

107TH CONGRESS
1ST SESSION

S. 190

To amend the Federal Food, Drug, and Cosmetic Act to grant the Secretary of Health and Human Services the authority to regulate tobacco products, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JANUARY 25, 2001

Mr. FRIST introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to grant the Secretary of Health and Human Services the authority to regulate tobacco products, and for other purposes.

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

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “National Youth Smok-
5 ing Reduction Act”.

6 **SEC. 2. FINDINGS.**

7 The Congress finds the following:

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

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

9 (3) Nicotine is addictive.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

13 (21) Restrictions on advertising are necessary
14 to prevent unrestricted tobacco advertising from un-
15 dermining legislation prohibiting access to young
16 people.

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

20 **SEC. 3. DEFINITIONS.**

21 In this Act:

22 (1) BRAND.—The term “brand” means a vari-
23 ety of tobacco product distinguished by the tobacco
24 used, tar content, nicotine content, flavoring used,
25 size, filtration, or packaging, logo, registered trade-

1 mark or brand name, identifiable pattern of colors,
2 or any combination of such attributes.

3 (2) CIGARETTE.—The term “cigarette” has the
4 meaning given that term by section 3(1) of the Fed-
5 eral Cigarette Labeling and Advertising Act (15
6 U.S.C. 1332(1)), but also includes tobacco, in any
7 form, that is functional in the product, which, be-
8 cause of its appearance, the type of tobacco used in
9 the filler, or its packaging and labeling, is likely to
10 be offered to, or purchased by, consumers as a ciga-
11 rette or as roll-your-own tobacco.

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

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

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

24 (6) DISTRIBUTOR.—The term “distributor” as
25 regards a tobacco product means any person who

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

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

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

21 (9) PACKAGE.—The term “package” means a
22 pack, box, carton, or container of any kind or, if no
23 other container, any wrapping (including cello-
24 phane), in which cigarettes or smokeless tobacco are

1 offered for sale, sold, or otherwise distributed to con-
2 sumers.

3 (10) RETAILER.—The term “retailer” means
4 any person who sells cigarettes or smokeless tobacco
5 to individuals for personal consumption, or who op-
6 erates a facility where self-service displays of tobacco
7 products are permitted.

8 (11) SECRETARY.—Except where the context
9 otherwise requires, the term “Secretary” means the
10 Secretary of Health and Human Services.

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

15 **SEC. 4. AMENDMENT OF FEDERAL FOOD, DRUG, AND COS-**
16 **METIC ACT OF 1938.**

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

20 “(kk) The term ‘tobacco product’ means any
21 product made or derived from tobacco that is in-
22 tended for human consumption, including any com-
23 ponent, part, or accessory of a tobacco product (ex-
24 cept for raw materials other than tobacco used in

1 manufacturing a component, part, or accessory of a
2 tobacco product).

3 “(ll) The definitions contained in section 3 of
4 the National Youth Smoking Reduction Act shall
5 apply with respect to chapter IX.”.

6 (b) FDA AUTHORITY OVER TOBACCO PRODUCTS.—
7 The Federal Food, Drug, and Cosmetic Act (21 U.S.C.
8 301 et seq.) is amended—

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

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

12 (3) by inserting after section 803 the following:

13 **“CHAPTER IX—TOBACCO**
14 **PRODUCTS**

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

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

19 “(1) such products are intended for use in the
20 diagnosis, cure, mitigation, treatment, or prevention
21 of disease (within the meaning of section
22 201(g)(1)(B) or section 201(h)(2)); or

23 “(2) a health claim is made for such products
24 under section 201(g)(1)(C) or 201(h)(3), unless the

1 product is a reduced risk product pursuant to sec-
2 tion 912.

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

8 “(c) SCOPE.—

9 “(1) Nothing in this chapter shall be construed
10 to affect the Secretary’s authority over, or the regu-
11 lation of, products under this Act that are not to-
12 bacco products under chapter V of the Federal
13 Food, Drug and Cosmetic Act or any other chapter
14 of that Act.

15 “(2) The provisions of this chapter shall not
16 apply to tobacco leaf that is not in the possession of
17 the manufacturer, or to the producers of tobacco
18 leaf, including tobacco growers, tobacco warehouses,
19 and tobacco grower cooperatives, nor shall any em-
20 ployee of the Food and Drug Administration have
21 any authority whatsoever to enter onto a farm
22 owned by a producer of tobacco leaf without the
23 written consent of such producer. Notwithstanding
24 any other provision of this subparagraph, if a pro-
25 ducer of tobacco leaf is also a tobacco product man-

1 manufacturer or controlled by a tobacco product manu-
2 facturer, the producer shall be subject to this chap-
3 ter in the producer's capacity as a manufacturer.
4 Nothing in this chapter shall be construed to grant
5 the Secretary authority to promulgate regulations on
6 any matter that involves the production of tobacco
7 leaf or a producer thereof, other than activities by
8 a manufacturer affecting production. For purposes
9 of the preceding sentence, the term 'controlled by'
10 means a member of the same controlled group of
11 corporations as that term is used in section 52(a)
12 of the Internal Revenue Code of 1986, or under
13 common control within the meaning of the regula-
14 tions promulgated under section 52(b) of such Code.

