTS.—A tobacco product may not be found to be substantially equivalent to a predicate tobacco product that has been removed from the market at the initiative

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

''(b) REQUIREMENT FOR PREMARKET APPROVAL.—

''(1) IN GENERAL.—Approval under this section of an application for premarket approval for any tobacco product, other than a reduced exposure tobacco product or a reduced risk tobacco product under section 913, that is not commercially marketed in the United States as of the date of enactment of the Tobacco Livelihood and Economic Assistance for Our Farmers Act of 2002 shall be required unless—

''(A) the manufacturer has submitted a report under section 906(j); and

''(B) the Secretary has not suspended the distribution of the product under this paragraph.

''(2) SUSPENSION OF DISTRIBUTION.—Not later than 90 days after the submission of a report under section 906(j), the Secretary may by order suspend the distribution of the tobacco product that is the subject of the report if the Secretary determines that there is a reasonable likelihood that the tobacco product is not substantially equivalent to a tobacco product that is—

''(A) commercially marketed in the United States as of the date of the Tobacco Livelihood and Economic Assistance for Our Farmers Act of 2002; and

''(B) in compliance with the requirements of this Act.

''(3) FAILURE TO ISSUE ORDER.—If the Secretary fails to issue an order within the 90-day period described in paragraph (2), the tobacco product that is the subject of the report shall be deemed to be substantially equivalent to a predicate tobacco product.

''(4) FINAL AGENCY ACTION.—

''(A) IN GENERAL.—Subject to subparagraph (B), the issuance of an order under this paragraph shall constitute final agency action for purposes of section 702 of title 5, United States Code.

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

''(c) HEALTH INFORMATION.—

''(1) IN GENERAL.—As part of a submission under section 906(j) with respect to a tobacco product, the person required to file a premarket notifica-

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

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

''(A) contain detailed information regarding data concerning adverse health effects; and

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

''(3) REQUIREMENTS.—The communication that the product is a reduced exposure tobacco product or a reduced risk tobacco product shall comply with requirements prescribed by the Secretary relating to the communication.

''(4) PRIOR APPROVAL.—The Secretary may require prior approval of the communication in each case in accordance with section 913.

''(d) APPLICATION.—

''(1) CONTENTS.—An application for premarket approval shall contain—

''(A) full reports of all information, published or known to, or that should reasonably be known to, the applicant, concerning investigations that have been made to show the health risks of the tobacco product and whether the tobacco product presents greater risk than other tobacco products;

''(B) a full statement of the components, ingredients, and properties, and of the principle or principles of operation, of the tobacco product;

''(C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, the tobacco product;

''(D) an identifying reference to any performance standard under section 908 that would be applicable to any aspect of the tobacco product, and either adequate information to show that the aspect of the tobacco product fully meets the performance standard or adequate information to justify any deviation from the standard;

''(E) such samples of the tobacco product and of components of the tobacco product as the Secretary may reasonably require;

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

''(G) such other information relevant to the subject matter of the application as the Secretary may require.

''(2) REFERENCE TO ADVISORY COMMITTEE.—On receipt of an application meeting the requirements set forth in paragraph (1), the Secretary—

''(A) on the Secretary's own initiative, may refer the application to an advisory committee for submission (within such period as the Secretary may establish) of a report and recommendation respecting approval of the application, together with all underlying data and the reasons or basis for the recommendation; or

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

''(e) ACTION ON APPLICATION.—

''(1) DEADLINE.—

''(A) IN GENERAL.—As promptly as practicable, but not later than 180 days, after the

date of receipt of an application under subsection (d), the Secretary, after considering the report and recommendation submitted under subsection (d)(2), shall—

"(i) issue an order approving the application, if the Secretary finds that none of the grounds for denying approval specified in paragraph (2) applies; or

"(ii) deny approval of the application, if the Secretary finds (and sets forth the basis for the finding as part of or accompanying the denial) that 1 or more grounds for denial specified in paragraph (2) apply.

"(B) SALES RESTRICTIONS.—An order approving an application for a tobacco product may require as a condition to the approval that the sale and distribution of the tobacco product be restricted, but only to the extent that the sale and distribution of a tobacco product may be restricted under a regulation promulgated under section 907(d).

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

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

"(A) there is a lack of a showing that permitting the tobacco product to be marketed would pose no greater risk to the public health than currently marketed tobacco products;

"(B) the methods used in, or the facilities or controls used for, the manufacture, processing, or packing of the tobacco product do not conform to the requirements of section 907(e);

"(C) based on a fair evaluation of all material facts, the proposed labeling is false or misleading; or

"(D)(i) the tobacco product is not shown to conform in all respects to a performance standard in effect under section 908, compliance with which is a condition to approval of the application; and

"(ii) there is a lack of adequate information to justify the deviation from the standard.

"(3) DENIAL INFORMATION.—Any denial of an application shall, to the extent that the Secretary determines to be practicable, be accompanied by a statement informing the applicant of the measures

required to make the application approvable (which measures may include further research by the applicant in accordance with 1 or more protocols prescribed by the Secretary).

''(4) BASIS FOR ACTION.—

''(A) IN GENERAL.—For purposes of paragraph (2)(A), whether permitting a tobacco product to be marketed would be appropriate for the protection of the public health shall, when appropriate, be determined on the basis of well-controlled investigations, which may include 1 or more clinical investigations by experts qualified by training and experience to evaluate the tobacco product.

''(B) EVIDENCE.—If the Secretary determines that there exists valid scientific evidence (other than evidence derived from investigations described in subparagraph (A)) that is sufficient to evaluate the tobacco product, the Secretary may authorize that the determination under paragraph (2)(A) be made on the basis of the evidence.

''(f) WITHDRAWAL AND TEMPORARY SUSPENSION.—

''(1) IN GENERAL.—The Secretary shall, on obtaining, where appropriate, advice on scientific mat-

ters from an advisory committee, and after due notice and opportunity for informal hearing to the holder of an approved application for a tobacco product, issue an order withdrawing approval of the application if the Secretary finds that—

''(A) the continued marketing of the tobacco product poses greater risks to the public health than other available products;

''(B) the application contained or was accompanied by a false or misleading statement of a material fact;

''(C) the applicant—

''(i) has failed to establish a system for maintaining records, or has repeatedly or deliberately failed to maintain records or to make reports, required by an applicable regulation under section 910;

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

''(iii) has not complied with the requirements of section 906;

''(D) on the basis of new information before the Secretary with respect to the tobacco product, evaluated, together with the evidence

before the Secretary when the application was approved, whether the methods used in, or the facilities and controls used for, the manufacture, processing, packing, or installation of the tobacco product do not conform with the requirements of section 907(e) and were not brought into conformity with the requirements within a reasonable time after receipt of written notice from the Secretary of nonconformity;

''(E) on the basis of new information before the Secretary, evaluated, together with the evidence before the Secretary when the application was approved, whether the labeling of the tobacco product, based on a fair evaluation of all material facts, is false or misleading and was not corrected within a reasonable time after receipt of written notice from the Secretary of the fact; or

''(F) on the basis of new information before the Secretary, evaluated, together with the evidence before the Secretary when the application was approved, whether the tobacco product is shown to conform in all respects to a performance standard that is in effect under section 908, compliance with which was a condi-

tion to approval of the application, and whether there is a lack of adequate information to justify the deviation from the standard.

