

106TH CONGRESS  
2D SESSION

# S. 2568

To protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products.

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IN THE SENATE OF THE UNITED STATES

MAY 16, 2000

Mr. KENNEDY (for himself, Mr. LAUTENBERG, Mr. DURBIN, Mr. KERRY, and Mr. WELLSTONE) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## A BILL

To protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products.

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

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

4 (a) SHORT TITLE.—This Act may be cited as the  
5 “Youth Smoking Prevention and Public Health Protection  
6 Act”.

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

Sec. 1. Short title.

Sec. 2. Findings.

- Sec. 3. Purpose.  
 Sec. 4. Scope and effect.

TITLE I—AUTHORITY OF THE FOOD AND DRUG  
 ADMINISTRATION

- Sec. 101. Amendment of Federal Food, Drug, and Cosmetic Act.

“CHAPTER IX—TOBACCO PRODUCTS

- “Sec. 900. Definitions.  
 “Sec. 901. FDA authority over tobacco products  
 “Sec. 902. Adulterated tobacco products.  
 “Sec. 903. Misbranded tobacco products.  
 “Sec. 904. Submission of health information to the Secretary.  
 “Sec. 905. Annual registration.  
 “Sec. 906. General provisions respecting control of tobacco products.  
 “Sec. 907. Performance standards.  
 “Sec. 908. Notification and other remedies  
 “Sec. 909. Records and reports on tobacco products.  
 “Sec. 910. Premarket review of certain tobacco products.  
 “Sec. 911. Judicial review.  
 “Sec. 912. Postmarket surveillance  
 “Sec. 913. Reduced risk tobacco products.  
 “Sec. 914. Equal treatment of retail outlets.  
 “Sec. 915. Jurisdiction of and coordination with the Federal Trade Commission.  
 “Sec. 916. Congressional review provisions.  
 “Sec. 917. Regulation requirement.  
 “Sec. 918. Preservation of State and local authority.  
 Sec. 102. Construction of current regulations.  
 Sec. 103. Conforming and other amendments to general provisions.

TITLE II—TOBACCO PRODUCT WARNINGS AND SMOKE  
 CONSTITUENT DISCLOSURE

- Sec. 201. Cigarette label and advertising warnings.  
 Sec. 202. Authority to revise cigarette warning label Statements.  
 Sec. 203. Smokeless tobacco labels and advertising warnings.  
 Sec. 204. Authority to revise smokeless tobacco product warning label Statements.  
 Sec. 205. Tar, nicotine, and other smoke constituent disclosure to the public.  
 Sec. 206. Unlawful advertisements.

**1 SEC. 2. FINDINGS.**

**2** The Congress finds the following:

- 3** (1) The use of tobacco products by the Nation’s  
**4** children is a pediatric disease of epic and worsening  
**5** proportions that results in new generations of to-  
**6** bacco-dependent children and adults.

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

5           (3) Nicotine is an addictive drug.

6           (4) Virtually all new users of tobacco products  
7           are under the minimum legal age to purchase such  
8           products.

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

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

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

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

1           (9) Under Article I, Section 8 of the Constitu-  
2           tion, the Congress is vested with the responsibility  
3           for regulating interstate commerce and commerce  
4           with Indian tribes.

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

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

17          (12) The citizens of the several States are ex-  
18          posed to, and adversely affected by, environmental  
19          smoke in public buildings and other facilities which  
20          imposes a burden on interstate commerce.

21          (13) It is in the public interest for Congress to  
22          adopt legislation that provides the Food and Drug  
23          Administration with the authority to regulate to-  
24          bacco products because of tobacco's unique position  
25          in the Nation's history and economy; the need to

1 prevent the sale, distribution, marketing and adver-  
2 tising of tobacco products to persons under the min-  
3 imum legal age to purchase such products; and the  
4 need to educate the public, especially young people,  
5 regarding the health effects of using tobacco prod-  
6 ucts.

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

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

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

23 (17) In 1995, the tobacco industry spent close  
24 to \$4,900,000,000 to attract new users, retain cur-  
25 rent users, increase current consumption, and gen-

1 erate favorable long-term attitudes toward smoking  
2 and tobacco use.

3 (18) Tobacco product advertising often  
4 misleadingly portrays the use of tobacco as socially  
5 acceptable and healthful to minors.

6 (19) Tobacco product advertising is regularly  
7 seen by persons under the age of 18, and persons  
8 under the age of 18 are regularly exposed to tobacco  
9 product promotional efforts.

10 (20) Through advertisements during and spon-  
11 sorship of sporting events, tobacco has become  
12 strongly associated with sports and has become por-  
13 trayed as an integral part of sports and the healthy  
14 lifestyle associated with rigorous sporting activity.

15 (21) Children are exposed to substantial and  
16 unavoidable tobacco advertising that leads to favor-  
17 able beliefs about tobacco use, plays a role in leading  
18 young people to overestimate the prevalence of to-  
19 bacco use, and increases the number of young people  
20 who begin to use tobacco.

21 (22) Tobacco advertising increases the size of  
22 the tobacco market by increasing consumption of to-  
23 bacco products including increasing tobacco use by  
24 young people.

1           (23) Children are more influenced by tobacco  
2 advertising than adults, they smoke the most adver-  
3 tised brands, and children as young as 3 to 6 years  
4 old can recognize a character associated with smok-  
5 ing at the same rate as they recognize cartoons and  
6 fast food characters.

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

10          (25) Comprehensive advertising restrictions will  
11 have a positive effect on the smoking rates of young  
12 people.

13          (26) Restrictions on advertising are necessary  
14 to prevent unrestricted tobacco advertising from un-  
15 dermining legislation prohibiting access to young  
16 people and providing for education about tobacco  
17 use.

18          (27) International experience shows that adver-  
19 tising regulations that are stringent and comprehen-  
20 sive have a greater impact on overall tobacco use  
21 and young people's use than weaker or less com-  
22 prehensive ones. Text-only requirements, while not  
23 as stringent as a ban, will help reduce underage use  
24 of tobacco products while preserving the informa-  
25 tional function of advertising.

1           (28) It is in the public interest for Congress to  
2           adopt legislation to address the public health crisis  
3           created by actions of the tobacco industry.

4           (29) The use of tobacco products in motion pic-  
5           tures and other mass media glamorizes its use for  
6           young people and encourages them to use tobacco  
7           products.

8 **SEC. 3. PURPOSE.**

9           The purposes of this Act are—

10           (1) to provide authority to the Food and Drug  
11           Administration to regulate tobacco products under  
12           the Federal Food, Drug, and Cosmetic Act (21  
13           U.S.C. 301 et seq.), by recognizing it as the primary  
14           Federal regulatory authority with respect to the  
15           manufacture, marketing, and distribution of tobacco  
16           products;

17           (2) to ensure that the Food and Drug Adminis-  
18           tration has the authority to address issues of par-  
19           ticular concern to public health officials, especially  
20           the use of tobacco by young people and dependence  
21           on tobacco;

22           (3) to authorize the Food and Drug Adminis-  
23           tration to set national standards controlling the  
24           manufacture of tobacco products and the identity,

1 public disclosure, and amount of ingredients used in  
2 such products;

3 (4) to provide new and flexible enforcement au-  
4 thority to ensure that there is effective oversight of  
5 the tobacco industry's efforts to develop and intro-  
6 duce less harmful tobacco products;

7 (5) to vest the Food and Drug Administration  
8 with the authority to regulate the levels of tar, nico-  
9 tine, and other harmful components of tobacco prod-  
10 ucts;

11 (6) in order to ensure that adults are better in-  
12 formed, to require tobacco product manufacturers to  
13 disclose research which has not previously been  
14 made available, as well as research generated in the  
15 future, relating to the health and dependency effects  
16 or safety of tobacco products;

17 (7) to continue to permit the sale of tobacco  
18 products to adults in conjunction with measures to  
19 ensure that they are not sold or accessible to under-  
20 age purchasers; and

21 (8) to impose appropriate regulatory controls on  
22 the tobacco industry

23 **SEC. 4. SCOPE AND EFFECT.**

24 (a) INTENDED EFFECT.—Nothing in this Act (or an  
25 amendment made by this Act) shall be construed to—

1 (1) establish a precedent with regard to any  
2 other industry, situation, circumstance, or legal ac-  
3 tion; or

4 (2) affect any action pending in State, Tribal,  
5 or Federal court, or any agreement, consent decree,  
6 or contract of any kind.

7 (b) AGRICULTURAL ACTIVITIES.—The provisions of  
8 this Act (or an amendment made by this Act) which au-  
9 thorize the Secretary to take certain actions with regard  
10 to tobacco and tobacco products shall not be construed to  
11 affect any authority of the Secretary of Agriculture under  
12 existing law regarding the growing, cultivation, or curing  
13 of raw tobacco.

14 **TITLE I—AUTHORITY OF THE**  
15 **FOOD AND DRUG ADMINIS-**  
16 **TRATION**

17 **SEC. 101. AMENDMENT OF FEDERAL FOOD, DRUG, AND**  
18 **COSMETIC ACT.**

19 (a) DEFINITION OF TOBACCO PRODUCTS.—Section  
20 201 of the Federal Food, Drug, and Cosmetic Act (21  
21 U.S.C. 321) is amended by adding at the end the fol-  
22 lowing:

23 “(kk) The term ‘tobacco product’ means any  
24 product made or derived from tobacco that is in-  
25 tended for human consumption, including any com-

1       ponent, part, or accessory of a tobacco product (ex-  
 2       cept for raw materials other than tobacco used in  
 3       manufacturing a component, part, or accessory of a  
 4       tobacco product).”.

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

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

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

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

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

14       **“SEC. 900. DEFINITIONS.**

15       “In this chapter:

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

22               “(2) CIGARETTE.—The term ‘cigarette’ has the  
 23       meaning given that term by section 3(1) of the Fed-  
 24       eral Cigarette Labeling and Advertising Act (15  
 25       U.S.C. 1332(1)), but also includes tobacco, in any

1 form, that is functional in the product, which, be-  
2 cause of its appearance, the type of tobacco used in  
3 the filler, or its packaging and labeling, is likely to  
4 be offered to, or purchased by, consumers as a ciga-  
5 rette or as roll-your-own tobacco.