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

16 “A tobacco product shall be deemed to be adulterated
17 if—

18 “(1) it consists in whole or in part of any filthy,
19 putrid, or decomposed substance, or is otherwise
20 contaminated by any poisonous or deleterious sub-
21 stance that may render the product more injurious
22 to health;

23 “(2) it has been prepared, packed, or held
24 under insanitary conditions whereby it may have

1 been contaminated with filth, or whereby it may
2 have been rendered more injurious to health;

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

7 “(4) it is, or purports to be or is represented
8 as, a tobacco product which is subject to a perform-
9 ance standard established under section 907 unless
10 such tobacco product is in all respects in conformity
11 with such standard;

12 “(5) it is required by section 910(a) to have
13 premarket approval, is not exempt under section
14 906(f), and does not have an approved application in
15 effect;

16 “(6) the methods used in, or the facilities or
17 controls used for, its manufacture, packing or stor-
18 age are not in conformity with applicable require-
19 ments under section 906(e)(1) or an applicable con-
20 dition prescribed by an order under section
21 906(e)(2); or

22 “(7) it is a tobacco product for which an ex-
23 emption has been granted under section 906(f) for
24 investigational use and the person who was granted
25 such exemption or any investigator who uses such

1 tobacco product under such exemption fails to com-
2 ply with a requirement prescribed by or under such
3 section.

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

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

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

9 “(2) if in package form unless it bears a label
10 containing—

11 “(A) the name and place of business of the
12 tobacco product manufacturer, packer, or dis-
13 tributor; and

14 “(B) an accurate statement of the quantity
15 of the contents in terms of weight, measure, or
16 numerical count,

17 except that under subparagraph (B) of this para-
18 graph reasonable variations shall be permitted, and
19 exemptions as to small packages shall be established,
20 by regulations prescribed by the Secretary;

21 “(3) if any word, statement, or other informa-
22 tion required by or under authority of this chapter
23 to appear on the label or labeling is not prominently
24 placed thereon with such conspicuousness (as com-
25 pared with other words, statements or designs in the

1 labeling) and in such terms as to render it likely to
2 be read and understood by the ordinary individual
3 under customary conditions of purchase and use;

4 “(4) if it has an established name, unless its
5 label bears, to the exclusion of any other nonpropri-
6 etary name, its established name prominently print-
7 ed in type as required by the Secretary by regula-
8 tion;

9 “(5) if the Secretary has issued regulations re-
10 quiring that its labeling bear adequate directions for
11 use, or adequate warnings against use by children,
12 that are necessary for the protection of users unless
13 its labeling conforms in all respects to such regula-
14 tions;

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

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

3 “(A) its advertising is false or misleading
4 in any particular; or

5 “(B) it is sold, distributed, or used in vio-
6 lation of regulations prescribed under section
7 906(d);

8 “(8) unless, in the case of any tobacco product
9 distributed or offered for sale in any State, the man-
10 ufacturer, packer, or distributor thereof includes in
11 all advertisements and other descriptive printed mat-
12 ter issued or caused to be issued by the manufac-
13 turer, packer, or distributor with respect to that to-
14 bacco product—

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

18 “(B) a brief statement of—

19 “(i) the uses of the tobacco product
20 and relevant warnings, precautions, side
21 effects, and contraindications; and

22 “(ii) in the case of specific tobacco
23 products made subject to a finding by the
24 Secretary after notice and opportunity for
25 comment that such action is necessary to

1 protect the public health, a full description
2 of the components of such tobacco product
3 or the formula showing quantitatively each
4 ingredient of such tobacco product to the
5 extent required in regulations which shall
6 be issued by the Secretary after an oppor-
7 tunity for a hearing;

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

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

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

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

17 “(b) PRIOR APPROVAL OF STATEMENTS ON
18 LABEL.—The Secretary may, by regulation, require prior
19 approval of statements made on the label of a tobacco
20 product. No regulation issued under this subsection may
21 require prior approval by the Secretary of the content of
22 any advertisement and no advertisement of a tobacco
23 product, published after the date of enactment of this Act
24 shall, with respect to the matters specified in this section
25 or covered by regulations issued hereunder, be subject to

1 the provisions of sections 12 through 15 of the Federal
2 Trade Commission Act (15 U.S.C. 52 through 55). This
3 subsection does not apply to any printed matter which the
4 Secretary determines to be labeling as defined in section
5 201(m).