''(2) APPEAL.—The holder of an application subject to an order issued under paragraph (1) withdrawing approval of the application may, by petition filed on or before the 30th day after the date on which the holder receives notice of the withdrawal, obtain review of the order in accordance with subsection (e).

''(3) TEMPORARY SUSPENSION.—

''(A) IN GENERAL.—If, after providing an opportunity for an informal hearing, the Secretary determines there is reasonable probability that the continuation of distribution of a tobacco product under an approved application would cause serious, adverse health consequences or death, that is greater than ordinarily caused by tobacco products on the market, the Secretary shall by order temporarily suspend the approval of the application approved under this section.

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

retary shall proceed expeditiously under paragraph (1) to withdraw the application.

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

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

''(2) by mailing the order by registered mail or certified mail addressed to the applicant at the applicant's last known address in the records of the Secretary.

''SEC. 912. JUDICIAL REVIEW.

''(a) DEFINITION OF RECORD.—In this section, the term 'record' means—

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

''(2) all information submitted to the Secretary with respect to—

''(A) a regulation or order;

''(B) proceedings of any panel or advisory committee with respect to the regulation or order; and

''(C) any hearing held with respect to the regulation or order; and

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

''(b) PETITION.—

''(1) IN GENERAL.—Not later than 30 days after the date of promulgation of a regulation under section 908 establishing, amending, or revoking a performance standard for a tobacco product, or a denial of an application for approval under section 911(c), any person adversely affected by the regulation or order may file a petition with the United States Court of Appeals for the District of Columbia, or for the circuit in which the person resides or has the person's principal place of business, for judicial review of the regulation or order.

''(2) COPY OF PETITION.—A copy of the petition shall be transmitted by the clerk of the court to the Secretary or other officer designated by the Secretary for that purpose.

''(3) RECORD OF PROCEEDINGS.—

''(A) FILING.—The Secretary shall file in the court the record of the proceedings on which the Secretary based the Secretary's regulation or order.

''(B) RATIONALE.—Each record or order shall contain a statement of the reasons for the issuance of the order and the basis, on the record, for the issuance of the order.

''(c) ADDITIONAL FINDINGS BY SECRETARY.—

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

''(A) applies to the court for leave to adduce additional data, views, or arguments respecting the regulation or order being reviewed; and

''(B) demonstrates to the satisfaction of the court that—

''(i) the additional data, views, or arguments are material; and

''(ii) there were reasonable grounds for the petitioner's failure to adduce the data, views, or arguments in the proceedings before the Secretary.

''(2) MODIFICATION.—The Secretary—

''(A) may modify the Secretary's findings, or make new findings by reason of the additional data, views, or arguments so taken; and

''(B) shall file with the court—

''(i) the modified or new findings;

''(ii) the Secretary's recommendation, if any, for the modification or setting aside of the regulation or order being reviewed; and

''(iii) the return of the additional data, views, or arguments.

''(d) STANDARD OF REVIEW.—

''(1) IN GENERAL.—On the filing of the petition under subsection (a) for judicial review of a regulation or order, the court shall have jurisdiction—

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

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

''(2) STANDARD.—A regulation or order described in paragraph (1) or (2) of subsection (a) shall not be affirmed if the regulation or order is found to be unsupported by substantial evidence on the record taken as a whole.

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

Supreme Court of the United States on certiorari or certification, as provided in section 1254 of title 28, United States Code.

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

''(g) REGULATIONS AND ORDERS MUST RECITE BASIS IN RECORD.—To facilitate judicial review under this section or under any other provision of law or a regulation or order issued under section 907, 908, 909, 910, 911, or 914, each such regulation or order shall contain a statement of—

''(1) the reasons for the issuance of the regulation or order; and

''(2) the basis, in the record of the proceedings held in connection with the issuance of the regulation or order, for the issuance of the regulation or order.

''SEC. 913. REDUCED EXPOSURE AND REDUCED RISK TOBACCO PRODUCTS.

''(a) DEFINITIONS OF REDUCED EXPOSURE AND REDUCED RISK TOBACCO PRODUCTS.—In this section, the terms 'reduced exposure tobacco product' and 'reduced risk tobacco product' mean a tobacco product designated by the Secretary as a reduced exposure tobacco product

or a reduced risk tobacco product, respectively, under subsection (b).

''(b) DESIGNATION.—

''(1) IN GENERAL.—A product may be designated by the Secretary as a reduced exposure tobacco product or a reduced risk tobacco product if the Secretary finds that the product is demonstrated to significantly reduce harm to individuals caused by a tobacco product in accordance with the standards provided under subparagraph (B), based on an application submitted by the manufacturer of the product (or other responsible person) that—

''(A)(i) demonstrates, through appropriate chemical and biological testing (including testing on animals and short-term human testing), that use of the product results in ingestion or inhalation of a substantially lower yield of toxic substances than use of another tobacco product in the same or different category as the subject tobacco product; or

''(ii) contains scientific evidence showing that use of the product results in a substantially lower potential risk to health in 1 or more specific respects than use of another tobacco product in the same or different category as the

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

''(B) if required by the Secretary, includes studies of the long-term health effects of the product.

''(2) CONSULTATION ON PROTOCOLS.—If studies are required under paragraph (1), the manufacturer may consult with the Secretary regarding protocols for conducting the studies.

''(3) BASIS FOR FINDING.—

''(A) REDUCED EXPOSURE TOBACCO PRODUCTS.—The Secretary shall designate a tobacco product as a reduced exposure tobacco product if the Secretary determines, based on such information as may be submitted by the applicant and other available information, that—

''(i) the product substantially reduces exposure to 1 or more tobacco toxicants; and

''(ii) independent scientific experts have found or predict, through clinical or epidemiological studies, a measurable reduction in the morbidity or mortality associated with the use of the product compared with the use of other tobacco prod-

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

''(B) REDUCED RISK TOBACCO PRODUCTS.—The Secretary shall designate a tobacco product as a reduced risk tobacco product only if the Secretary determines, based on such information as may be submitted by the applicant and other available information, that—

''(i) the product meets the criteria established under subparagraph (A); and

''(ii) there is sufficient evidence that the product can reasonably be expected to reduce the risk of 1 or more specific diseases or other adverse health effects, as compared with the use of other tobacco products (whether in the same or a different category) commercially marketed in the United States.

''(4) MARKETING REQUIREMENTS.—A tobacco product may be marketed and labeled as a reduced exposure tobacco product or a reduced risk tobacco product if the tobacco product—

''(A) has been designated by the Secretary under paragraph (1);

''(B) bears a label statement prescribed by the Secretary concerning the product's contribution to reducing harm to health; and

''(C) complies with—

''(i) requirements prescribed by the Secretary relating to marketing and advertising of the product to ensure that neither the marketing nor the labeling is false or misleading; and

''(ii) other provisions of this chapter, as prescribed by the Secretary.

''(c) REVOCATION OF DESIGNATION.—At any time after the date on which a tobacco product is designated as a reduced exposure tobacco product or a reduced risk tobacco product under this section, the Secretary may, after providing an opportunity for an informal hearing, revoke the designation if the Secretary determines, based on information not available at the time of the designation, that—

''(1) the finding made under subsection (b)(1) is no longer valid; or

''(2) the product is being marketed in violation of subsection (b)(3).

''(d) LIMITATION.—A tobacco product that is designated as a reduced exposure tobacco product or a re-

duced risk tobacco product that is in compliance with subsection (b) shall not be regulated as a drug or device.