6 “(3) CIGARETTE TOBACCO.—The term ‘ciga-  
7 rette tobacco’ means any product that consists of  
8 loose tobacco that is intended for use by consumers  
9 in a cigarette. Unless otherwise stated, the require-  
10 ments for cigarettes shall also apply to cigarette to-  
11 bacco.

12 “(4) COMMERCE.—The term ‘commerce’ has  
13 the meaning given that term by section 3(2) of the  
14 Federal Cigarette Labeling and Advertising Act (15  
15 U.S.C. 1332(2)).

16 “(5) DISTRIBUTOR.—The term ‘distributor’ as  
17 regards a tobacco product means any person who  
18 furthers the distribution of cigarette or smokeless to-  
19 bacco, whether domestic or imported, at any point  
20 from the original place of manufacture to the person  
21 who sells or distributes the product to individuals for  
22 personal consumption. Common carriers are not con-  
23 sidered distributors for purposes of this chapter.

24 “(6) INDIAN TRIBE.—The term ‘Indian tribe’  
25 has the meaning given such term in section 4(e) of

1 the Indian Self Determination and Education Assist-  
2 ance Act (25 U.S.C. 450b(e)).

3 “(7) LITTLE CIGAR.—The term ‘little cigar’ has  
4 the meaning given that term by section 3(7) of the  
5 Federal Cigarette Labeling and Advertising Act (15  
6 U.S.C. 1332(7)).

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

11 “(9) PACKAGE.—The term ‘package’ means a  
12 pack, box, carton, or container of any kind or, if no  
13 other container, any wrapping (including cello-  
14 phane), in which cigarettes or smokeless tobacco are  
15 offered for sale, sold, or otherwise distributed to con-  
16 sumers.

17 “(10) RETAILER.—The term ‘retailer’ means  
18 any person who sells cigarettes or smokeless tobacco  
19 to individuals for personal consumption, or who op-  
20 erates a facility where self-service displays of tobacco  
21 products are permitted.

22 “(11) ROLL-YOUR-OWN TOBACCO.—The term  
23 ‘roll-your-own tobacco’ means any tobacco which, be-  
24 cause of its appearance, type, packaging, or labeling,  
25 is suitable for use and likely to be offered to, or pur-

1 chased by, consumers as tobacco for making ciga-  
2 rettes.

3 “(12) SMOKELESS TOBACCO.—The term  
4 ‘smokeless tobacco’ means any product that consists  
5 of cut, ground, powdered, or leaf tobacco and that  
6 is intended to be placed in the oral or nasal cavity.

7 “(13) STATE.—The term ‘State’ means any  
8 State of the United States and, for purposes of this  
9 chapter, includes the District of Columbia, the Com-  
10 monwealth of Puerto Rico, Guam, the Virgin Is-  
11 lands, American Samoa, Wake Island, Midway Is-  
12 lands, Kingman Reef, Johnston Atoll, the Northern  
13 Mariana Islands, and any other trust territory or  
14 possession of the United States.

15 “(14) TOBACCO PRODUCT.—The term ‘tobacco  
16 product’ means cigarettes, cigarette tobacco, smoke-  
17 less tobacco, little cigars, roll-your-own tobacco, and  
18 fine cut products.

19 “(15) TOBACCO PRODUCT MANUFACTURER.—  
20 Term ‘tobacco product manufacturer’ means any  
21 person, including any repacker or relabeler, who—

22 “(A) manufactures, fabricates, assembles,  
23 processes, or labels a finished cigarette or  
24 smokeless tobacco product; or

1           “(B) imports a finished cigarette or  
2           smokeless tobacco product for sale or distribu-  
3           tion in the United States.

4           “(16) UNITED STATES.—The term ‘United  
5           States’ means the 50 States of the United States of  
6           America and the District of Columbia, the Common-  
7           wealth of Puerto Rico, Guam, the Virgin Islands,  
8           American Samoa, Wake Island, Midway Islands,  
9           Kingman Reef, Johnston Atoll, the Northern Mar-  
10          iana Islands, and any other trust territory or posses-  
11          sion of the United States.

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

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

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

20               “(2) a health claim is made for such products  
21               under section 201(g)(1)(C) or 201(h)(3).

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

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

3 “(c) SCOPE.—

4 “(1) IN GENERAL.—Nothing in this chapter, or  
5 any policy issued or regulation promulgated there-  
6 under, or the Youth Smoking Prevention and Public  
7 Health Protection Act, shall be construed to affect  
8 the Secretary’s authority over, or the regulation of,  
9 products under this Act that are not tobacco prod-  
10 ucts under chapter V or any other chapter.

11 “(2) TOBACCO LEAF.—

12 “(A) IN GENERAL.—The provisions of this  
13 chapter shall not apply to tobacco leaf that is  
14 not in the possession of the manufacturer, or to  
15 the producers of tobacco leaf, including tobacco  
16 growers, tobacco warehouses, and tobacco grow-  
17 er cooperatives, nor shall any employee of the  
18 Food and Drug Administration have any au-  
19 thority to enter onto a farm owned by a pro-  
20 ducer of tobacco leaf without the written con-  
21 sent of such producer.

22 “(B) EXCEPTION.—Notwithstanding any  
23 other provision of this subparagraph, if a pro-  
24 ducer of tobacco leaf is also a tobacco product  
25 manufacturer or controlled by a tobacco prod-

1           uct manufacturer, the producer shall be subject  
2           to this chapter in the producer’s capacity as a  
3           manufacturer.

4                   “(C) RULE OF CONSTRUCTION.—Nothing  
5           in this chapter shall be construed to grant the  
6           Secretary authority to promulgate regulations  
7           on any matter that involves the production of  
8           tobacco leaf or a producer thereof, other than  
9           activities by a manufacturer affecting produc-  
10          tion. For purposes of the preceding sentence,  
11          the term ‘controlled by’ means a member of the  
12          same controlled group of corporations as that  
13          term is used in section 52(a) of the Internal  
14          Revenue Code of 1986, or under common con-  
15          trol within the meaning of the regulations pro-  
16          mulgated under section 52(b) of such Code.

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

18           “A tobacco product shall be deemed to be adulterated  
19 if—

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

1           “(2) it has been prepared, packed, or held  
2 under insanitary conditions whereby it may have  
3 been contaminated with filth, or whereby it may  
4 have been rendered injurious to health;

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

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

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

17           “(6) the methods used in, or the facilities or  
18 controls used for, its manufacture, packing or stor-  
19 age are not in conformity with applicable require-  
20 ments under section 906(e)(1) or an applicable con-  
21 dition prescribed by an order under section  
22 906(e)(2); or

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

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

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

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

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

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

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

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

18 except that under subparagraph (B) reasonable vari-  
19 ations shall be permitted, and exemptions as to  
20 small packages shall be established, by regulations  
21 prescribed by the Secretary;

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

1       pared with other words, statements or designs in the  
2       labeling) and in such terms as to render it likely to  
3       be read and understood by the ordinary individual  
4       under customary conditions of purchase and use;

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

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

16          “(6) if it was manufactured, prepared, propa-  
17       gated, compounded, or processed in any State in an  
18       establishment not duly registered under section  
19       905(b), if it was not included in a list required by  
20       section 905(i), if a notice or other information re-  
21       specting it was not provided as required by such sec-  
22       tion or section 905(j), or if it does not bear such  
23       symbols from the uniform system for identification  
24       of tobacco products prescribed under section 905(e)  
25       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), 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;

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

17 “(C) to comply with a requirement under  
18 section 912.

19 “(b) PRIOR APPROVAL OF LABEL STATEMENTS.—  
20 The Secretary may, by regulation, require prior approval  
21 of statements made on the label of a tobacco product. No  
22 regulation issued under this subsection may require prior  
23 approval by the Secretary of the content of any advertise-  
24 ment. No advertisement of a tobacco product, published  
25 after the date of enactment of the Youth Smoking Preven-

1 tion and Public Health Protection Act shall, with respect  
2 to the language of label statements as prescribed under  
3 section 4 of the Cigarette Labeling and Advertising Act  
4 and section 3 of the Comprehensive Smokeless Tobacco  
5 Health Education Act of 1986 or the regulations issued  
6 under such sections, be subject to the provisions of sec-  
7 tions 12 through 15 of the Federal Trade Commission Act  
8 (15 U.S.C. 52 through 55).

9 **“SEC. 904. SUBMISSION OF HEALTH INFORMATION TO THE**  
10 **SECRETARY.**

11 “(a) REQUIREMENT.—Not later than 6 months after  
12 the date of enactment of the Youth Smoking Prevention  
13 and Public Health Protection Act, each tobacco product  
14 manufacturer or importer of tobacco products, or agents  
15 thereof, shall submit to the Secretary the following infor-  
16 mation:

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

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

1           “(3) All documents (including underlying sci-  
2           entific information) relating to research activities,  
3           and research findings, conducted, supported, or pos-  
4           sessed by the manufacturer (or agents thereof) on  
5           the health, behavioral, or physiologic effects of to-  
6           bacco products, their constituents, ingredients, and  
7           components, and tobacco additives, described in  
8           paragraph (1).

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

17          “(5) All documents (including underlying sci-  
18          entific information) relating to marketing research  
19          involving the use of tobacco products.

20          An importer of a tobacco product not manufactured in the  
21          United States shall supply the information required of a  
22          tobacco product manufacturer under this subsection.

23          “(b) ANNUAL SUBMISSION.—A tobacco product man-  
24          ufacturer or importer that is required to submit informa-  
25          tion under subsection (a) shall update such information

1 on an annual basis under a schedule determined by the  
2 Secretary.

3 “(c) TIME FOR SUBMISSION.—

4 “(1) NEW PRODUCTS.—At least 90 days prior  
5 to the delivery for introduction into interstate com-  
6 merce of a tobacco product not on the market on the  
7 date of enactment of the Youth Smoking Prevention  
8 and Public Health Protection Act, the manufacturer  
9 of such product shall provide the information re-  
10 quired under subsection (a) and such product shall  
11 be subject to the annual submission under sub-  
12 section (b).