6 **“SEC. 904. SUBMISSION OF HEALTH INFORMATION TO THE**
7 **SECRETARY.**

8 “(a) REQUIREMENT.—Not later than 6 months after
9 the date of enactment of this Act, each tobacco product
10 manufacturer or importer of tobacco products, or agents
11 thereof, shall submit to the Secretary the following infor-
12 mation:

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

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

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

1 bacco products, their constituents, ingredients, and
2 components, and tobacco additives, described in
3 paragraph (1).

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

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

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

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

23 “(c) TIME FOR SUBMISSION.—

24 “(1) NEW PRODUCTS.—At least 90 days prior
25 to the delivery for introduction into interstate com-

1 merce of a tobacco product not on the market on the
2 date of enactment of this chapter, the manufacturer
3 of such product shall provide the information re-
4 quired under subsection (a) and such product shall
5 be subject to the annual submission under sub-
6 section (b).

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

17 **“SEC. 905. ANNUAL REGISTRATION.**

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

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

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

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

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

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

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

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

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

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

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

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

17 “(i) REGISTRATION INFORMATION.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

10 “(d) RESTRICTIONS.—

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

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

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

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

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

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

1 “(B) The Secretary shall—

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

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

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

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

1 “(2) EXEMPTIONS; VARIANCES.—

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

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

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

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

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

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

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

15 “(C) The Secretary may approve—

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

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

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

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

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

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

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

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

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

7 “(a) IN GENERAL.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

9 “(b) ESTABLISHMENT OF STANDARDS.—

10 “(1) NOTICE.—

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

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

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

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

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

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

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

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

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

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

5 “(2) PROMULGATION.—

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

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

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

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

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

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

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

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

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

17 “(4) AMENDMENT; REVOCATION.—

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

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

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

6 “(5) REFERENCE TO ADVISORY COMMITTEE.—

7 The Secretary—

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

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

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

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

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

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

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

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

24 the Secretary may issue such order as may be necessary
25 to assure that adequate notification is provided in an ap-

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

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

13 “(c) RECALL AUTHORITY.—

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

1 later than 10 days after the date of the issuance of
2 the order, on the actions required by the order and
3 on whether the order should be amended to require
4 a recall of such tobacco product. If, after providing
5 an opportunity for such a hearing, the Secretary de-
6 termines that inadequate grounds exist to support
7 the actions required by the order, the Secretary shall
8 vacate the order.

9 “(2) AMENDMENT OF ORDER TO REQUIRE RE-
10 CALL.—

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

22 “(B) An amended order under subpara-
23 graph (A)—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 importer if the removal or correction was
2 undertaken—

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

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

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

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

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

20 “(a) IN GENERAL.—

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

1 keting) in the United States as of the date of this
2 Act’s enactment, is required unless the manufacturer
3 has submitted a report under section 905(j), and the
4 Secretary has issued an order within 90 days under
5 section 905(j) that the tobacco product is substan-
6 tially equivalent to a tobacco product commercially
7 marketed (other than for test marketing) in the
8 United States as of the date of this Act’s enactment,
9 that is in compliance with the requirements of this
10 Act.

11 “(2) SUBSTANTIALLY EQUIVALENT DEFINED.—

12 “(A) For purposes of this section and sec-
13 tion 905(j), the term ‘substantially equivalent’
14 or ‘substantial equivalence’ mean, with respect
15 to the tobacco product being compared to the
16 predicate tobacco product, that the Secretary by
17 order has found that the tobacco product—

18 “(i) has the same characteristics as
19 the predicate tobacco product; or

20 “(ii) has different characteristics and
21 the information submitted contains infor-
22 mation, including clinical data if deemed
23 necessary by the Secretary, that dem-
24 onstrates that it is not appropriate to reg-
25 ulate the product under this section be-

1 cause the product does not raise different
2 questions of public health.

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

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

13 “(3) HEALTH INFORMATION.—

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

21 “(B) Any summary under subparagraph
22 (A) respecting a tobacco product shall contain
23 detailed information regarding data concerning
24 adverse health effects and shall be made avail-
25 able to the public by the Secretary within 30

1 days of the issuance of a determination that
2 such tobacco product is substantially equivalent
3 to another tobacco product. The communication
4 that such product is a reduced risk product
5 may comply with requirements prescribed by
6 the Secretary relating to such communication,
7 and the Secretary may require prior approval
8 of the communication.