''(e) DEVELOPMENT OF REDUCED EXPOSURE AND RISK TOBACCO PRODUCT TECHNOLOGY.—A tobacco product manufacturer shall provide written notice to the Secretary on the development or acquisition by the manufacturer of any technology that would reduce exposure to 1 or more tobacco toxicants, or the risk of a tobacco product to the health of the user, for which the manufacturer is not seeking designation as a reduced exposure tobacco product or a reduced risk tobacco product under this section.

''(f) POSTMARKET SURVEILLANCE.—

''(1) DISCRETIONARY SURVEILLANCE.—The Secretary may require a tobacco product manufacturer to conduct postmarket surveillance for a reduced exposure tobacco product or a reduced risk tobacco product of the manufacturer if the Secretary determines that postmarket surveillance of the tobacco product is necessary to protect the public health or is necessary to provide information regarding the health risks and other safety issues involving the tobacco product.

''(2) SURVEILLANCE APPROVAL.—

''(A) IN GENERAL.—Each tobacco product manufacturer required to conduct a surveillance of a reduced exposure tobacco product or a reduced risk tobacco product under paragraph (1) shall, not later than 30 days after receiving notice that the manufacturer is required to conduct the surveillance, submit, for the approval of the Secretary, a protocol for the required surveillance.

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

''(i) the principal investigator proposed to be used in the surveillance has sufficient qualifications and experience to conduct the surveillance; and

''(ii) the protocol will result in collection of useful data or other information necessary to protect the public health.

''(C) REVIEW.—The Secretary may not approve such a protocol until the protocol has been reviewed by an appropriately qualified scientific and technical review committee established by the Secretary.

"SEC. 914. PRESERVATION OF STATE AND LOCAL AUTHORITY.

"(a) ADDITIONAL REQUIREMENTS.—

"(1) IN GENERAL.—Except as provided in paragraph (2), nothing in this Act prohibits a State or political subdivision of a State from adopting or enforcing a requirement applicable to a tobacco product that is in addition to, or more stringent than, requirements established under this chapter.

"(2) PREEMPTION OF CERTAIN STATE AND LOCAL REQUIREMENTS.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), no State or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement that is different from, or in addition to, any requirement applicable under the provisions of this chapter relating to performance standards, premarket approval, adulteration, misbranding, registration, labeling, good manufacturing standards, or reduced exposure tobacco products or reduced risk tobacco products.

"(B) SALE, DISTRIBUTION, OR USE.—Subparagraph (A) does not apply to requirements relating to the sale, use, or distribution of a to-

bacco product, including requirements relating to the access to, and the advertising and promotion of, a tobacco product.

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

''SEC. 915. EQUAL TREATMENT OF RETAIL OUTLETS.

''The Secretary shall promulgate regulations that require that retail establishments for which the predominant business is the sale of tobacco products to comply with any advertising restrictions applicable to retail establishments accessible to individuals under the age of 18.

''SEC. 916. ACCESS AND MARKETING RESTRICTIONS.

''(a) DEFINITIONS.—In this section:

''(1) ADULT.—The term 'adult' means any person who is older than the minimum age at which it is legal to purchase or possess (whichever minimum age is older) tobacco products.

''(2) ADULT-ONLY FACILITY.—

''(A) IN GENERAL.—The term 'adult-only facility' means a facility or restricted area (whether open-air or enclosed) where the operator ensures or has a reasonable basis to believe (such as by checking identification as required

under State law, or by checking the identification of any person appearing to be under the age of 27) that only adults are present.

''(B) TEMPORARY ADULT-ONLY FACILITY.—A facility or restricted area need not be permanently restricted to adults in order to constitute an adult-only facility, if the operator ensures or has a reasonable basis to believe that only adults are present during the event or time period in question.

''(3) BRAND NAME.—

''(A) IN GENERAL.—The term 'brand name' means a brand name (alone or in conjunction with any other word), trademark, logo, symbol, motto, selling message, recognizable pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any domestic brand of tobacco products.

''(B) EXCLUSION.—The term 'brand name' shall not include the corporate name of any tobacco product manufacturer that does not, after the date of enactment of the Tobacco Livelihood and Economic Assistance for Our Farmers Act of 2002, sell a brand of tobacco prod-

ucts in the United States that includes the corporate name.

''(b) CIGARETTE AND SMOKELESS TOBACCO PRODUCT REQUIREMENTS.—

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

''(2) PROOF OF AGE.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), each retailer shall verify by means of photographic identification containing the bearer's date of birth that no person purchasing the product is younger than 18 years of age.

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

''(3) ENFORCEMENT BY STATES.—

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

''(i) the State has in effect a State law that is at least as restrictive as this subsection under which the State agrees to enforce the State law in a manner reasonably designed to prevent the violation of the State law; and

''(ii) the Secretary provides a grant to the State for the purpose of enforcing the State law.

''(B) AUTHORITY OF SECRETARY.—No action taken by the Secretary under subparagraph (A) limits the authority of the Secretary under this subsection.

''(4) MAIL ORDER SALES.—Not later than 2 years after the date of enactment of the Tobacco Livelihood and Economic Assistance for Our Farmers Act of 2002, the Secretary shall submit to Congress a report describing the extent, if any, to which individuals younger than 18 years of age are obtaining tobacco products through the mail.

''(c) MINIMUM PACKAGE SIZE REQUIREMENTS.—

''(1) MINIMUM NUMBER OF CIGARETTES.—No manufacturer, distributor, or retailer may sell or cause to be sold, or distribute or cause to be distributed, any cigarette package that contains fewer than 20 cigarettes.

''(2) OPENING TOBACCO PRODUCT PACKAGES.—No retailer may break or otherwise open any tobacco product package to sell or distribute individual cigarettes or a number of unpackaged cigarettes that is smaller than—

''(A) the quantity in the minimum cigarette package size provided under paragraph (1); or

''(B) any quantity of another tobacco product that is smaller than the smallest package distributed by the manufacturer for individual consumer use.

''(d) PROHIBITION ON YOUTH ACCESS TO FREE SAMPLES.—

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

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

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

''(2) PROHIBITION.—No manufacturer, distributor, or retailer may distribute or cause to be distributed any free sample of a tobacco product, except in an adult-only facility.

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

''(1) DEFINITION OF SELF-SERVICE DISPLAY.—In this subsection, the term 'self-service display' means any display located in an area in which the customer has access to the tobacco products without the aid of a sales clerk.

''(2) REQUIREMENT.—Except as provided in paragraph (3), a retailer may sell a tobacco product—

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

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

''(3) PERMITTED METHODS.—The following methods of sale of tobacco products shall be permitted under this subsection:

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

''(B) Vending machines that are located in an adult-only facility.

''(f) PROHIBITION ON YOUTH TARGETING.

''(1) DEFINITION OF YOUTH.—In this subsection, the term 'youth' means any person or persons under 18 years of age.

''(2) PROHIBITION.—No manufacturer, distributor, or retailer may take—

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

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

''(g) PROHIBITION ON USE OF CARTOONS.—

''(1) DEFINITION OF CARTOON.—In this subsection:

''(A) IN GENERAL.—The term 'cartoon' means any drawing or other depiction of an object, person, animal, or creature, or any similar caricature, that satisfies any of the following criteria:

''(i) The use of comically exaggerated features.

''(ii) The attribution of human characteristics to animals, plants, or other objects, or the similar use of anthropomorphic technique.