13 “(2) MODIFICATION OF EXISTING PRODUCTS.—

14 If at any time a tobacco product manufacturer adds  
15 to its tobacco products a new tobacco additive, in-  
16 creases or decreases the quantity of an existing to-  
17 bacco additive or the nicotine content, delivery, or  
18 form, or eliminates a tobacco additive from any to-  
19 bacco product, the manufacturer shall within 60  
20 days of such action so advise the Secretary in writ-  
21 ing and reference such modification in submissions  
22 made under subsection (b).

23 **“SEC. 905. ANNUAL REGISTRATION.**

24 “(a) DEFINITIONS.—In this section:

1           “(1)       MANUFACTURE,       PREPARATION,  
2       COMPOUNDING, OR PROCESSING.—The term ‘manu-  
3       facture, preparation, compounding, or processing’  
4       shall include repackaging or otherwise changing the  
5       container, wrapper, or labeling of any tobacco prod-  
6       uct package in furtherance of the distribution of the  
7       tobacco product from the original place of manufac-  
8       ture to the person who makes final delivery or sale  
9       to the ultimate consumer or user.

10           “(2) NAME.—The term ‘name’ shall include in  
11       the case of a partnership the name of each partner  
12       and, in the case of a corporation, the name of each  
13       corporate officer and director, and the State of in-  
14       corporation.

15           “(b) REGISTRATION BY OWNERS AND OPERATORS.—  
16       On or before December 31 of each year every person who  
17       owns or operates any establishment in any State engaged  
18       in the manufacture, preparation, compounding, or proc-  
19       essing of a tobacco product or tobacco products shall reg-  
20       ister with the Secretary the name, places of business, and  
21       all such establishments of that person.

22           “(c) REGISTRATION OF NEW OWNERS AND OPERA-  
23       TORS.—Every person upon first engaging in the manufac-  
24       ture, preparation, compounding, or processing of a tobacco  
25       product or tobacco products in any establishment owned

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

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

11       “(e) UNIFORM PRODUCT IDENTIFICATION SYS-  
12 TEM.—The Secretary may by regulation prescribe a uni-  
13 form system for the identification of tobacco products and  
14 may require that persons who are required to list such  
15 tobacco products under subsection (i) shall list such to-  
16 bacco products in accordance with such system.

17       “(f) PUBLIC ACCESS TO REGISTRATION INFORMA-  
18 TION.—The Secretary shall make available for inspection,  
19 to any person so requesting, any registration filed under  
20 this section.

21       “(g) BIENNIAL INSPECTION OF REGISTERED ESTAB-  
22 LISHMENTS.—Every establishment in any State registered  
23 with the Secretary under this section shall be subject to  
24 inspection under section 704, and every such establish-  
25 ment engaged in the manufacture, compounding, or proc-

1 essing of a tobacco product or tobacco products shall be  
2 so inspected by one or more officers or employees duly  
3 designated by the Secretary at least once in the 2-year  
4 period beginning with the date of registration of such es-  
5 tablishment under this section and at least once in every  
6 successive 2-year period thereafter.

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

23       “(i) REGISTRATION INFORMATION.—

24               “(1) PRODUCT LIST.—Every person who reg-  
25       isters with the Secretary under subsection (b), (c),

1 or (d) shall, at the time of registration under any  
2 such subsection, file with the Secretary a list of all  
3 tobacco products which are being manufactured, pre-  
4 pared, compounded, or processed by that person for  
5 commercial distribution and which has not been in-  
6 cluded in any list of tobacco products filed by that  
7 person with the Secretary under this paragraph or  
8 paragraph (2) before such time of registration. Such  
9 list shall be prepared in such form and manner as  
10 the Secretary may prescribe and shall be accom-  
11 panied by—

12 “(A) in the case of a tobacco product con-  
13 tained in the applicable list with respect to  
14 which a performance standard has been estab-  
15 lished under section 907 or which is subject to  
16 section 910, a reference to the authority for the  
17 marketing of such tobacco product and a copy  
18 of all labeling for such tobacco product;

19 “(B) in the case of any other tobacco prod-  
20 uct contained in an applicable list, a copy of all  
21 consumer information and other labeling for  
22 such tobacco product, a representative sampling  
23 of advertisements for such tobacco product,  
24 and, upon request made by the Secretary for

1 good cause, a copy of all advertisements for a  
2 particular tobacco product; and

3 “(C) if the registrant filing a list has de-  
4 termined that a tobacco product contained in  
5 such list is not subject to a performance stand-  
6 ard established under section 907, a brief state-  
7 ment of the basis upon which the registrant  
8 made such determination if the Secretary re-  
9 quests such a statement with respect to that  
10 particular tobacco product.

11 “(2) BIENNIAL REPORT OF ANY CHANGE IN  
12 PRODUCT LIST.—Each person who registers with the  
13 Secretary under this section shall report to the Sec-  
14 retary once during the month of June of each year  
15 and once during the month of December of each  
16 year the following:

17 “(A) A list of each tobacco product intro-  
18 duced by the registrant for commercial distribu-  
19 tion which has not been included in any list  
20 previously filed by that person with the Sec-  
21 retary under this subparagraph or paragraph  
22 (1). A list under this subparagraph shall list a  
23 tobacco product by its established name and  
24 shall be accompanied by the other information  
25 required by paragraph (1).

1           “(B) If since the date the registrant last  
2           made a report under this paragraph that person  
3           has discontinued the manufacture, preparation,  
4           compounding, or processing for commercial dis-  
5           tribution of a tobacco product included in a list  
6           filed under subparagraph (A) or paragraph (1),  
7           notice of such discontinuance, the date of such  
8           discontinuance, and the identity of its estab-  
9           lished name.

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

23           “(D) Any material change in any informa-  
24           tion previously submitted under this paragraph  
25           or paragraph (1).

1       “(j) REPORT PRECEDING INTRODUCTION OF CER-  
2 TAIN SUBSTANTIALLY-EQUIVALENT PRODUCTS INTO  
3 INTERSTATE COMMERCE.—

4           “(1) IN GENERAL.—Each person who is re-  
5 quired to register under this section and who pro-  
6 poses to begin the introduction or delivery for intro-  
7 duction into interstate commerce for commercial dis-  
8 tribution of a tobacco product intended for human  
9 use that was not commercially marketed (other than  
10 for test marketing) in the United States as of Au-  
11 gust 11, 1995, as defined by the Secretary by regu-  
12 lation shall, at least 90 days before making such in-  
13 troduction or delivery, report to the Secretary (in  
14 such form and manner as the Secretary shall by regu-  
15 lation prescribe)—

16           “(A) the basis for such person’s determina-  
17 tion that the tobacco product is substantially  
18 equivalent, within the meaning of section 910,  
19 to a tobacco product commercially marketed  
20 (other than for test marketing) in the United  
21 States as of August 11, 1995, that is in compli-  
22 ance with the requirements of this Act; and

23           “(B) action taken by such person to com-  
24 ply with the requirements under section 907  
25 that are applicable to the tobacco product.

1           “(2) APPLICATION TO CERTAIN POST-AUGUST  
2           11TH PRODUCTS.—A report under this subsection  
3           for a tobacco product that was first introduced or  
4           delivered for introduction into interstate commerce  
5           for commercial distribution in the United States  
6           after August 11, 1995, and before the date of enact-  
7           ment of the Youth Smoking Prevention and Public  
8           Health Protection Act shall be submitted to the Sec-  
9           retary within 6 months after the date of enactment  
10          of that Act.

11   **“SEC. 906. GENERAL PROVISIONS RESPECTING CONTROL**  
12                           **OF TOBACCO PRODUCTS.**

13          “(a) IN GENERAL.—Any requirement established by  
14          or under section 902, 903, 905, or 909 applicable to a  
15          tobacco product shall apply to such tobacco product until  
16          the applicability of the requirement to the tobacco product  
17          has been changed by action taken under section 907, sec-  
18          tion 910, or subsection (d) of this section, and any re-  
19          quirement established by or under section 902, 903, 905,  
20          or 909 which is inconsistent with a requirement imposed  
21          on such tobacco product under section 907, section 910,  
22          or subsection (d) of this section shall not apply to such  
23          tobacco product.

24          “(b) INFORMATION ON PUBLIC ACCESS AND COM-  
25          MENT.—Each notice of proposed rulemaking under section

1 907, 908, 909, or 910, or under this section, any other  
2 notice which is published in the Federal Register with re-  
3 spect to any other action taken under any such section  
4 and which states the reasons for such action, and each  
5 publication of findings required to be made in connection  
6 with rulemaking under any such section shall set forth—

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

10           “(2) the period within which interested persons  
11           may present their comments on the notice or find-  
12           ings (including the need therefore) orally or in writ-  
13           ing, which period shall be at least 60 days but may  
14           not exceed 90 days unless the time is extended by  
15           the Secretary by a notice published in the Federal  
16           Register stating good cause therefore.

17           “(c) LIMITED CONFIDENTIALITY OF INFORMA-  
18           TION.—Any information reported to or otherwise obtained  
19           by the Secretary or the Secretary’s representative under  
20           section 904, 907, 908, 909, or 910 or 704, or under sub-  
21           section (e) or (f) of this section, which is exempt from  
22           disclosure under subsection (a) of section 552 of title 5,  
23           United States Code, by reason of subsection (b)(4) of that  
24           section shall be considered confidential and shall not be  
25           disclosed, except that the information may be disclosed to

1 other officers or employees concerned with carrying out  
2 this chapter, or when relevant in any proceeding under  
3 this chapter.

4 “(d) RESTRICTIONS.—

5 “(1) IN GENERAL.—The Secretary may by reg-  
6 ulation require that a tobacco product be restricted  
7 to sale, distribution, or use upon such conditions, in-  
8 cluding restrictions on the access to, and the adver-  
9 tising and promotion of, the tobacco product, as the  
10 Secretary may prescribe in such regulation if, be-  
11 cause of its potentiality for harmful effect or the col-  
12 lateral measures necessary to its use, the Secretary  
13 determines that such regulation would be appro-  
14 priate for the protection of the public health. The  
15 finding as to whether such regulation would be ap-  
16 propriate for the protection of the public health shall  
17 be determined with respect to the risks and benefits  
18 to the population as a whole, including users and  
19 non-users of the tobacco product, and taking into  
20 account—

21 “(A) the increased or decreased likelihood  
22 that existing users of tobacco products will stop  
23 using such products; and

1           “(B) the increased or decreased likelihood  
2           that those who do not use tobacco products will  
3           start using such products.