9 “(b) APPLICATION.—

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

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

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

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

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

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

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

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

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

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

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

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

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

7 “(c) ACTION ON APPLICATION.—

8 “(1) DEADLINE.—

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

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

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

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

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

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

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

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

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

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

18 “(4) BASIS FOR FINDING.—For purposes of
19 this section, the finding as to whether approval of a
20 tobacco product is appropriate for the protection of
21 the public health shall be determined with respect to
22 the risks and benefits to the population as a whole,
23 including users and non-users of the tobacco prod-
24 uct, and taking into account—

1 “(A) the increased or decreased likelihood
2 that existing users of tobacco products will stop
3 using such products; and

4 “(B) the increased or decreased likelihood
5 that those who do not use tobacco products will
6 start using such products.

7 “(5) BASIS FOR ACTION.—

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

17 “(B) If the Secretary determines that
18 there exists valid scientific evidence (other than
19 evidence derived from investigations described
20 in subparagraph (A)) which is sufficient to
21 evaluate the tobacco product the Secretary may
22 authorize that the determination for purposes
23 of paragraph (2)(A) be made on the basis of
24 such evidence.

25 “(d) WITHDRAWAL AND TEMPORARY SUSPENSION.—

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

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

11 “(B) that the application contained or was
12 accompanied by an untrue statement of a mate-
13 rial fact;

14 “(C) that the applicant—

15 “(i) has failed to establish a system
16 for maintaining records, or has repeatedly
17 or deliberately failed to maintain records
18 or to make reports, required by an applica-
19 ble regulation under section 909;

20 “(ii) has refused to permit access to,
21 or copying or verification of, such records
22 as required by section 704; or

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

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

13 “(E) on the basis of new information be-
14 fore the Secretary, evaluated together with the
15 evidence before the Secretary when the applica-
16 tion was approved, that the labeling of such to-
17 bacco product, based on a fair evaluation of all
18 material facts, is false or misleading in any par-
19 ticular and was not corrected within a reason-
20 able time after receipt of written notice from
21 the Secretary of such fact; or

22 “(F) on the basis of new information be-
23 fore the Secretary, evaluated together with the
24 evidence before the Secretary when the applica-
25 tion was approved, that such tobacco product is

1 not shown to conform in all respects to a per-
2 formance standard which is in effect under sec-
3 tion 907, compliance with which was a condi-
4 tion to approval of the application, and that
5 there is a lack of adequate information to jus-
6 tify the deviation from such standard.

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

14 “(3) TEMPORARY SUSPENSION.—If, after pro-
15 viding an opportunity for an informal hearing, the
16 Secretary determines there is reasonable probability
17 that the continuation of distribution of a tobacco
18 product under an approved application would cause
19 serious, adverse health consequences or death, that
20 is greater than ordinarily caused by tobacco prod-
21 ucts on the market, the Secretary shall by order
22 temporarily suspend the approval of the application
23 approved under this section. If the Secretary issues
24 such an order, the Secretary shall proceed expedi-

1 tiously under paragraph (1) to withdraw such appli-
2 cation.

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

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

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

11 **“SEC. 911. JUDICIAL REVIEW.**

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

13 “(1) the promulgation of a regulation under
14 section 907 establishing, amending, or revoking a
15 performance standard for a tobacco product; or

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

18 any person adversely affected by such regulation or order
19 may file a petition with the United States Court of Ap-
20 peals for the District of Columbia or for the circuit where-
21 in such person resides or has his principal place of busi-
22 ness for judicial review of such regulation or order. A copy
23 of the petition shall be transmitted by the clerk of the
24 court to the Secretary or other officer designated by the
25 Secretary for that purpose. The Secretary shall file in the

1 court the record of the proceedings on which the Secretary
2 based the Secretary's regulation or order and each record
3 or order shall contain a statement of the reasons for its
4 issuance and the basis, on the record, for its issuance. For
5 purposes of this section, the term 'record' means all no-
6 tices and other matter published in the Federal Register
7 with respect to the regulation or order reviewed, all infor-
8 mation submitted to the Secretary with respect to such
9 regulation or order, proceedings of any panel or advisory
10 committee with respect to such regulation or order, any
11 hearing held with respect to such regulation or order, and
12 any other information identified by the Secretary, in the
13 administrative proceeding held with respect to such regu-
14 lation or order, as being relevant to such regulation or
15 order.

16 “(b) COURT MAY ORDER SECRETARY TO MAKE AD-
17 DITIONAL FINDINGS.—If the petitioner applies to the
18 court for leave to adduce additional data, views, or argu-
19 ments respecting the regulation or order being reviewed
20 and shows to the satisfaction of the court that such addi-
21 tional data, views, or arguments are material and that
22 there were reasonable grounds for the petitioner's failure
23 to adduce such data, views, or arguments in the pro-
24 ceedings before the Secretary, the court may order the
25 Secretary to provide additional opportunity for the oral

1 presentation of data, views, or arguments and for written
2 submissions. The Secretary may modify the Secretary's
3 findings, or make new findings by reason of the additional
4 data, views, or arguments so taken and shall file with the
5 court such modified or new findings, and the Secretary's
6 recommendation, if any, for the modification or setting
7 aside of the regulation or order being reviewed, with the
8 return of such additional data, views, or arguments.