''(iii) The attribution of unnatural or extrahuman abilities, such as imperviousness to pain or injury, X-ray vision, tunneling at very high speeds, or transformation.

''(B) INCLUSION.—The term 'cartoon' includes a drawing or other depiction of the character popularly known as 'Joe Camel'.

''(C) EXCLUSIONS.—The term 'cartoon' does not include any drawing or other depiction that, on July 1, 1998, was in use in the United States in any manufacturer's corporate logo or in any manufacturer's tobacco product packaging.

''(2) PROHIBITION.—No manufacturer, distributor, or retailer may use or cause to be used any cartoon in the advertising, promoting, packaging, or labeling of tobacco products.

''(h) PROHIBITION ON OUTDOOR ADVERTISING.—

''(1) DEFINITIONS.—In this subsection:

''(A) OUTDOOR ADVERTISING.—

''(i) IN GENERAL.—The term 'outdoor advertising' means advertising through—

''(I) billboards;

''(II) signs and placards in arenas, stadiums, shopping malls, and video game arcades (regardless of whether located in the open air or enclosed); and

''(III) any other advertisements placed—

''(aa) outdoors; or

''(bb) on the inside surface of a window facing outward.

''(ii) EXCLUSIONS.—The term 'outdoor advertising' does not include—

''(I) an advertisement on the outside of a tobacco product manufacturing facility;

''(II) an individual advertisement that—

''(aa) does not occupy an area larger than 14 square feet;

''(bb) is not placed in such proximity to any other such advertisement so as to create a single mosaic-type advertisement larger than 14 square feet;

"(cc) does not function solely as a segment of a larger advertising unit or series; and

"(dd) is placed on the outside of any retail establishment that sells tobacco products (other than solely through a vending machine), on the outside (but on the property of) any such establishment, or on the inside surface of a window facing outward in any such establishment; or

"(III) an advertisement inside a retail establishment that sells tobacco products (other than solely through a vending machine) that is not placed on the inside surface of a window facing outward.

"(B) VIDEO GAME ARCADE.—The term 'video game arcade' means an entertainment establishment primarily consisting of video games (other than video games intended primarily for use by persons 18 years of age or older) or pinball machines.

''(2) PROHIBITION.—No manufacturer, distributor, or retailer may place or cause to be placed any outdoor advertisement for tobacco products.

''(i) PROHIBITION ON TRANSIT ADVERTISEMENTS.—

''(1) DEFINITION OF TRANSIT ADVERTISEMENT.—In this subsection:

''(A) IN GENERAL.—The term 'transit advertisement' means—

''(i) advertising on or within a private or public vehicle; and

''(ii) an advertisement placed at, on, or within any bus stop, taxi stand, transportation waiting area, train station, airport, or any similar location.

''(B) EXCLUSION.—The term 'transit advertisement' does not include any advertisement placed in, on, or outside the premises of any retail establishment that sells tobacco products (other than solely through a vending machine), unless the individual advertisement—

''(i) occupies an area larger than 14 square feet;

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

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

"(iii) functions solely as a segment of a larger advertising unit or series.

"(2) PROHIBITION.—No manufacturer, distributor, or retailer may place or cause to be placed any transit advertisement advertising tobacco products.

"(j) PROHIBITION ON ADVERTISING IN YOUTH-ORIENTED PUBLICATIONS.—

"(1) DEFINITION OF YOUTH-ORIENTED PUBLICATION.—In this subsection, the term 'youth-oriented publication' means a newspaper, magazine, periodical, or other publication—

"(A) at least 15 percent of the total readership of which is comprised of readers younger than 18 years of age, as measured by competent and reliable survey evidence; or

"(B) that is read by 2,000,000 or more persons younger than 18 years of age, as measured by competent and reliable survey evidence.

"(2) PROHIBITION.—No manufacturer, distributor, or retailer shall advertise a tobacco product in any youth-oriented publication, regardless of

whether the publication has periodic or limited distribution.

''(k) PROHIBITION ON TOBACCO PRODUCT BRAND NAME SPONSORSHIPS.—

''(1) IN GENERAL.—No manufacturer, distributor, or retailer may sponsor or cause to be sponsored any athletic, musical, artistic, or other social or cultural event, or any entry or team in any event, using the brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, that used for any brand of cigarettes or smokeless tobacco.

''(2) EXCEPTIONS.—Nothing in this subsection prevents a manufacturer, distributor, or retailer from sponsoring or causing to be sponsored any athletic, musical, artistic, or other social or cultural event, or team or entry, in the name of the corporation that manufactures the tobacco product, if—

''(A) both the corporate name and the corporation were registered and in use in the United States before January 1, 2001; and

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

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

''(3) ADULT-ONLY FACILITIES.—This subsection shall not apply to any event sponsored in an adult-only facility.

''(l) PROHIBITION ON TOBACCO BRAND NAME MERCHANDISE.—

''(1) IN GENERAL.—No manufacturer may market, distribute, offer, sell, license or cause to be marketed, distributed, offered, sold, or licensed (including by catalog or direct mail), any apparel or other merchandise that bears the brand name of a tobacco product, other than items the sole function of which is to advertise tobacco products or written or electronic publications.

''(2) EXCEPTIONS.—Nothing in this subsection shall—

''(A) prohibit the distribution to any manufacturer's employee who is an adult of any item described in paragraph (1) that is intended for the personal use of the employee;

''(B) require any manufacturer to retrieve, collect, or otherwise recover any item that, before the date of enactment of the Tobacco Livelihood and Economic Assistance for Our Farmers Act of 2002, was marketed, distributed, offered, sold, licensed, or caused to be marketed, distributed, offered, sold, or licensed by the manufacturer;

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

''(D) apply to apparel or other merchandise used within an adult-only facility that is not distributed (by sale or otherwise) to any member of the general public.

''(m) PROHIBITION ON GIFTS TO UNDERAGE PERSONS BASED ON PROOFS OF PURCHASE.—

''(1) IN GENERAL.—No manufacturer, distributor, or retailer may provide or cause to be provided to any person, without sufficient proof that the person is an adult, any item in exchange for the purchase of tobacco products, or the furnishing of credits, proofs-of-purchase, or coupons with respect to such a purchase.

''(2) PROOF OF AGE.—

''(A) IN GENERAL.—For purposes of paragraph (1), a driver's license or other government-issued identification (or legible photocopy of the license or identification), the validity of which is certified by the person to whom the item is provided, shall by itself be deemed to be a sufficient form of proof of age.

''(B) RETAILERS.—In the case of items provided (or to be redeemed) at retail establishments, a manufacturer shall be entitled to rely on verification of proof of age by the retailer, if the retailer is required to obtain verification under applicable Federal, State, or local law.

''(n) PROHIBITION ON NON-TOBACCO PRODUCT BRAND NAMES.—

''(1) DEFINITION OF OTHER VALUABLE CONSIDERATION.—In this subsection, the term 'other valuable consideration' does not include an agreement between 2 entities that enter into an agreement for the sole purpose of avoiding infringement claims.

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

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

''(A) any nationally recognized or nationally established brand name or trade name of any non-tobacco item or service; or

''(B) any nationally recognized or nationally established sports team, entertainment group, or individual celebrity.

''(3) NONAPPLICABILITY.—Paragraph (2) shall not apply to any tobacco product brand name in existence as of July 1, 1998.

''(o) LIMITATION ON THIRD PARTY USE OF TOBACCO BRAND NAMES.—

''(1) IN GENERAL.—No manufacturer may license or otherwise expressly authorize any third party to use or advertise any brand name of a tobacco product in a manner prohibited by this chapter if used or advertised by the manufacturer itself.