4           No such condition may require that the sale or dis-  
5           tribution of a tobacco product be limited to the writ-  
6           ten or oral authorization of a practitioner licensed  
7           by law to prescribe medical products.

8           “(2) LABEL STATEMENTS.—The label of a to-  
9           bacco product shall bear such appropriate state-  
10          ments of the restrictions required by a regulation  
11          under subsection (a) as the Secretary may in such  
12          regulation prescribe.

13          “(3) LIMITATION.—No restriction under para-  
14          graph (1) may prohibit the sale of any tobacco prod-  
15          uct in face-to face transactions by a specific category  
16          of retail outlets.

17          “(e) GOOD MANUFACTURING PRACTICE REQUIRE-  
18          MENTS.—

19                 “(1) METHODS, FACILITIES, AND CONTROLS TO  
20                 CONFORM.—

21                         “(A) IN GENERAL.—The Secretary may, in  
22                         accordance with subparagraph (B), prescribe  
23                         regulations requiring that the methods used in,  
24                         and the facilities and controls used for, the  
25                         manufacture, pre-production design validation

1 (including a process to assess the performance  
2 of a tobacco product), packing and storage of a  
3 tobacco product, conform to current good man-  
4 ufacturing practice, as prescribed in such regu-  
5 lations, to assure that the public health is pro-  
6 tected and that the tobacco product is in com-  
7 pliance with this chapter.

8 “(B) REQUIREMENTS.—The Secretary  
9 shall—

10 “(i) before promulgating any regula-  
11 tion under subparagraph (A), afford an ad-  
12 visory committee an opportunity to submit  
13 recommendations with respect to the regu-  
14 lation proposed to be promulgated;

15 “(ii) before promulgating any regula-  
16 tion under subparagraph (A), afford oppor-  
17 tunity for an oral hearing;

18 “(iii) provide the advisory committee a  
19 reasonable time to make its recommenda-  
20 tion with respect to proposed regulations  
21 under subparagraph (A); and

22 “(iv) in establishing the effective date  
23 of a regulation promulgated under this  
24 subsection, take into account the dif-  
25 ferences in the manner in which the dif-

1           ferent types of tobacco products have his-  
2           torically been produced, the financial re-  
3           sources of the different tobacco product  
4           manufacturers, and the state of their exist-  
5           ing manufacturing facilities, and shall pro-  
6           vide for a reasonable period of time for  
7           such manufacturers to conform to good  
8           manufacturing practices.

9           “(2) EXEMPTIONS; VARIANCES.—

10           “(A) PETITION.—Any person subject to  
11           any requirement prescribed under paragraph  
12           (1) may petition the Secretary for a permanent  
13           or temporary exemption or variance from such  
14           requirement. Such a petition shall be submitted  
15           to the Secretary in such form and manner as  
16           the Secretary shall prescribe and shall—

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

24           “(ii) in the case of a petition for a  
25           variance from a requirement, set forth the

1 methods proposed to be used in, and the  
2 facilities and controls proposed to be used  
3 for, the manufacture, packing, and storage  
4 of the tobacco product in lieu of the meth-  
5 ods, facilities, and controls prescribed by  
6 the requirement; and

7 “(iii) contain such other information  
8 as the Secretary shall prescribe.

9 “(B) REFERRAL TO ADVISORY COM-  
10 MITTEE.—The Secretary may refer to an advi-  
11 sory committee any petition submitted under  
12 subparagraph (A). The advisory committee  
13 shall report its recommendations to the Sec-  
14 retary with respect to a petition referred to it  
15 within 60 days after the date of the petition’s  
16 referral. Within 60 days after—

17 “(i) the date the petition was sub-  
18 mitted to the Secretary under subpara-  
19 graph (A); or

20 “(ii) the day after the petition was re-  
21 ferred to an advisory committee,  
22 whichever occurs later, the Secretary shall by  
23 order either deny the petition or approve it.

24 “(C) APPROVAL.—The Secretary may  
25 approve—

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

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

17           “(D) CONDITIONS.—An order of the Sec-  
18 retary approving a petition for a variance shall  
19 prescribe such conditions respecting the meth-  
20 ods used in, and the facilities and controls used  
21 for, the manufacture, packing, and storage of  
22 the tobacco product to be granted the variance  
23 under the petition as may be necessary to as-  
24 sure that the tobacco product will be in compli-  
25 ance with this chapter.

1           “(E) HEARING.—After the issuance of an  
2           order under subparagraph (B) respecting a pe-  
3           tition, the petitioner shall have an opportunity  
4           for an informal hearing on such order.

5           “(3) COMPLIANCE.—Compliance with require-  
6           ments under this subsection shall not be required be-  
7           fore the period ending 3 years after the date of en-  
8           actment of the Youth Smoking Prevention and Pub-  
9           lic Health Protection Act.

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

14          “(g) RESEARCH AND DEVELOPMENT.—The Sec-  
15          retary may enter into contracts for research, testing, and  
16          demonstrations respecting tobacco products and may ob-  
17          tain tobacco products for research, testing, and dem-  
18          onstration purposes without regard to section 3324(a) and  
19          (b) of title 31, United States Code, and section 5 of title  
20          41, United States Code.

21          **“SEC. 907. PERFORMANCE STANDARDS.**

22          “(a) IN GENERAL.—

23                 “(1) FINDING REQUIRED.—The Secretary may  
24                 adopt performance standards for a tobacco product  
25                 if the Secretary finds that a performance standard

1 is appropriate for the protection of the public health.  
2 This finding shall be determined with respect to the  
3 risks and benefits to the population as a whole, in-  
4 cluding users and non-users of the tobacco product,  
5 and taking into account—

6 “(A) the increased or decreased likelihood  
7 that existing users of tobacco products will stop  
8 using such products; and

9 “(B) the increased or decreased likelihood  
10 that those who do not use tobacco products will  
11 start using such products.

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

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

19 “(i) for the reduction or elimination of  
20 nicotine yields of the product;

21 “(ii) for the reduction or elimination  
22 of other constituents or harmful compo-  
23 nents of the product; or

24 “(iii) relating to any other require-  
25 ment under (B);

1           “(B) shall, where necessary to be appro-  
2           priate for the protection of the public health,  
3           include—

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

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

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

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

20                  “(v) a provision requiring that the  
21                  sale and distribution of the tobacco prod-  
22                  uct be restricted but only to the extent  
23                  that the sale and distribution of a tobacco  
24                  product may be restricted under a regula-  
25                  tion under section 906(d); and

1           “(C) shall, where appropriate, require the  
2           use and prescribe the form and content of label-  
3           ing for the proper use of the tobacco product.

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

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

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

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

23                 “(C) invite appropriate participation,  
24                 through joint or other conferences, workshops,  
25                 or other means, by informed persons represent-

1           ative of scientific, professional, industry, or con-  
2           sumer organizations who in the Secretary's  
3           judgment can make a significant contribution.

4           “(b) ESTABLISHMENT OF STANDARDS.—

5           “(1) NOTICE.—

6           “(A) IN GENERAL.—The Secretary shall  
7           publish in the Federal Register a notice of pro-  
8           posed rulemaking for the establishment, amend-  
9           ment, or revocation of any performance stand-  
10          ard for a tobacco product.

11          “(B) REQUIREMENTS OF NOTICE.—A no-  
12          tice of proposed rulemaking for the establish-  
13          ment or amendment of a performance standard  
14          for a tobacco product shall—

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

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

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

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

3           “(C) FINDING.—A notice of proposed rule-  
4           making for the revocation of a performance  
5           standard shall set forth a finding with sup-  
6           porting justification that the performance  
7           standard is no longer necessary to be appro-  
8           priate for the protection of the public health.

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

23          “(E) COMMENT.—The Secretary shall pro-  
24          vide for a comment period of not less than 60  
25          days.

1           “(2) PROMULGATION.—

2                   “(A) IN GENERAL.—After the expiration of  
3 the period for comment on a notice of proposed  
4 rulemaking published under paragraph (1) re-  
5 specting a performance standard and after con-  
6 sideration of such comments and any report  
7 from an advisory committee, the Secretary  
8 shall—

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

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

17                   “(B) EFFECTIVE DATE.—A regulation es-  
18 tablishing a performance standard shall set  
19 forth the date or dates upon which the standard  
20 shall take effect, but no such regulation may  
21 take effect before one year after the date of its  
22 publication unless the Secretary determines  
23 that an earlier effective date is necessary for  
24 the protection of the public health. Such date or  
25 dates shall be established so as to minimize,

1 consistent with the public health, economic loss  
2 to, and disruption or dislocation of, domestic  
3 and international trade.

4 “(3) SPECIAL RULE FOR STANDARD BANNING  
5 CLASS OF PRODUCT OR ELIMINATING NICOTINE CON-  
6 TENT.—Because of the importance of a decision of  
7 the Secretary to issue a regulation establishing a  
8 performance standard—

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

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

14 it is appropriate for the Congress to have the oppor-  
15 tunity to review such a decision. Therefore, any such  
16 standard may not take effect before a date that is  
17 2 years after the President notifies the Congress  
18 that a final regulation imposing the restriction has  
19 been issued.

20 “(4) AMENDMENT; REVOCATION.—

21 “(A) AUTHORITY.—The Secretary, upon  
22 the Secretary’s own initiative or upon petition  
23 of an interested person may by a regulation,  
24 promulgated in accordance with the require-

1           ments of paragraphs (1) and (2)(B), amend or  
2           revoke a performance standard.

3           “(B) EFFECTIVE DATE.—The Secretary  
4           may declare a proposed amendment of a per-  
5           formance standard to be effective on and after  
6           its publication in the Federal Register and until  
7           the effective date of any final action taken on  
8           such amendment if the Secretary determines  
9           that making it so effective is in the public inter-  
10          est.