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

19 “(d) FINALITY OF JUDGMENT.—The judgment of the
20 court affirming or setting aside, in whole or in part, any
21 regulation or order shall be final, subject to review by the
22 Supreme Court of the United States upon certiorari or
23 certification, as provided in section 1254 of title 28,
24 United States Code.

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

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

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

13 “(a) REQUIREMENTS.—

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

18 “(2) DESIGNATION.—

19 “(A) IN GENERAL.—A product may be
20 designated by the Secretary as a reduced risk
21 tobacco product if the Secretary finds that the
22 product will significantly reduce harm to indi-
23 viduals caused by a tobacco product and is oth-
24 erwise appropriate to protect public health,
25 based on an application submitted by the manu-

1 facturer of the product (or other responsible
2 person) that—

3 “(i) demonstrates through testing on
4 animals and short-term human testing that
5 use of such product results in ingestion or
6 inhalation of a substantially lower yield of
7 toxic substances than use of conventional
8 tobacco products in the same category as
9 the proposed reduced risk product; and

10 “(ii) if required by the Secretary, in-
11 cludes studies of the long-term health ef-
12 fects of the product.

13 If such studies are required, the manufacturer
14 may consult with the Secretary regarding proto-
15 cols for conducting the studies.

16 “(B) BASIS FOR FINDING.—In making the
17 finding under subparagraph (A), the Secretary
18 shall take into account—

19 “(i) the risks and benefits to the pop-
20 ulation as a whole, including both users of
21 tobacco products and non-users of tobacco
22 products;

23 “(ii) the increased or decreased likeli-
24 hood that existing users of tobacco prod-

1 ucts will stop using such products includ-
2 ing reduced risk tobacco products;

3 “(iii) the increased or decreased likeli-
4 hood that those who do not use tobacco
5 products will start to use such products,
6 including reduced risk tobacco products;
7 and

8 “(iv) the risks and benefits to con-
9 sumers from the use of a reduced risk to-
10 bacco product as compared to the use of
11 products approved under chapter V to re-
12 duce exposure to tobacco.

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

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

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

22 “(C) complies with requirements prescribed
23 by the Secretary relating to marketing and ad-
24 vertising of the product, and other provisions of
25 this chapter as prescribed by the Secretary, al-

1 though in no event shall such requirements pro-
2 hibit the communication that such product is a
3 reduced risk product. The communication that
4 such product is a reduced risk product may
5 comply with requirements prescribed by the
6 Secretary relating to such communication, and
7 the Secretary may require prior approval of the
8 communication.

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

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

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

20 “(c) LIMITATION.—A tobacco product that is des-
21 ignated as a reduced risk tobacco product that is in com-
22 pliance with subsection (a) shall not be regulated as a
23 drug or device.

24 “(d) DEVELOPMENT OF REDUCED RISK TOBACCO
25 PRODUCT TECHNOLOGY.—A tobacco product manufac-

1 turer shall provide written notice to the Secretary upon
2 the development or acquisition by the manufacturer of any
3 technology that would reduce the risk of a tobacco product
4 to the health of the user for which the manufacturer is
5 not seeking designation as a ‘reduced risk tobacco product’
6 under subsection (a).

7 “(e) POSTMARKET SURVEILLANCE.—

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

17 “(2) SURVEILLANCE APPROVAL.—Each tobacco
18 product manufacturer required to conduct a surveil-
19 lance of a reduced risk tobacco product under para-
20 graph (1) shall, within 30 days after receiving notice
21 that the manufacturer is required to conduct such
22 surveillance, submit, for the approval of the Sec-
23 retary, a protocol for the required surveillance. The
24 Secretary, within 60 days of the receipt of such pro-
25 tocol, shall determine if the principal investigator

1 proposed to be used in the surveillance has sufficient
2 qualifications and experience to conduct such sur-
3 veillance and if such protocol will result in collection
4 of useful data or other information necessary to pro-
5 tect the public health. The Secretary may not ap-
6 prove such a protocol until it has been reviewed by
7 an appropriately qualified scientific and technical re-
8 view committee established by the Secretary.

9 **“SEC. 913. PRESERVATION OF STATE AND LOCAL AUTHOR-**
10 **ITY.**

11 “(a) ADDITIONAL REQUIREMENTS.—

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

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

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

1 ment applicable under the provisions of this
2 chapter relating to performance standards, pre-
3 market approval, adulteration, misbranding,
4 registration, labeling, good manufacturing
5 standards, or reduced risk products.