''(2) EXCEPTIONS.—Nothing in this subsection requires any manufacturer to retrieve, collect, or otherwise recover any item that, before the date of enactment of the Tobacco Livelihood and Economic Assistance for Our Farmers Act of 2002, was marketed, distributed, offered, sold, licensed, or caused

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

''(p) PROHIBITION ON PRODUCT PLACEMENT IN CERTAIN MEDIA.—

''(1) IN GENERAL.—Except as provided in paragraph (2), no manufacturer may make, or cause to be made, any payment or other consideration to any other person or entity to use, display, make reference to, or use as a prop any tobacco product, tobacco product package, advertisement for a tobacco product, or any other item bearing a brand name in any motion picture, television show, theatrical production or other live performance, live or recorded performance of music, commercial film or video, or video game (collectively referred to in this subsection as 'media').

''(2) EXCEPTIONS.—Paragraph (1) shall not apply to—

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

''(B) media not intended for distribution or display to the public; or

''(C) instructional media concerning non-conventional tobacco products or tobacco products designated as reduced exposure tobacco products or reduced risk tobacco products viewed only by or provided only to consumers who are adults.

''(q) EFFECTIVE DATES.—

''(1) IN GENERAL.—Except as provided in paragraph (2), this section shall apply beginning on the date that is 180 days after the date of enactment of the Tobacco Livelihood and Economic Assistance for Our Farmers Act of 2002.

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

''SEC. 917. MANDATORY DISCLOSURES.

''(a) DISCLOSURE OF INGREDIENTS TO THE PUBLIC.—

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

the common or usual name of each ingredient of a tobacco product in descending order of predominance by weight.

''(2) SPICES, FLAVORINGS, AND COLORINGS.—A manufacturer may elect to designate spices, flavorings, and colorings under paragraph (1) without naming each spice, flavoring, or coloring.

''(3) OTHER LAWS.—Any ingredient that has been disclosed to the public pursuant to any other law (including regulations) with respect to a particular brand may be required to be disclosed for the brand pursuant to this subsection.

''(4) INCIDENTAL ADDITIVES.—The regulations required by this subsection shall provide that incidental additives that are present in a tobacco product at insignificant levels and that do not have any technical or functional effect in the finished tobacco product shall be exempt from disclosure.

''(5) SMALL QUANTITIES.—The requirement of this subsection to disclose ingredients in descending order of predominance shall not apply to ingredients in quantities of 2 percent or less by weight if a listing of the ingredients is placed at the end of the ingredients statement following an appropriate quanti-

fying statement, such as 'contains ____ percent or less of ____', or 'less than ____ percent of ____'.

''(6) MEANS OF DISCLOSURE.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), any disclosure required pursuant to this subsection may be required by appropriate means.

''(B) LISTING OF INGREDIENTS.—Notwithstanding any other provision of this Act, the Secretary shall not require the listing of any ingredient of a tobacco product on any package or in any advertisement.

''(b) DISCLOSURE OF PERCENTAGE OF DOMESTIC AND FOREIGN TOBACCO.—Not later than 1 year after the date of enactment of the Tobacco Livelihood and Economic Assistance for Our Farmers Act of 2002, the Secretary shall promulgate regulations that require that each package of a tobacco product disclose, with respect to the tobacco contained in that brand—

''(1) the percentage of tobacco that is domestic tobacco; and

''(2) the percentage of tobacco that is foreign tobacco.

''(c) MANDATORY DISCLAIMER.—

''(1) IN GENERAL.—Except as otherwise provided in this subsection, any tobacco product advertising that includes a term classifying a brand of tobacco product according to the tar yield or the yield of the brand to consumers of any substance, including terms such as 'light' or 'low tar', shall also include the following disclaimer: '[Brand] not shown to be less hazardous than other [type of tobacco product]'.

''(2) FILTERED.—This section shall apply to the use of the terms 'filtered' or 'filter'.

''(3) TOBACCO PRODUCT PACKAGES.—A disclaimer described in paragraph (1) shall not be required on any tobacco product package.

''(4) USE OF TERMS.—Not later than 1 year after the date of enactment of the Tobacco Livelihood and Economic Assistance for Our Farmers Act of 2002, the Secretary shall promulgate regulations relating to the use of the terms described in paragraph (1) to ensure that the terms are not false or misleading.

''(5) REDUCED EXPOSURE AND REDUCED RISK TOBACCO PRODUCTS.—The Secretary may modify or waive any requirement under this subsection with respect to any product that has been designated by the

Secretary as a reduced exposure tobacco product or a reduced risk tobacco product under section 913.

"SEC. 918. REGULATORY RECORD.

"(a) IN GENERAL.—Notwithstanding subchapter II of chapter 5 of title 5, United States Code, in promulgating regulations under this chapter, the record developed and used by the Secretary for the purposes of promulgating subparts (B) and (D) of the regulations relating to the sale, distribution, and use of tobacco products on or about August 28, 1996, as reflected in articles IV and VI of the preamble to the 1996 Food and Drug Administration Tobacco Rule (including public comments, Food and Drug Administration documents, and any other information generated or compiled for purposes of promulgating the regulations), shall be deemed to have the same legal status as if the record had been developed under a rulemaking proceeding conducted pursuant to section 907(d)(1).

"(b) OTHER RESPECTS.—In all other respects (including the issue of whether the regulations conform to section 907(d)(1)), the procedural requirements of this chapter and subchapter II of chapter 5, and chapter 7, of title 5, United States Code (commonly known as the 'Administrative Procedure Act') shall apply to this chapter.

"SEC. 919. REGULATION REQUIREMENT.

''(a) TESTING, REPORTING, AND DISCLOSURE.—Not later than 2 years after the date of enactment of the Tobacco Livelihood and Economic Assistance for Our Farmers Act of 2002, the Secretary, acting through the Commissioner of Food and Drugs, shall promulgate regulations under this Act that meet the requirements of subsection (b).

''(b) CONTENTS OF RULES.—

''(1) IN GENERAL.—The rules promulgated under subsection (a) shall require the testing, reporting, and disclosure of tobacco product smoke constituents and ingredients that the Secretary determines should be disclosed to the public in order to protect the public health.

''(2) CONSTITUENTS.—The constituents shall include tar, nicotine, carbon monoxide, and such other smoke constituents or ingredients as the Secretary may determine to be appropriate.

''(3) ADMINISTRATION.—The rules may require that tobacco product manufacturers, packagers, or importers make—

''(A) the disclosures relating to tar and nicotine through labels or advertising; and

''(B) the disclosures regarding other smoke constituents or ingredients that the Secretary

determines are necessary to protect the public health.

''(c) AUTHORITY.—The Secretary, acting through the Commissioner of Food and Drugs, shall have authority to conduct or to require the testing, reporting, or disclosure of tobacco product smoke constituents.''.

SEC. 513. CONFORMING AND TECHNICAL AMENDMENTS.