11          “(5) REFERENCE TO ADVISORY COMMITTEE.—  
12          The Secretary—

13                 “(A) may, on the Secretary’s own initia-  
14                 tive, refer a proposed regulation for the estab-  
15                 lishment, amendment, or revocation of a per-  
16                 formance standard; or

17                 “(B) shall, upon the request of an inter-  
18                 ested person which demonstrates good cause for  
19                 referral and which is made before the expiration  
20                 of the period for submission of comments on  
21                 such proposed regulation,

22 refer such proposed regulation to an advisory committee,  
23 for a report and recommendation with respect to any mat-  
24 ter involved in the proposed regulation which requires the  
25 exercise of scientific judgment. If a proposed regulation

1 is referred under this paragraph to the advisory com-  
2 mittee, the Secretary shall provide the advisory committee  
3 with the data and information on which such proposed  
4 regulation is based. The advisory committee shall, within  
5 60 days after the referral of a proposed regulation and  
6 after independent study of the data and information fur-  
7 nished to it by the Secretary and other data and informa-  
8 tion before it, submit to the Secretary a report and rec-  
9 ommendation respecting such regulation, together with all  
10 underlying data and information and a statement of the  
11 reason or basis for the recommendation. A copy of such  
12 report and recommendation shall be made public by the  
13 Secretary.

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

15 “(a) NOTIFICATION.—If the Secretary determines  
16 that—

17 “(1) a tobacco product which is introduced or  
18 delivered for introduction into interstate commerce  
19 for commercial distribution presents an unreasonable  
20 risk of substantial harm to the public health; and

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

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

11 “(b) NO EXEMPTION FROM OTHER LIABILITY.—  
12 Compliance with an order issued under this section shall  
13 not relieve any person from liability under Federal or  
14 State law. In awarding damages for economic loss in an  
15 action brought for the enforcement of any such liability,  
16 the value to the plaintiff in such action of any remedy  
17 provided under such order shall be taken into account.

18 “(c) RECALL AUTHORITY.—

19 “(1) IN GENERAL.—If the Secretary finds that  
20 there is a reasonable probability that a tobacco prod-  
21 uct contains a manufacturing or other defect not or-  
22 dinarily contained in tobacco products on the market  
23 that would cause serious, adverse health con-  
24 sequences or death, the Secretary shall issue an  
25 order requiring the appropriate person (including

1 the manufacturers, importers, distributors, or retail-  
2 ers of the tobacco product) to immediately cease dis-  
3 tribution of such tobacco product. The order shall  
4 provide the person subject to the order with an op-  
5 portunity for an informal hearing, to be held not  
6 later than 10 days after the date of the issuance of  
7 the order, on the actions required by the order and  
8 on whether the order should be amended to require  
9 a recall of such tobacco product. If, after providing  
10 an opportunity for such a hearing, the Secretary de-  
11 termines that inadequate grounds exist to support  
12 the actions required by the order, the Secretary shall  
13 vacate the order.

14 “(2) AMENDMENT OF ORDER TO REQUIRE RE-  
15 CALL.—

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

1 the Secretary describing the progress of the re-  
2 call.

3 “(B) NOTICE.—An amended order under  
4 subparagraph (A)—

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

7 “(ii) shall provide for notice to per-  
8 sons subject to the risks associated with  
9 the use of such tobacco product.

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

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

19 **“SEC. 909. RECORDS AND REPORTS ON TOBACCO PROD-**  
20 **UCTS.**

21 “(a) IN GENERAL.—Every person who is a tobacco  
22 product manufacturer or importer of a tobacco product  
23 shall establish and maintain such records, make such re-  
24 ports, and provide such information, as the Secretary may  
25 by regulation reasonably require to assure that such to-

1   bacco product is not adulterated or misbranded and to  
2   otherwise protect public health. Regulations prescribed  
3   under the preceding sentence—

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

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

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

23          “(4) when prescribing the procedure for making  
24          requests for reports or information, shall require  
25          that each request made under such regulations for

1 submission of a report or information to the Sec-  
2 retary state the reason or purpose for such request  
3 and identify to the fullest extent practicable such re-  
4 port or information;

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

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

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

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

1           “(1) IN GENERAL.—Except as provided in para-  
2           graph (2), the Secretary shall by regulation require  
3           a tobacco product manufacturer or importer of a to-  
4           bacco product to report promptly to the Secretary  
5           any corrective action taken or removal from the  
6           market of a tobacco product undertaken by such  
7           manufacturer or importer if the removal or correc-  
8           tion was undertaken—

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

11                   “(B) to remedy a violation of this chapter  
12                   caused by the tobacco product which may  
13                   present a risk to health.

14           A tobacco product manufacturer or importer of a to-  
15           bacco product who undertakes a corrective action or  
16           removal from the market of a tobacco product which  
17           is not required to be reported under this subsection  
18           shall keep a record of such correction or removal.

19           “(2) EXCEPTION.—No report of the corrective  
20           action or removal of a tobacco product may be re-  
21           quired under paragraph (1) if a report of the correc-  
22           tive action or removal is required and has been sub-  
23           mitted under subsection (a).

1 **“SEC. 910. PREMARKET REVIEW OF CERTAIN TOBACCO**  
2 **PRODUCTS.**

3 “(a) IN GENERAL.—

4 “(1) PREMARKET APPROVAL REQUIRED.—

5 “(A) NEW PRODUCTS.—Approval under  
6 this section of an application for premarket ap-  
7 proval for any tobacco product that is not com-  
8 mercially marketed (other than for test mar-  
9 keting) in the United States as of August 11,  
10 1995, is required unless the manufacturer has  
11 submitted a report under section 905(j), and  
12 the Secretary has issued an order that the to-  
13 bacco product is substantially equivalent to a  
14 tobacco product commercially marketed (other  
15 than for test marketing) in the United States  
16 as of August 11, 1995, that is in compliance  
17 with the requirements of this Act.

18 “(B) PRODUCTS INTRODUCED BETWEEN  
19 AUGUST 11, 1995, AND ENACTMENT OF THIS  
20 CHAPTER.—Subparagraph (A) does not apply  
21 to a tobacco product that—

22 “(i) was first introduced or delivered  
23 for introduction into interstate commerce  
24 for commercial distribution in the United  
25 States after August 11, 1995, and before  
26 the date of enactment of the Youth Smok-

1           ing Prevention and Public Health Protec-  
2           tion Act; and

3                   “(ii) for which a report was submitted  
4                   under section 905(j) within 6 months after  
5                   such date,

6           until the Secretary issues an order that the to-  
7           bacco product is substantially equivalent for  
8           purposes of this section or requires premarket  
9           approval.

10           “(2) SUBSTANTIALLY EQUIVALENT DEFINED.—

11                   “(A) IN GENERAL.—For purposes of this  
12                   section and section 905(j), the terms ‘substan-  
13                   tially equivalent’ or ‘substantial equivalence’  
14                   mean, with respect to the tobacco product being  
15                   compared to the predicate tobacco product, that  
16                   the Secretary by order has found that the to-  
17                   bacco 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) CHARACTERISTICS.—For purposes of  
4           subparagraph (A), the term ‘characteristics’  
5           means the materials, ingredients, design, com-  
6           position, heating source, or other features of a  
7           tobacco product.

8           “(C) LIMITATION.—A tobacco product may  
9           not be found to be substantially equivalent to a  
10          predicate tobacco product that has been re-  
11          moved from the market at the initiative of the  
12          Secretary or that has been determined by a ju-  
13          dicial order to be misbranded or adulterated.

14          “(3) HEALTH INFORMATION.—

15                 “(A) SUMMARY.—As part of a submission  
16                 under section 905(j) respecting a tobacco prod-  
17                 uct, the person required to file a premarket no-  
18                 tification under such section shall provide an  
19                 adequate summary of any health information  
20                 related to the tobacco product or state that  
21                 such information will be made available upon  
22                 request by any person.

23                 “(B) REQUIRED INFORMATION.—Any sum-  
24                 mary under subparagraph (A) respecting a to-  
25                 bacco product shall contain detailed information

1           regarding data concerning adverse health ef-  
2           fects and shall be made available to the public  
3           by the Secretary within 30 days of the issuance  
4           of a determination that such tobacco product is  
5           substantially equivalent to another tobacco  
6           product.

7           “(b) APPLICATION.—

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

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

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

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

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

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

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

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

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

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

22                 “(B) shall, upon the request of an appli-  
23                 cant,

24                 refer such application to an advisory committee and  
25                 for submission (within such period as the Secretary

1 may establish) of a report and recommendation re-  
2 specting approval of the application, together with  
3 all underlying data and the reasons or basis for the  
4 recommendation.

5 “(c) ACTION ON APPLICATION.—

6 “(1) DEADLINE.—

7 “(A) IN GENERAL.—As promptly as pos-  
8 sible, but in no event later than 180 days after  
9 the receipt of an application under subsection  
10 (b), the Secretary, after considering the report  
11 and recommendation submitted under para-  
12 graph (2) of such subsection, shall—

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

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

24 “(B) RESTRICTIONS ON SALE AND DIS-  
25 TRIBUTION.—An order approving an application

1           for a tobacco product may require as a condi-  
2           tion to such approval that the sale and distribu-  
3           tion of the tobacco product be restricted but  
4           only to the extent that the sale and distribution  
5           of a tobacco product may be restricted under a  
6           regulation under section 906(d).

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

14                 “(A) there is a lack of a showing that per-  
15                 mitting such tobacco product to be marketed  
16                 would be appropriate for the protection of the  
17                 public health;

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

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

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

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

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

22           “(A) the increased or decreased likelihood  
23 that existing users of tobacco products will stop  
24 using such products; and

1           “(B) the increased or decreased likelihood  
2           that those who do not use tobacco products will  
3           start using such products.

4           “(5) BASIS FOR ACTION.—

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

14          “(B) OTHER EVIDENCE.—If the Secretary  
15          determines that there exists valid scientific evi-  
16          dence (other than evidence derived from inves-  
17          tigations described in subparagraph (A)) which  
18          is sufficient to evaluate the tobacco product the  
19          Secretary may authorize that the determination  
20          for purposes of paragraph (2)(A) be made on  
21          the basis of such evidence.