6 “(B) Subparagraph (A) does not apply to
7 requirements relating to the sale, use, or dis-
8 tribution of a tobacco product including require-
9 ments related to the access to, and the adver-
10 tising and promotion of, a tobacco product.

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

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

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

22 **SEC. 5. REGULATORY RECORD.**

23 Notwithstanding the provisions of subchapter II of
24 chapter 5 of title 5, United States Code, in promulgating
25 regulations under this chapter, the record developed and

1 utilized by the Secretary for the purposes of promulgating
2 subparts (B) and (D) of the regulations relating to the
3 sale, distribution, and use of tobacco products on or about
4 August 28, 1996, as reflected in articles IV and VI of the
5 preamble to the 1996 Food and Drug Administration To-
6 bacco Rule (including public comments, Food and Drug
7 Administration documents, and any other information
8 generated or compiled for purposes of promulgating such
9 regulations), shall be deemed to have the same legal status
10 as if such record had been developed under a rulemaking
11 proceeding conducted pursuant to section 906(d)(1). In all
12 other respects, including with respect to the issue of
13 whether such regulations conform to section 906(d)(1),
14 the procedural requirements of this chapter and the Ad-
15 ministration Procedure Act will apply.

16 **SEC. 6. CONFORMING AND OTHER AMENDMENTS TO GEN-**
17 **ERAL PROVISIONS.**

18 (a) AMENDMENT OF FEDERAL FOOD, DRUG, AND
19 COSMETIC ACT.—Except as otherwise expressly provided,
20 whenever in this section an amendment is expressed in
21 terms of an amendment to, or repeal of, a section or other
22 provision, the reference is to a section or other provision
23 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
24 301 et seq.).

1 (b) SECTION 301.—Section 301 (21 U.S.C. 331) is
2 amended—

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

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

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

9 (4) in subsection (e), by striking “515(f), or
10 519” and inserting “515(f), 519, or 909”;

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

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

15 (7) in subsection (j), by striking “708, or 721”
16 and inserting “708, 721, 903, 904, 905, 906, 907,
17 908, 909, 910, or 912”;

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

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

22 “(p) The failure to register in accordance with section
23 510 or 905, the failure to provide any information re-
24 quired by section 510(j), 510(k), 905(i), or 905(j), or the

1 failure to provide a notice required by section 510(j)(2)
2 or 905(J)(2).”;

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

5 “(1) The failure or refusal—

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

8 “(B) to furnish any notification or other mate-
9 rial or information required by or under section 519,
10 520(g), 904, 906(f), or 909; or

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

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

15 (12) in subsection (r), by inserting “or tobacco
16 product” after “device” each time that it appears;
17 and

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

19 “(aa) The sale of tobacco products in violation
20 of a no-tobacco-sale order issued under section
21 303(f).”.

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

24 (1) by striking the subsection heading and in-
25 serting the following:

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

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

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

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

9 “(3) If the Secretary finds that a person has
10 committed repeated violations of restrictions promul-
11 gated under section 906(d) at a particular retail out-
12 let then the Secretary may impose a no-tobacco-sale
13 order on that person prohibiting the sale of tobacco
14 products in that outlet. A no-tobacco-sale order may
15 be imposed with a civil penalty under paragraph
16 (1).”;

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

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

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

1 (6) in subparagraph (B) of paragraph (4), as so
2 redesignated—

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

6 (B) by adding at the end the following: “A
7 no-tobacco-sale order permanently prohibiting
8 an individual retail outlet from selling tobacco
9 products shall include provisions that allow the
10 outlet, after a specified period of time, to re-
11 quest that the Secretary compromise, modify,
12 or terminate the order.”;

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

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

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

19 (A) by striking “(3)(A)” and inserting
20 “(4)(A)”;

21 (B) by inserting “or the imposition of a
22 no-tobacco-sale order” after “penalty” the first
23 2 places it appears;

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

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

7 (d) SECTION 304.—Section 304 (21 U.S.C. 334) is
8 amended—

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

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

13 “(E) Any adulterated or misbranded to-
14 bacco product.”;

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

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

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

22 (e) SECTION 702.—Section 702(a) (21 U.S.C.
23 372(a)) is amended—

24 (1) by inserting “(1)” after “(a)”;

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

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

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

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

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

11 (g) SECTION 704.—Section 704 (21 U.S.C. 374) is
12 amended—

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

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

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

21 (h) SECTION 705.—Section 705(b) (21 U.S.C.
22 375(b)) is amended by inserting “tobacco products,” after
23 “devices,”.