(a) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended—

(1) in subsections (a), (b), (c), (g), (h), and (k), by inserting ''tobacco product,'' after ''device,'' each place it appears;

(2) in subsection (e), by striking ''515(f), or 519'' and inserting ''515(f), 519, or 910'';

(3) in subsection (j), by striking ''708, or 721'' and inserting ''708, 721, 904, 905, 906, 907, 908, 909, 910, 911, or 913'';

(4) by striking subsection (p) and inserting the following:

''(p) The failure—

''(1) to register in accordance with section 510 or 906;

''(2) to provide any information required by section 510(j), 510(k), 906(i), or 906(j); or

''(3) to provide a notice required by section 510(j)(2) or 906(j)(2).'';

(5) in subsection (q)—

(A) by striking paragraph (1) and inserting the following:

''(1) The failure or refusal—

''(A) to comply with any requirement prescribed under section 518, 520(g), 907(f), or 909;

''(B) to furnish any notification or other material or information required by or under section 519, 520(g), 905, 907(f), or 910; or

''(C) to comply with a requirement under section 522.''; and

(B) in paragraph (2), by striking ''device,'' and inserting ''device or tobacco product,'';

(6) in subsection (r), by inserting ''or tobacco product'' after ''device'' each place it appears; and

(7) by adding at the end the following:

''(bb) The sale of a tobacco product in violation of a no-tobacco-sale order issued under section 303(g)(3).''.

(b) PENALTIES.—Section 303(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(g)) is amended—

(1) by striking ''(g)(1)(A) Except'' and inserting the following:

''(g) CIVIL PENALTIES.—

''(1) IN GENERAL.—

''(A) PENALTY.—Except'';

(2) in paragraph (1)(A), by inserting ''or tobacco products'' after ''devices'';

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

(4) by inserting after paragraph (2) the following:

''(3) NO-TOBACCO-SALE ORDERS.—

''(A) IN GENERAL.—If the Secretary finds that a person has committed repeated violations of restrictions promulgated under section 906(d) at a particular retail outlet, the Secretary may impose a no-tobacco-sale order on the person prohibiting the sale of tobacco products in the outlet.

''(B) CIVIL PENALTIES.—A no-tobacco-sale order may be imposed with a civil penalty under paragraph (1).'';

(5) in paragraph (4) (as redesignated by paragraph (3))—

(A) in subparagraph (A)—

(i) in the first sentence, by striking ''assessed'' the first place it appears and

inserting ''assessed, or a no-tobacco-sale order may be imposed,''; and

(ii) in the second sentence, by striking ''penalty'' and inserting ''penalty, or on whom a no-tobacco-order is to be imposed,'';

(B) in subparagraph (B)—

(i) by striking ''(B) In'' and inserting the following:

''(B) ADMINISTRATION.—

''(i) FACTORS.—In''

(ii) by inserting after ''penalty'' the following: ''or the period to be covered by a no-tobacco-sale order,''; and

(iii) by adding at the end the following:

''(ii) NO-TOBACCO-SALE ORDERS.—A no-tobacco-sale order permanently prohibiting an individual retail outlet from selling tobacco products shall include provisions that allow the outlet, after a specified period of time, to request that the Secretary compromise, modify, or terminate the order.''; and

(C) by adding at the end the following:

''(D) COMPROMISE, MODIFICATION, OR TERMINATION OF NO-TOBACCO-SALE ORDERS.—The Secretary may compromise, modify, or terminate, with or without conditions, any no-to-bacco-sale order.'';

(6) in paragraph (5) (as redesignated by paragraph (3))—

(A) in the first sentence—

(i) by striking ''(3)(A)'' and inserting ''(4)(A)''; and

(ii) by inserting ''or the imposition of a no-tobacco-sale order'' after ''penalty'' the first 2 places it appears; and

(B) in the second sentence, by inserting before the period at the end the following: '', or on which the no-tobacco-sale order was imposed, as the case may be''; and

(7) in paragraph (6) (as redesignated by paragraph (3)), by striking ''paragraph (4)'' each place it appears and inserting ''paragraph (5)''.

(c) SEIZURE.—Section 304 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334) is amended—

(1) in subsection (a)(2)—

(A) by striking ''and'' before ''(D)''; and

(B) by inserting before the period at the end the following: ‘‘, and (E) Any adulterated or misbranded tobacco product’’;

(2) in the first sentence of subsection (d)(1), by inserting ‘‘tobacco product,’’ after ‘‘device,’’; and

(3) in subsection (g), by inserting ‘‘or tobacco product’’ after ‘‘device’’ each place it appears.

(d) EXAMINATIONS AND INVESTIGATIONS.—Section 702(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 372(a)) is amended—

(1) by striking the section heading through ‘‘(a) The Secretary’’ and inserting the following:

‘‘SEC. 702. EXAMINATIONS AND INVESTIGATIONS.

‘‘(a) IN GENERAL.—

‘‘(1) AUTHORITY.—The Secretary’’; and

(2) by adding at the end the following:

‘‘(2) TOBACCO PRODUCTS.—In the case of a tobacco product, to the maximum extent practicable, the Secretary shall contract with States in accordance with paragraph (1) to carry out inspections of retailers in connection with the enforcement of this Act.’’.

(e) RECORDS OF INTERSTATE SHIPMENT.—Section 703 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 373) is amended—

(1) by inserting ''tobacco products,'' after ''devices,'' each place it appears; and

(2) by inserting ''tobacco product,'' after ''device,'' each place it appears.

(f) FACTORY INSPECTION.—Section 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374) is amended—

(1) in subsection (a)(1), by inserting ''tobacco products,'' after ''devices,'' each place it appears; and

(2) in subsection (b), by inserting ''tobacco product,'' after ''device,''.

(g) PUBLICITY.—Section 705(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 375(b)) is amended in the first sentence by inserting ''tobacco products,'' after ''devices,''.

(h) PRESUMPTION.—Section 709 of the Federal Food, Drug, and Cosmetic Act (21 U.S. C. 379) is amended by inserting ''tobacco product,'' after ''device,''.

(i) IMPORTS AND EXPORTS.—Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381) is amended—

(1) in subsection (a)—

(A) in the first sentence, by inserting ''tobacco products,'' after ''devices,'';

(B) in the second sentence, by striking ''subsection (i) of section 510'' and inserting ''section 510(i) or 906(j)''; and

(C) by striking ''drugs or devices'' each place it appears and inserting ''drugs, devices, or tobacco products''; and

(2) in subsection (e)(1), by inserting ''tobacco product,'' after ''device,''.

(j) FOOD AND DRUG ADMINISTRATION.—Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (as redesignated by section 512(2)) is amended by striking ''and devices'' and inserting ''devices, and tobacco products''.

(k) EFFECTIVE DATE FOR NO-TOBACCO-SALE ORDER AMENDMENTS.—The amendments made by subsection (a), other than the amendment to section 301(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(b)) made by subsection (a)(1), shall take effect only on the promulgation of final regulations by the Secretary of Health and Human Services—

(1) defining the term ''repeated violation'', as used in section 303(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(g)) (as amended by subsection (b)), by identifying the number of vio-

lations of particular requirements over a specified period of time that constitute a repeated violation;

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

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

(4) establishing a period of time during which, if there are no violations by a particular retail outlet, the outlet will not be considered to have been the site of repeated violations when the next violation occurs; and

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

Subtitle B—Cigarette Labeling and Advertising

SEC. 521. DEFINITION OF CIGARETTE.

Section 3(1) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1332) is amended—

(1) in subparagraph (A), by striking ''and'' at the end;

(2) in subparagraph (B), by striking the period at the end and inserting ''; and''; and

(3) by adding at the end the following:

''(C) any tobacco product, in any form (including Bidi and Kretek cigarettes), if—

''(i) the tobacco in the product—

''(I) is heated or burned; and

''(II) is functional in the product; and

''(ii) the product, because of the appearance of the product, the type of tobacco used in the filler, or the packaging and labeling of the product, is likely to be offered to, or purchased by, consumers as a cigarette or as roll-your-own tobacco.''.