22          “(d) WITHDRAWAL AND TEMPORARY SUSPENSION.—

23          “(1) IN GENERAL.—The Secretary shall, upon  
24          obtaining, where appropriate, advice on scientific  
25          matters from an advisory committee, and after due

1 notice and opportunity for informal hearing to the  
2 holder of an approved application for a tobacco  
3 product, issue an order withdrawing approval of the  
4 application if the Secretary finds—

5 “(A) that the continued marketing of such  
6 tobacco product no longer is appropriate for the  
7 protection of the public health;

8 “(B) that the application contained or was  
9 accompanied by an untrue statement of a mate-  
10 rial fact;

11 “(C) that the applicant—

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

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

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

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

1 approved, that the methods used in, or the fa-  
2 cilities and controls used for, the manufacture,  
3 processing, packing, or installation of such to-  
4 bacco product do not conform with the require-  
5 ments of section 906(e) and were not brought  
6 into conformity with such requirements within  
7 a reasonable time after receipt of written notice  
8 from the Secretary of nonconformity;

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

18 “(F) on the basis of new information be-  
19 fore the Secretary, evaluated together with the  
20 evidence before the Secretary when the applica-  
21 tion was approved, that such tobacco product is  
22 not shown to conform in all respects to a per-  
23 formance standard which is in effect under sec-  
24 tion 907, compliance with which was a condi-  
25 tion to approval of the application, and that

1           there is a lack of adequate information to jus-  
2           tify the deviation from such standard.

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

10           “(3) TEMPORARY SUSPENSION.—If, after pro-  
11           viding an opportunity for an informal hearing, the  
12           Secretary determines there is reasonable probability  
13           that the continuation of distribution of a tobacco  
14           product under an approved application would cause  
15           serious, adverse health consequences or death, that  
16           is greater than ordinarily caused by tobacco prod-  
17           ucts on the market, the Secretary shall by order  
18           temporarily suspend the approval of the application  
19           approved under this section. If the Secretary issues  
20           such an order, the Secretary shall proceed expedi-  
21           tiously under paragraph (1) to withdraw such appli-  
22           cation.

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

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

3           “(2) by mailing the order by registered mail or  
4 certified mail addressed to the applicant at the ap-  
5 plicant’s last known address in the records of the  
6 Secretary.

7 **“SEC. 911. JUDICIAL REVIEW.**

8           “(a) RIGHT TO REVIEW.—

9           “(1) IN GENERAL.—Not later than 30 days  
10 after—

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

15           “(B) a denial of an application for ap-  
16 proval under section 910(c),

17 any person adversely affected by such regulation or  
18 order may file a petition with the United States  
19 Court of Appeals for the District of Columbia or for  
20 the circuit wherein such person resides or has his or  
21 her principal place of business for judicial review of  
22 such regulation or order.

23           “(2) REQUIREMENTS.—

24           “(A) COPY OF PETITION.—A copy of the  
25 petition filed under paragraph (1) shall be

1 transmitted by the clerk of the court to the Sec-  
2 retary or other officer designated by the Sec-  
3 retary for that purpose.

4 “(B) RECORD OF PROCEEDINGS.—With re-  
5 spect to an action under paragraph (1), the  
6 Secretary shall file in the court the record of  
7 the proceedings on which the Secretary based  
8 the Secretary’s regulation or order and each  
9 record or order shall contain a statement of the  
10 reasons for its issuance and the basis, on the  
11 record, for its issuance.

12 “(C) DEFINITION.—For purposes of this  
13 section, the term ‘record’ means all notices and  
14 other matter published in the Federal Register  
15 with respect to the regulation or order reviewed,  
16 all information submitted to the Secretary with  
17 respect to such regulation or order, proceedings  
18 of any panel or advisory committee with respect  
19 to such regulation or order, any hearing held  
20 with respect to such regulation or order, and  
21 any other information identified by the Sec-  
22 retary, in the administrative proceeding held  
23 with respect to such regulation or order, as  
24 being relevant to such regulation or order.

1       “(b) COURT MAY ORDER SECRETARY TO MAKE AD-  
2     DITIONAL FINDINGS.—

3           “(1) IN GENERAL.—If the petitioner in an ac-  
4     tion under subsection (a)(1) applies to the court for  
5     leave to adduce additional data, views, or arguments  
6     respecting the regulation or order being reviewed  
7     and shows to the satisfaction of the court that such  
8     additional data, views, or arguments are material  
9     and that there were reasonable grounds for the peti-  
10    tioner’s failure to adduce such data, views, or argu-  
11    ments in the proceedings before the Secretary, the  
12    court may order the Secretary to provide additional  
13    opportunity for the oral presentation of data, views,  
14    or arguments and for written submissions.

15           “(2) MODIFICATION OF OR ADDITIONAL FIND-  
16    INGS.—The Secretary may modify the Secretary’s  
17    findings, or make new findings by reason of the ad-  
18    ditional data, views, or arguments under paragraph  
19    (1) and shall file with the court such modified or  
20    new findings, and the Secretary’s recommendation,  
21    if any, for the modification or setting aside of the  
22    regulation or order being reviewed, with the return  
23    of such additional data, views, or arguments.

24           “(c) STANDARD OF REVIEW.—Upon the filing of the  
25    petition under subsection (a) for judicial review of a regu-

1 lation or order, the court shall have jurisdiction to review  
2 the regulation or order in accordance with chapter 7 of  
3 title 5, United States Code, and to grant appropriate re-  
4 lief, including interim relief, as provided in such chapter.  
5 A regulation or order described in paragraph (1) or (2)  
6 of subsection (a) shall not be affirmed if it is found to  
7 be unsupported by substantial evidence on the record  
8 taken as a whole.

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

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

18       “(f) REGULATIONS AND ORDERS MUST RECITE  
19 BASIS IN RECORD.—To facilitate judicial review under  
20 this section or under any other provision of law or a regu-  
21 lation or order issued under section 906, 907, 908, 909,  
22 910, or 914, each such regulation or order shall contain  
23 a statement of the reasons for its issuance and the basis,  
24 in the record of the proceedings held in connection with  
25 its issuance, for its issuance.

1 **“SEC. 912. POSTMARKET SURVEILLANCE.**

2       “(a) DISCRETIONARY SURVEILLANCE.—The Sec-  
3 retary may require a tobacco product manufacturer to  
4 conduct postmarket surveillance for a tobacco product of  
5 the manufacturer if the Secretary determines that  
6 postmarket surveillance of the tobacco product is nec-  
7 essary to protect the public health or is necessary to pro-  
8 vide information regarding the health risks and other safe-  
9 ty issues involving the tobacco product.

10       “(b) SURVEILLANCE APPROVAL.—Each tobacco  
11 product manufacturer required to conduct a surveillance  
12 of a tobacco product under subsection (a) shall, within 30  
13 days after receiving notice that the manufacturer is re-  
14 quired to conduct such surveillance, submit, for the ap-  
15 proval of the Secretary, a protocol for the required surveil-  
16 lance. The Secretary, within 60 days of the receipt of such  
17 protocol, shall determine if the principal investigator pro-  
18 posed to be used in the surveillance has sufficient quali-  
19 fications and experience to conduct such surveillance and  
20 if such protocol will result in collection of useful data or  
21 other information necessary to protect the public health.  
22 The Secretary may not approve such a protocol until it  
23 has been reviewed by an appropriately qualified scientific  
24 and technical review committee established by the Sec-  
25 retary.

1 **“SEC. 913. REDUCED RISK TOBACCO PRODUCTS.**

2 “(a) REQUIREMENTS.—

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

7 “(2) DESIGNATION.—

8 “(A) IN GENERAL.—A product may be  
9 designated by the Secretary as a reduced risk  
10 tobacco product if the Secretary finds that the  
11 product will significantly reduce harm to indi-  
12 viduals caused by a tobacco product and is oth-  
13 erwise appropriate to protect public health,  
14 based on an application submitted by the manu-  
15 facturer of the product (or other responsible  
16 person) that—

17 “(i) demonstrates through testing on  
18 animals and short-term human testing that  
19 use of such product results in ingestion or  
20 inhalation of a substantially lower yield of  
21 toxic substances than use of conventional  
22 tobacco products in the same category as  
23 the proposed reduced risk product; and

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

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

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

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

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

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

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

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

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

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

10                   “(C) complies with requirements prescribed  
11           by the Secretary relating to marketing and ad-  
12           vertising of the product, and other provisions of  
13           this chapter as prescribed by the Secretary.

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

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

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

1       “(c) LIMITATION.—A tobacco product that is des-  
2       ignated as a reduced risk tobacco product that is in com-  
3       pliance with subsection (a) shall not be regulated as a  
4       drug or device.

5       “(d) DEVELOPMENT OF REDUCED RISK TOBACCO  
6       PRODUCT TECHNOLOGY.—A tobacco product manufac-  
7       turer shall provide written notice to the Secretary upon  
8       the development or acquisition by the manufacturer of any  
9       technology that would reduce the risk of a tobacco product  
10      to the health of the user for which the manufacturer is  
11      not seeking designation as a ‘reduced risk tobacco product’  
12      under subsection (a).

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

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

19      **“SEC. 915. JURISDICTION OF AND COORDINATION WITH**  
20                              **THE FEDERAL TRADE COMMISSION.**

21      “(a) JURISDICTION.—

22              “(1) IN GENERAL.—Except where expressly  
23      provided in this chapter, nothing in this chapter  
24      shall be construed as limiting or diminishing the au-  
25      thority of the Federal Trade Commission to enforce

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

3 “(2) ENFORCEMENT.—Any advertising that vio-  
4 lates this chapter or part 897 of title 21, Code of  
5 Federal Regulations, is an unfair or deceptive act or  
6 practice under section 5(a) of the Federal Trade  
7 Commission Act (15 U.S.C. 45(a)) and shall be con-  
8 sidered a violation of a rule promulgated under sec-  
9 tion 18 of that Act (15 U.S.C. 57a).

10 “(b) COORDINATION.—With respect to the require-  
11 ments of section 4 of the Federal Cigarette Labeling and  
12 Advertising Act (15 U.S.C. 1333) and section 3 of the  
13 Comprehensive Smokeless Tobacco Health Education Act  
14 of 1986 (15 U.S.C. 4402)—

15 “(1) the Chairman of the Federal Trade Com-  
16 mission shall coordinate with the Secretary con-  
17 cerning the enforcement of such Act as such enforce-  
18 ment relates to unfair or deceptive acts or practices  
19 in the advertising of cigarettes or smokeless tobacco;  
20 and

21 “(2) the Secretary shall consult with the Chair-  
22 man of such Commission in revising the label state-  
23 ments and requirements under such sections.