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

1 (j) SECTION 801.—Section 801 (21 U.S.C. 381) is
2 amended—

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

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

7 (3) in subsection (a), by striking “drugs or de-
8 vices” each time it appears and inserting “drugs, de-
9 vices, or tobacco products”.

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

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

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

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

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

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

3 (3) providing that a person may not be charged
4 with repeated violations at a particular retail outlet
5 unless the Secretary has provided notice of previous
6 violations at that outlet;

7 (4) establishing a period of time during which,
8 if there are no violations by a particular retail out-
9 let, that outlet will not considered to have been the
10 site of repeated violations when the next violation oc-
11 curs; and

12 (5) providing that good faith reliance on false
13 identification does not constitute a violation of any
14 minimum age requirement for the sale of tobacco
15 products.

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

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

20 **“SEC. 4. LABELING.**

21 “(a) LABEL REQUIREMENTS.—

22 “(1) IN GENERAL.—It shall be unlawful for any
23 person to manufacture, package, or import for sale
24 or distribution within the United States any ciga-
25 rettes the package of which fails to bear, in accord-

1 ance with the requirements of this section, one of
2 the following labels:

3 “WARNING: Cigarettes are addictive”

4 “WARNING: Tobacco smoke can harm your chil-
5 dren”

6 “WARNING: Cigarettes cause fatal lung disease”

7 “WARNING: Cigarettes cause cancer”

8 “WARNING: Cigarettes cause strokes and heart
9 disease”

10 “WARNING: Smoking during pregnancy can harm
11 your baby”

12 “WARNING: Smoking can kill you”

13 “WARNING: Tobacco smoke causes fatal lung dis-
14 ease in non-smokers”

15 “WARNING: Quitting smoking now greatly reduces
16 serious risks to your health”

17 “(2) PLACEMENT; TYPOGRAPHY; ETC.—

18 “(A) IN GENERAL.—Each label statement
19 required by paragraph (1) shall be located in
20 the upper portion of the front and rear panels
21 of the package, directly on the package under-
22 neath the cellophane or other clear wrapping.
23 Except as provided in subparagraph (B), each
24 label statement shall comprise at least the top
25 25 percent of the front and rear panels of the

1 package. The word “WARNING” shall appear
2 in capital letters and all text shall be in con-
3 spicuous and legible 17-point type, unless the
4 text of the label statement would occupy more
5 than 70 percent of such area, in which case the
6 text may be in a smaller conspicuous and leg-
7 ible type size, provided that at least 60 percent
8 of such area is occupied by required text. The
9 text shall be black on a white background, or
10 white on a black background, in a manner that
11 contrasts, by typography, layout, or color, with
12 all other printed material on the package, in an
13 alternating fashion under the plan submitted
14 under subsection (b)(4).

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

1 “(3) DOES NOT APPLY TO FOREIGN DISTRIBUTION.—The provisions of this subsection do not
2 apply to a tobacco product manufacturer or distributor of cigarettes which does not manufacture,
3 package, or import cigarettes for sale or distribution within the United States.
4
5

6 “(b) ADVERTISING REQUIREMENTS.—
7

8 “(1) IN GENERAL.—It shall be unlawful for any
9 tobacco product manufacturer, importer, distributor, or retailer of cigarettes to advertise or cause to be
10 advertised within the United States any cigarette unless its advertising bears, in accordance with the
11 requirements of this section, one of the labels specified in subsection (a) of this section.
12
13
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15 “(2) TYPOGRAPHY, ETC.—Each label statement
16 required by subsection (a) of this section in cigarette advertising shall comply with the standards set forth
17 in this paragraph. For press and poster advertisements, each such statement and (where applicable)
18 any required statement relating to tar, nicotine, or other constituent yield shall comprise at least 20
19 percent of the area of the advertisement and shall appear in a conspicuous and prominent format and
20 location at the top of each advertisement within the trim area. The Secretary may revise the required
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1 type sizes in such area in such manner as the Sec-
2 retary determines appropriate. The word “WARN-
3 ING” shall appear in capital letters, and each label
4 statement shall appear in conspicuous and legible
5 type. The text of the label statement shall be black
6 if the background is white and white if the back-
7 ground is black, under the plan submitted under
8 paragraph (4) of this subsection. The label state-
9 ments shall be enclosed by a rectangular border that
10 is the same color as the letters of the statements
11 and that is the width of the first downstroke of the
12 capital “W” of the word “WARNING” in the label
13 statements. The text of such label statements shall
14 be in a typeface pro rata to the following require-
15 ments: 45-point type for a whole-page broadsheet
16 newspaper advertisement; 39-point type for a half-
17 page broadsheet newspaper advertisement; 39-point
18 type for a whole-page tabloid newspaper advertise-
19 ment; 27-point type for a half-page tabloid news-
20 paper advertisement; 31.5-point type for a double
21 page spread magazine or whole-page magazine ad-
22 vertisement; 22.5-point type for a 28 centimeter by
23 3 column advertisement; and 15-point type for a 20
24 centimeter by 2 column advertisement. The label

1 statements shall be in English, except that in the
2 case of—

3 “(A) an advertisement that appears in a
4 newspaper, magazine, periodical, or other publi-
5 cation that is not in English, the statements
6 shall appear in the predominant language of the
7 publication; and

8 “(B) in the case of any other advertise-
9 ment that is not in English, the statements
10 shall appear in the same language as that prin-
11 cipally used in the advertisement.