SEC. 522. CIGARETTE LABEL AND ADVERTISING WARNINGS.

Section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) is amended to read as follows:

''SEC. 4. LABELING.

''(a) LABEL REQUIREMENTS.—

''(1) IN GENERAL.—It shall be unlawful for any person to manufacture, package, or import for sale or distribution within the United States any cigarettes the package of which fails to bear, in accord-

ance with the requirements of this section, 1 of the following labels:

"WARNING: Cigarettes are addictive.

"WARNING: Tobacco smoke can harm your children.

"WARNING: Cigarettes cause fatal lung disease.

"WARNING: Cigarettes cause cancer.

"WARNING: Cigarettes cause strokes and heart disease.

"WARNING: Smoking during pregnancy can harm your baby.

"WARNING: Smoking can kill you.

"WARNING: Tobacco smoke causes fatal lung disease in non-smokers.

"WARNING: Quitting smoking now greatly reduces serious risks to your health.

"(2) FORMAT.—

"(A) LOCATION.—Each label statement required by paragraph (1) shall be located in the upper portion of the front and rear panels of the package, directly on the package underneath the cellophane or other clear wrapping.

"(B) PERCENTAGE OF PANELS.—Except as provided in subparagraph (C), each label

statement shall comprise at least the top 25 percent of the front and rear panels of the package.

''(C) TEXT.—

''(i) IN GENERAL.—Except as provided in clause (ii), the word 'WARNING' shall appear in capital letters and all text shall be in conspicuous and legible 17-point type.

''(ii) SMALLER TYPE SIZE.—If the text of the label statement would occupy more than 70 percent of the area of a panel, the text may be in a smaller conspicuous and legible type size, if at least 60 percent of the area of the panel is occupied by required text.

''(iii) CONTRAST.—The text shall be black on a white background, or white on a black background, in a manner that contrasts, by typography, layout, or color, with all other printed material on the package, in an alternating fashion under the plan submitted under subsection (b)(4).

''(D) FLIP-TOP BOXES.—

''(i) IN GENERAL.—For any cigarette brand package manufactured or distributed before January 1, 2000, that employs a flip-top style (if the packaging was used for that brand in commerce before June 21, 1997), the label statement required by paragraph (1) shall be located on the flip-top area of the package, even if the area is less than 25 percent of the area of the front panel.

''(ii) PACKAGES.—Except as provided in clause (i), the provisions of this subsection shall apply to the package.

''(3) FOREIGN DISTRIBUTION.—This subsection does not apply to a tobacco product manufacturer or distributor of cigarettes that does not manufacture, package, or import cigarettes for sale or distribution within the United States.

''(4) TAR, NICOTINE, AND OTHER SMOKE CONSTITUENT DISCLOSURE TO THE PUBLIC.—

''(A) IN GENERAL.—The Secretary shall, by a rulemaking conducted under section 553 of title 5, United States Code, determine (in the Secretary's sole discretion) whether cigarette and other tobacco product manufacturers shall

be required to include in the area of each cigarette advertisement specified by subsection (b), or on the package label, or both, the tar and nicotine yields of the advertised or packaged brand.

''(B) METHOD.—Any such disclosure shall—

''(i) be in accordance with the methodology established under the regulations;

''(ii) conform to the type size requirements of subsection (b); and

''(iii) appear within the area specified in subsection (b).

''(C) CONSISTENCY WITH FTC REPORTING REQUIREMENTS.—Any differences between the requirements established by the Secretary under subparagraph (A) and tar and nicotine yield reporting requirements established by the Federal Trade Commission shall be resolved by a memorandum of understanding between the Secretary and the Federal Trade Commission.

''(D) SMOKE CONSTITUENTS.—

''(i) IN GENERAL.—In addition to the disclosures required by subparagraph (A), the Secretary may, under a rulemaking conducted

under section 553 of title 5, United States Code, prescribe disclosure requirements regarding the level of any cigarette or other tobacco product smoke constituent.

''(ii) CONDITIONS.—Any disclosure under this subparagraph may be required if the Secretary determines that disclosure would—

''(I) be of benefit to the public health; or

''(II) otherwise increase consumer awareness of the health consequences of the use of tobacco products.

''(iii) FACE OF CIGARETTE PACKAGE OR ADVERTISEMENT.—No disclosure shall be required under this subparagraph on the face of any cigarette package or advertisement.

''(iv) OTHER MEANS.—Nothing in this section prohibits the Secretary from requiring disclosure under this subparagraph through a cigarette or other tobacco product package or advertisement insert, or by any other means, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

''(b) ADVERTISING REQUIREMENTS.—

''(1) IN GENERAL.—It shall be unlawful for any tobacco product manufacturer, importer, distributor, or retailer of cigarettes to advertise or cause to be advertised within the United States any cigarette unless the advertising for the cigarette bears, in accordance with this section, 1 of the labels specified in subsection (a)(1).

''(2) FORMAT.—

''(A) IN GENERAL.—Each label statement required by subsection (a) in cigarette advertising shall comply with the standards set forth in this paragraph.

''(B) PRESS AND POSTER ADVERTISEMENTS.—In the case of a press or poster advertisement, each such statement and (if applicable) any required statement relating to tar, nicotine, or other constituent yield shall—

''(i) comprise at least 20 percent of the area of the advertisement; and

''(ii) appear in a conspicuous and prominent format and location at the top of each advertisement within the border area.

''(C) REVISION OF TYPE SIZES.—The Secretary may revise the required type sizes in the

border area in such manner as the Secretary determines appropriate.

''(D) TEXT.—

''(i) IN GENERAL.—The word 'WARNING' shall appear in capital letters, and each label statement shall appear in conspicuous and legible type.

''(ii) CONTRAST.—The text of the label statement shall be black if the background is white and white if the background is black, under the plan submitted under paragraph (4).

''(E) BORDER.—The label statement shall be enclosed by a rectangular border that is—

''(i) the same color as the letters of the statement; and

''(ii) the width of the first downstroke of the capital 'W' of the word 'WARNING' in the label statement.

''(F) TYPEFACE.—The text of the label statement shall be in a typeface pro rata to the following requirements:

''(i) 45-point type for a whole-page broadsheet newspaper advertisement.

"(ii) 39-point type for a half-page broadsheet newspaper advertisement.

"(iii) 39-point type for a whole-page tabloid newspaper advertisement.

"(iv) 27-point type for a half-page tabloid newspaper advertisement.

"(v) 31.5-point type for a double page spread magazine or whole-page magazine advertisement.

"(vi) 22.5-point type for a 28-centimeter-by-3-column advertisement.

"(vii) 15-point type for a 20-centimeter-by-2-column advertisement.

"(G) LANGUAGE.—

"(i) IN GENERAL.—Except as provided in clauses (ii) and (iii), the label statements shall be in English.

"(ii) NON-ENGLISH PUBLICATIONS.—In the case of an advertisement that appears in a newspaper, magazine, periodical, or other publication that is not in English, the statement shall appear in the predominant language of the publication.

"(iii) NON-ENGLISH ADVERTISEMENTS.—In the case of any other adver-

tisement that is not in English, the statement shall appear in the same language as that principally used in the advertisement.