1 **“SEC. 916. CONGRESSIONAL REVIEW PROVISIONS.**

2 “In accordance with section 801 of title 5, United  
3 States Code, the Congress shall review, and may dis-  
4 approve, any rule under this chapter that is subject to sec-  
5 tion 801. This section does not apply to the rule set forth  
6 in part 897 of title 21, Code of Federal Regulations.

7 **“SEC. 917. REGULATION REQUIREMENT.**

8 “(a) TESTING, REPORTING, AND DISCLOSURE.—Not  
9 later than 24 months after the date of enactment of the  
10 Youth Smoking Prevention and Public Health Protection  
11 Act, the Secretary, acting through the Commissioner of  
12 the Food and Drug Administration, shall promulgate reg-  
13 ulations under this Act that meet the requirements of sub-  
14 section (b).

15 “(b) CONTENTS OF RULES.—The regulations pro-  
16 mulgated under subsection (a) shall require the testing,  
17 reporting, and disclosure of tobacco product smoke con-  
18 stituents and ingredients that the Secretary determines  
19 should be disclosed to the public in order to protect the  
20 public health. Such constituents shall include tar, nicotine,  
21 carbon monoxide, and such other smoke constituents or  
22 ingredients as the Secretary may determine to be appro-  
23 priate. The regulations may require that tobacco product  
24 manufacturers, packagers, or importers make such disclo-  
25 sures relating to tar and nicotine through labels or adver-  
26 tising, and make such disclosures regarding other smoke

1 constituents or ingredients as the Secretary determines  
2 are necessary to protect the public health.

3 “(c) **AUTHORITY.**—The Food and Drug Administra-  
4 tion shall have the authority under this chapter to conduct  
5 or to require the testing, reporting, or disclosure of to-  
6 bacco product smoke constituents.

7 **“SEC. 918. PRESERVATION OF STATE AND LOCAL AUTHOR-**  
8 **ITY.**

9 “(a) **ADDITIONAL REQUIREMENTS.**—

10 “(1) **IN GENERAL.**—Except as provided in para-  
11 graph (2), nothing in this chapter, or rules promul-  
12 gated under this chapter, shall be construed to limit  
13 the authority of a Federal agency (including the  
14 Armed Forces), a State or political subdivision of a  
15 State, or the government of an Indian tribe to enact,  
16 adopt, promulgate, and enforce any law, rule, regu-  
17 lation, or other measure with respect to tobacco  
18 products, including laws, rules, regulations, or other  
19 measures relating to or prohibiting the sale, dis-  
20 tribution, possession, exposure to, or use of tobacco  
21 products by individuals of any age that are in addi-  
22 tion to, or more stringent than, requirements estab-  
23 lished under this chapter. No provision of this chap-  
24 ter shall limit or otherwise affect any State, Tribal,  
25 or local taxation of tobacco products.

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

3           “(A) IN GENERAL.—Except as provided in  
4 subparagraph (B), no State or political subdivi-  
5 sion of a State may establish or continue in ef-  
6 fect with respect to a tobacco product any re-  
7 quirement which is different from, or in addi-  
8 tion to, any requirement applicable under the  
9 provisions of this chapter relating to perform-  
10 ance standards, premarket approval, adultera-  
11 tion, misbranding, registration, reporting, good  
12 manufacturing standards, or reduced risk prod-  
13 ucts.

14           “(B) EXCEPTION.—Subparagraph (A)  
15 does not apply to requirements relating to the  
16 sale, use, or distribution of a tobacco product  
17 including requirements related to the access to,  
18 and the advertising and promotion of, a tobacco  
19 product.

20           “(b) ADDITIONAL RESTRICTIONS ON UNDERAGE  
21 USAGE.—Nothing in this chapter shall be construed to  
22 prevent a Federal agency (including the Armed Forces),  
23 a State or a political subdivision of a State, or the govern-  
24 ment of an Indian tribe from adopting and enforcing addi-  
25 tional measures that further restrict or prohibit tobacco

1 product sale to, use by, and accessibility to individuals  
2 under the legal age of purchase established by such agen-  
3 cy, State, subdivision, or government of an Indian tribe.

4 “(c) NO LESS STRINGENT.—Nothing in this chapter  
5 is intended to supersede any State, local, or Tribal law  
6 that is not less stringent than this chapter.

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

12 “(e) WAIVERS.—Upon the application of a State or  
13 political subdivision thereof, the Secretary may, by regula-  
14 tion promulgated after notice and an opportunity for an  
15 oral hearing, exempt from subsection (a), under such con-  
16 ditions as may be prescribed in such regulation, a require-  
17 ment of such State or political subdivision applicable to  
18 a tobacco product if—

19 “(1) the requirement is more stringent than a  
20 requirement applicable under the provisions de-  
21 scribed in subsection (a)(1) which would be applica-  
22 ble to the tobacco product if an exemption were not  
23 in effect under this subsection; or

24 “(2) the requirement—

1           “(A) is required by compelling local condi-  
2           tions; and

3           “(B) compliance with the requirement  
4           would not cause the tobacco product to be in  
5           violation of any applicable requirement of this  
6           chapter.”.

7 **SEC. 102. CONSTRUCTION OF CURRENT REGULATIONS.**

8           (a) **IN GENERAL.**—The final regulations promulgated  
9 by the Secretary of Health and Human Services in the  
10 August 28, 1996, issue of the Federal Register (62 Fed.  
11 Reg. 44615–44618) and codified at part 897 of title 21,  
12 Code of Federal Regulations, are hereby deemed to be law-  
13 ful and to have been lawfully promulgated by the Sec-  
14 retary under chapter IX and section 701 of the Federal  
15 Food, Drug, and Cosmetic Act, as amended by this Act,  
16 and not under chapter V of the Federal Food, Drug, and  
17 Cosmetic Act. The provisions of such part 897 shall take  
18 effect on the date of enactment of this Act or upon such  
19 later date as determined by the Secretary by order. The  
20 Secretary shall amend the designation of authority in such  
21 regulations in accordance with this subsection.

22           (b) **LIMITATION ON ADVISORY OPINIONS.**—As of the  
23 date of enactment of this Act, the following documents  
24 issued by the Food and Drug Administration shall not  
25 constitute advisory opinions under section 10.85(d)(1) of

1 title 21, Code of Federal Regulations, except as they apply  
2 to tobacco products, and shall not be cited by the Sec-  
3 retary of Health and Human Services or the Food and  
4 Drug Administration as binding precedent:

5 (1) The preamble to the proposed rule in the  
6 document entitled “Regulations Restricting the Sale  
7 and Distribution of Cigarettes and Smokeless To-  
8 bacco Products to Protect Children and Adoles-  
9 cents” (60 Fed. Reg. 41314–41372 (August 11,  
10 1995)).

11 (2) The document entitled “Nicotine in Ciga-  
12 rettes and Smokeless Tobacco Products is a Drug  
13 and These Products Are Nicotine Delivery Devices  
14 Under the Federal Food, Drug, and Cosmetic Act”  
15 (60 Fed. Reg. 41453–41787 (August 11, 1995)).

16 (3) The preamble to the final rule in the docu-  
17 ment entitled “Regulations Restricting the Sale and  
18 Distribution of Cigarettes and Smokeless Tobacco to  
19 Protect Children and Adolescents” (61 Fed. Reg.  
20 44396–44615 (August 28, 1996)).

21 (4) The document entitled “Nicotine in Ciga-  
22 rettes and Smokeless Tobacco is a Drug and These  
23 Products are Nicotine Delivery Devices Under the  
24 Federal Food, Drug, and Cosmetic Act; Jurisdic-

1 tional Determination” (61 Fed. Reg. 44619–45318  
2 (August 28, 1996)).

3 **SEC. 103. CONFORMING AND OTHER AMENDMENTS TO GEN-**  
4 **ERAL PROVISIONS.**

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

12 (b) SECTION 301.—Section 301 (21 U.S.C. 331) is  
13 amended—

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

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

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

20 (4) in subsection (e), by striking “515(f), or  
21 519” and inserting “515(f), 519, or 909”;

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

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

1           (7) in subsection (j), by striking “708, or 721”  
2           and inserting “708, 721, 904, 905, 906, 907, 908,  
3           or 909”;

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

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

8           “(p) The failure to register in accordance with section  
9           510 or 905, the failure to provide any information re-  
10          quired by section 510(j), 510(k), 905(i), or 905(j), or the  
11          failure to provide a notice required by section 510(j)(2)  
12          or 905(j)(2).”;

13          (10) by striking subsection (q)(1) and inserting  
14          the following:

15          “(q)(1) The failure or refusal—

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

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

21                “(C) to comply with a requirement under sec-  
22                tion 522 or 912.”;

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

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

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

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

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

10           (1) by striking the subsection heading and in-  
11           serting the following:

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

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

16           (3) by redesignating paragraphs (3), (4), and  
17           (5) as paragraphs (4), (5), and (6), and inserting  
18           after paragraph (2) the following:

19           “(3) If the Secretary finds that a person has  
20           committed repeated violations of restrictions promul-  
21           gated under section 906(d) at a particular retail out-  
22           let then the Secretary may impose a no-tobacco-sale  
23           order on that person prohibiting the sale of tobacco  
24           products in that outlet. A no-tobacco-sale order may

1 be imposed with a civil penalty under paragraph  
2 (1).”;

3 (4) in paragraph (4) as so redesignated—

4 (A) in subparagraph (A)—

5 (i) by striking “assessed” the first  
6 time it appears and inserting “assessed, or  
7 a no-tobacco-sale order may be imposed,”;  
8 and

9 (ii) by striking “penalty” and insert-  
10 ing “penalty, or upon whom a no-tobacco-  
11 order is to be imposed,”;

12 (B) in subparagraph (B)—

13 (i) by inserting after “penalty,” the  
14 following: “or the period to be covered by  
15 a no-tobacco-sale order,”; and

16 (ii) by adding at the end the fol-  
17 lowing: “A no-tobacco-sale order perma-  
18 nently prohibiting an individual retail out-  
19 let from selling tobacco products shall in-  
20 clude provisions that allow the outlet, after  
21 a specified period of time, to request that  
22 the Secretary compromise, modify, or ter-  
23 minate the order.”; and

24 (C) by adding at the end, the following:

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

4           (5) in paragraph (5) as so redesignated—

5           (A) by striking “(3)(A)” as redesignated,  
6 and inserting “(4)(A)”;

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

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

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

16           (d) SECTION 304.—Section 304 (21 U.S.C. 334) is  
17 amended—

18           (1) in subsection (a)(2)—

19           (A) by striking “and” before “(D)”;

20           (B) by striking “device.” and inserting the  
21 following: “, (E) Any adulterated or misbranded  
22 tobacco product.”;

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

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

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

6           (e) SECTION 702.—Section 702(a) (21 U.S.C.  
7 372(a)) is amended—

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

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

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

14          (f) SECTION 703.—Section 703 (21 U.S.C. 373) is  
15 amended—

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

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

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

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

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

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

6           (h) SECTION 705.—Section 705(b) (21 U.S.C.  
7           375(b)) is amended by inserting “tobacco products,” after  
8           “devices,”.