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

1 justments in the format and type sizes of any text
2 required to appear in such area to ensure that the
3 total text required to appear by law will fit within
4 such area.

5 “(4) MARKETING REQUIREMENTS.—

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

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

23 “(C) The Secretary shall review each plan
24 submitted under subparagraph (B) and approve
25 it if the plan—

1 “(i) will provide for the equal distribu-
2 tion and display on packaging and the ro-
3 tation required in advertising under this
4 subsection; and

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

10 **SEC. 8. AUTHORITY TO REVISE CIGARETTE WARNING**
11 **LABEL STATEMENTS.**

12 Section 4 of the Federal Cigarette Labeling and Ad-
13 vertising Act (15 U.S.C. 1333), as amended by section 4,
14 is further amended by adding at the end the following:

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

1 promote greater public understanding of the risks associ-
 2 ated with the use of smokeless tobacco products.”.

3 **SEC. 9. SMOKELESS TOBACCO LABELS AND ADVERTISING**
 4 **WARNINGS.**

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

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

9 “(a) GENERAL RULE.—

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

16 “WARNING: This product can cause mouth cancer”

17 “WARNING: This product can cause gum disease
 18 and tooth loss”

19 “WARNING: This product is not a safe alternative
 20 to cigarettes”

21 “WARNING: Smokeless tobacco is addictive”

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

24 “(A) located on the 2 principal display
 25 panels of the package, and each label statement

1 shall comprise at least 25 percent of each such
2 display panel; and

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

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

21 “(4) The provisions of this subsection do not
22 apply to a tobacco product manufacturer or dis-
23 tributor of any smokeless tobacco product that does
24 not manufacture, package, or import smokeless to-

1 bacco products for sale or distribution within the
2 United States.

3 “(b) REQUIRED LABELS.—

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

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

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

22 “(B) the word “WARNING” shall appear
23 in capital letters and each label statement shall
24 appear in conspicuous and legible type. The text
25 of the label statement shall be black on a white

1 background, or white on a black background, in
2 an alternating fashion under the plan submitted
3 under paragraph (3).

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

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

20 “(C) The Secretary shall review each plan sub-
21 mitted under subparagraph (B) and approve it if the
22 plan—

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

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

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

9 **SEC. 10. AUTHORITY TO REVISE SMOKELESS TOBACCO**
10 **PRODUCT WARNING LABEL STATEMENTS.**

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

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

1 derstanding of the risks associated with the use of smoke-
2 less tobacco products.”.

3 **SEC. 11. TAR, NICOTINE, AND OTHER SMOKE CONSTITUENT**
4 **DISCLOSURE TO THE PUBLIC.**

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

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

23 “(B) Any differences between the requirements
24 established by the Secretary under subparagraph (A)
25 and tar and nicotine yield reporting requirements es-

1 established by the Federal Trade Commission shall be
2 resolved by a memorandum of understanding be-
3 tween the Secretary and the Federal Trade Commis-
4 sion.

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

23 **SEC. 12. REGULATION REQUIREMENT.**

24 (a) TESTING, REPORTING, AND DISCLOSURE.—Not
25 later than 24 months after the date of enactment of this

1 Act, the Secretary, through the Commissioner of the Food
2 and Drug Administration, shall promulgate regulations
3 under the Federal Food, Drug, and Cosmetic Act (21
4 U.S.C. 301 et seq.) that meet the requirements of sub-
5 section (b) of this section.

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

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

1 **SEC. 13. FTC JURISDICTION NOT AFFECTED.**

2 (a) IN GENERAL.—Except where expressly provided
3 in this Act, nothing in this Act shall be construed as lim-
4 iting or diminishing the authority of the Federal Trade
5 Commission to enforce the laws under its jurisdiction with
6 respect to the advertising, sale, or distribution of tobacco
7 products.

8 (b) ENFORCEMENT BY FTC.—Any advertising that
9 violates this Act is an unfair or deceptive act or practice
10 under section 5(a) of the Federal Trade Commission Act
11 (15 U.S.C. 45(a)) and shall be considered a violation of
12 a rule promulgated under section 18 of that Act (15
13 U.S.C. 57a).

○