''(3) ADJUSTMENTS BY SECRETARY.—

''(A) IN GENERAL.—The Secretary may, through a rulemaking under section 553 of title 5, United States Code—

''(i) adjust the format and type sizes for the label statements required by this subsection;

''(ii) adjust the text, format, and type sizes of any required tar, nicotine yield, or other constituent disclosures; or

''(iii) establish the text, format, and type sizes for any other disclosures required under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

''(B) LOCATION.—

''(i) IN GENERAL.—The text of any such label statements or disclosures adjusted under this paragraph shall be required to appear only within the 20 percent area of cigarette advertisements required under paragraph (2).

''(ii) REGULATIONS.—The Secretary shall promulgate regulations that provide for adjustments in the format and type sizes of any text required to appear in the 20 percent area to ensure that the total text required to appear by law will fit within the area.

''(4) MARKETING REQUIREMENTS.—

''(A) IN GENERAL.—The label statements specified in subsection (a)(1) shall be randomly displayed—

''(i) in each 12-month period, in as equal a number of times as is practicable on each brand of the product; and

''(ii) in all areas of the United States in which the product is marketed in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer and approved by the Secretary.

''(B) QUARTERLY ROTATION.—The label statements specified in subsection (a)(1) shall be rotated quarterly in alternating sequence in advertisements for each brand of cigarettes in accordance with a plan submitted by the to-

bacco product manufacturer, importer, distributor, or retailer to, and approved by, the Secretary.

''(C) APPROVAL OF PLAN.—The Secretary shall review each plan submitted under subparagraph (B) and approve the plan if the plan—

''(i) will provide for the equal distribution and display on packaging and the rotation required in advertising under this subsection; and

''(ii) ensures that all of the labels required under this section will be displayed by the tobacco product manufacturer, importer, distributor, or retailer at the same time.

''(c) CHANGE IN REQUIRED STATEMENTS.—The Secretary may, by a rulemaking conducted under section 553 of title 5, United States Code, adjust the format, type size, and text of any of the warning label statements required by this section (subject to the limitation on proportional size of the warning contained in subsections (a)(2) and (b)(2)), or establish the format, type size, and text of any other disclosures required under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), if the Secretary

finds that such a change would promote greater public understanding of the risks associated with the use of cigarettes or smokeless tobacco products.''.

Subtitle C—Smokeless Tobacco Labels and Advertising Warnings

SEC. 531. SMOKELESS TOBACCO LABELS AND ADVERTISING WARNINGS.

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

''SEC. 3. SMOKELESS TOBACCO WARNING.

''(a) GENERAL RULE.—

''(1) LABELS.—It shall be unlawful for any person to manufacture, package, or import for sale or distribution within the United States any smokeless tobacco product unless the product package bears, in accordance with the requirements of this Act, 1 of the following labels:

''WARNING: This product can cause mouth cancer.

''WARNING: This product can cause gum disease and tooth loss.

''WARNING: This product is not a safe alternative to cigarettes.

''WARNING: Smokeless tobacco is addictive.

"(2) FORMAT.—

"(A) LOCATION.—Each label statement required by paragraph (1) shall be located on the 2 principal display panels of the package.

"(B) PERCENT OF PANEL.—Each label statement shall comprise at least 25 percent of each display panel.

"(C) TEXT.—

"(i) IN GENERAL.—Except as provided in clause (ii), under the plan submitted under subsection (b)(3), each label statement shall be—

"(I) in 17-point conspicuous and legible type; and

"(II) in black text on a white background, or white text on a black background, in a manner that contrasts by typography, layout, or color, with all other printed material on the package, in an alternating fashion.

"(ii) SMALLER TYPE.—If the text of a label statement would occupy more than 70 percent of the warning area of a package, the text may appear in a smaller type

size, if least 60 percent of the warning area is occupied by the label statement.

''(3) CONCURRENT INTRODUCTION.—The label statements required by paragraph (1) shall be introduced by each tobacco product manufacturer, packager, importer, distributor, or retailer of smokeless tobacco products concurrently into the distribution chain of the products.

''(4) FOREIGN DISTRIBUTION.—This subsection does not apply to a tobacco product manufacturer or distributor of any smokeless tobacco product that does not manufacture, package, or import smokeless tobacco products for sale or distribution within the United States.

''(b) REQUIRED LABELS.—

''(1) IN GENERAL.—It shall be unlawful for any tobacco product manufacturer, packager, importer, distributor, or retailer of smokeless tobacco products to advertise or cause to be advertised within the United States any smokeless tobacco product unless the advertising for the product bears, in accordance with this section, 1 of the labels specified in subsection (a)(1).

''(2) STANDARDS.—

''(A) IN GENERAL.—Each label statement required by subsection (a) in smokeless tobacco advertising shall comply with the standards set forth in this paragraph.

''(B) PRESS AND POSTER ADVERTISEMENTS.—For press and poster advertisements, each such statement and (where applicable) any required statement relating to tar, nicotine, or other constituent yield shall—

''(i) comprise at least 20 percent of the area of the advertisement, and the warning area shall be delineated by a dividing line of contrasting color from the advertisement; and

''(ii) the word 'WARNING' shall appear in capital letters and each label statement shall appear in conspicuous and legible type.

''(C) TEXT.—The text of the label statement shall be black on a white background, or white on a black background, in an alternating fashion under the plan submitted under paragraph (3).

''(3) MARKETING REQUIREMENTS.—

"(A) IN GENERAL.—The label statements specified in paragraph (1) shall be randomly displayed—

"(i) in each 12-month period, in as equal a number of times as is practicable on each brand of the product; and

"(ii) in all areas of the United States in which the product is marketed in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer and approved by the Secretary.

"(B) QUARTERLY ROTATION.—The label statements specified in paragraph (1) shall be rotated quarterly in alternating sequence in advertisements for each brand of smokeless tobacco product in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer to, and approved by, the Secretary.

"(C) APPROVAL OF PLAN.—The Secretary shall review each plan submitted under subparagraph (B) and approve the plan if the plan, as determined by the Secretary—

''(i) will provide for the equal distribution and display on packaging and the rotation required in advertising under this subsection; and

''(ii) ensures that all of the labels required under this section will be displayed by the tobacco product manufacturer, importer, distributor, or retailer at the same time.

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

''(d) AUTHORITY TO REVISE WARNING LABEL STATEMENTS.—The Secretary may, by a rulemaking conducted under section 553 of title 5, United States Code, adjust the format, type size, and text of any of the warning label statements required by this section (subject to the limitations on proportional size of the warning required under this section), or establish the format, type size, and text of any other disclosures required under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), if the Secretary finds that such a change would promote greater public understanding of the risks associated with the use of smokeless tobacco products.''.

Subtitle D—Administration

SEC. 541. FTC JURISDICTION NOT AFFECTED.

(a) IN GENERAL.—Except as otherwise expressly provided in this Act or an amendment made by this Act, nothing in this Act or an amendment made by this Act limits or diminishes the authority of the Federal Trade Commission to enforce the laws under the jurisdiction of the Commission with respect to the advertising, sale, or distribution of tobacco products.

(b) ENFORCEMENT BY FTC.—Any advertising that violates this Act or an amendment made by this Act shall be considered—

(1) an unfair or deceptive act or practice under section 5(a) of the Federal Trade Commission Act (15 U.S.C. 45(a)); and

(2) a violation of a rule promulgated under section 18 of that Act (15 U.S.C. 57a).

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