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

11          (j) SECTION 801.—Section 801 (21 U.S.C. 381) is  
12          amended—

13               (1) in subsection (a)—

14                   (A) by inserting “tobacco products,” after  
15                   “devices,” the first time it appears;

16                   (B) by inserting “or subsection (j) of sec-  
17                   tion 905” after “section 510”; and

18                   (C) by striking “drugs or devices” each  
19                   time it appears and inserting “drugs, devices,  
20                   or tobacco products”;

21               (2) in subsection (e)—

22                   (A) in paragraph (1), by inserting “tobacco  
23                   product,” after “device,”; and

1 (B) by redesignating paragraph (4) as  
2 paragraph (5) and inserting after paragraph  
3 (3), the following:

4 “(4) Paragraph (1) does not apply to any to-  
5 bacco product—

6 “(A) which does not comply with an appli-  
7 cable requirement of section 907 or 910; or

8 “(B) which under section 906(f) is exempt  
9 from either such section.

10 This paragraph does not apply if the Secretary has  
11 determined that the exportation of the tobacco prod-  
12 uct is not contrary to the public health and safety  
13 and has the approval of the country to which it is  
14 intended for export or the tobacco product is eligible  
15 for export under section 802.”.

16 (k) SECTION 802.—Section 802 (21 U.S.C. 382) is  
17 amended—

18 (1) in subsection (a), by striking “device—”  
19 and inserting “device or tobacco product—”;

20 (2) in subsection (a)(1)(C), by striking “and”  
21 after the semicolon;

22 (3) in subsection (a)(2), by striking subpara-  
23 graph (C) and all that follows in that subsection and  
24 inserting the following:

1           “(C) is a banned device under section 516;

2           or

3           “(3) which, in the case of a tobacco product—

4           “(A) does not comply with an applicable  
5           requirement of section 907 or 910; or

6           “(B) under section 906(f) is exempt from  
7           either such section,

8           is adulterated, misbranded, and in violation of such  
9           sections or Act unless the export of the drug, device,  
10          or tobacco product is, except as provided in sub-  
11          section (f), authorized under subsection (b), (c), (d),  
12          or (e) of this section or section 801(e)(2) or  
13          801(e)(4). If a drug, device, or tobacco product de-  
14          scribed in paragraph (1), (2), or (3) may be ex-  
15          ported under subsection (b) and if an application for  
16          such drug or device under section 505, 515, or 910  
17          of this Act or section 351 of the Public Health Serv-  
18          ice Act (42 U.S.C. 262) was disapproved, the Sec-  
19          retary shall notify the appropriate public health offi-  
20          cial of the country to which such drug, device, or to-  
21          bacco product will be exported of such disapproval.”;

22          (4) in subsection (b)(1)(A), by inserting “or to-  
23          bacco product” after “device” each time it appears;

1 (5) in subsection (c), by inserting “or tobacco  
2 product” after “device” and inserting “or section  
3 906(f)” after “520(g).”;

4 (6) in subsection (f), by inserting “or tobacco  
5 product” after “device” each time it appears; and

6 (7) in subsection (g), by inserting “or tobacco  
7 product” after “device” each time it appears.

8 (l) SECTION 1003.—Section 1003(d)(2)(C) (as redес-  
9 igned by section 101(a)) is amended—

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

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

13 (m) EFFECTIVE DATE FOR NO-TOBACCO-SALE  
14 ORDER AMENDMENTS.—The amendments made by sub-  
15 section (c), other than the amendment made by paragraph  
16 (2) of such subsection, shall take effect only upon the pro-  
17 mulgation of final regulations by the Secretary of Health  
18 and Human Services—

19 (1) defining the term “repeated violation”, as  
20 used in section 303(f) of the Federal Food, Drug,  
21 and Cosmetic Act (21 U.S.C. 333(f)) as amended by  
22 subsection (c), by identifying the number of viola-  
23 tions of particular requirements over a specified pe-  
24 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 a violation at a particular retail outlet unless  
5 the Secretary has provided notice to the retailer of  
6 all previous 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 **TITLE II—TOBACCO PRODUCT**  
17 **WARNINGS AND SMOKE CON-**  
18 **STITUENT DISCLOSURE**

19 **SEC. 201. CIGARETTE LABEL AND ADVERTISING WARNINGS.**

20           (a) IN GENERAL.—Section 4 of the Federal Cigarette  
21 Labeling and Advertising Act (15 U.S.C. 1333) is amend-  
22 ed to read as follows:

23 **“SEC. 4. LABELING.**

24           “(a) LABEL REQUIREMENTS.—

1           “(1) IN GENERAL.—It shall be unlawful for any  
2 person to manufacture, package, or import for sale  
3 or distribution within the United States any ciga-  
4 rettes the package of which fails to bear, in accord-  
5 ance with the requirements of this section, one of  
6 the following labels:

7           “WARNING: Cigarettes are addictive”

8           “WARNING: Tobacco smoke can harm your chil-  
9 dren”

10          “WARNING: Cigarettes cause fatal lung disease”

11          “WARNING: Cigarettes cause cancer”

12          “WARNING: Cigarettes cause strokes and heart  
13 disease”

14          “WARNING: Smoking during pregnancy can harm  
15 your baby”

16          “WARNING: Smoking can kill you”

17          “WARNING: Tobacco smoke causes fatal lung dis-  
18 ease in non-smokers”

19          “WARNING: Quitting smoking now greatly reduces  
20 serious risks to your health”

21           “(2) PLACEMENT; TYPOGRAPHY; ETC.—

22           “(A) IN GENERAL.—Each label statement  
23 required by paragraph (1) shall be located in  
24 the upper portion of the front and rear panels  
25 of the package, directly on the package under-

1           neath the cellophane or other clear wrapping.  
2           Except as provided in subparagraph (B), each  
3           label statement shall comprise at least the top  
4           25 percent of the front and rear panels of the  
5           package. The word “WARNING” shall appear  
6           in capital letters and all text shall be in con-  
7           spicuous and legible 17-point type, unless the  
8           text of the label statement would occupy more  
9           than 70 percent of such area, in which case the  
10          text may be in a smaller conspicuous and leg-  
11          ible type size, provided that at least 60 percent  
12          of such area is occupied by required text. The  
13          text shall be black on a white background, or  
14          white on a black background, in a manner that  
15          contrasts, by typography, layout, or color, with  
16          all other printed material on the package, in an  
17          alternating fashion under the plan submitted  
18          under subsection (b)(4).

19                 “(B) FLIP-TOP BOXES.—For any cigarette  
20                 brand package manufactured or distributed be-  
21                 fore January 1, 2000, which employs a flip-top  
22                 style (if such packaging was used for that  
23                 brand in commerce prior to June 21, 1997), the  
24                 label statement required by paragraph (1) shall  
25                 be located on the flip-top area of the package,

1           even if such area is less than 25 percent of the  
2           area of the front panel. Except as provided in  
3           this paragraph, the provisions of this subsection  
4           shall apply to such packages.

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

11          “(b) ADVERTISING REQUIREMENTS.—

12           “(1) IN GENERAL.—It shall be unlawful for any  
13           tobacco product manufacturer, importer, distributor,  
14           or retailer of cigarettes to advertise or cause to be  
15           advertised within the United States any cigarette  
16           unless its advertising bears, in accordance with the  
17           requirements of this section, one of the labels specified in subsection (a) of this section.

19           “(2) TYPOGRAPHY, ETC.—Each label statement  
20           required by subsection (a) of this section in cigarette  
21           advertising shall comply with the standards set forth  
22           in this paragraph. For press and poster advertisements, each such statement and (where applicable)  
23           any required statement relating to tar, nicotine, or  
24           other constituent yield shall comprise at least 20  
25

1 percent of the area of the advertisement and shall  
2 appear in a conspicuous and prominent format and  
3 location at the top of each advertisement within the  
4 trim area. The Secretary may revise the required  
5 type sizes in such area in such manner as the Sec-  
6 retary determines appropriate. The word “WARN-  
7 ING” shall appear in capital letters, and each label  
8 statement shall appear in conspicuous and legible  
9 type. The text of the label statement shall be black  
10 if the background is white and white if the back-  
11 ground is black, under the plan submitted under  
12 paragraph (4) of this subsection. The label state-  
13 ments shall be enclosed by a rectangular border that  
14 is the same color as the letters of the statements  
15 and that is the width of the first downstroke of the  
16 capital “W” of the word “WARNING” in the label  
17 statements. The text of such label statements shall  
18 be in a typeface pro rata to the following require-  
19 ments: 45-point type for a whole-page broadsheet  
20 newspaper advertisement; 39-point type for a half-  
21 page broadsheet newspaper advertisement; 39-point  
22 type for a whole-page tabloid newspaper advertise-  
23 ment; 27-point type for a half-page tabloid news-  
24 paper advertisement; 31.5-point type for a double  
25 page spread magazine or whole-page magazine ad-

1 advertisement; 22.5-point type for a 28 centimeter by  
2 3 column advertisement; and 15-point type for a 20  
3 centimeter by 2 column advertisement. The label  
4 statements shall be in English, except that in the  
5 case of—

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

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

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

1 20 percent area of cigarette advertisements provided  
2 by paragraph (2) of this subsection. The Secretary  
3 shall promulgate regulations which provide for ad-  
4 justments in the format and type sizes of any text  
5 required to appear in such area to ensure that the  
6 total text required to appear by law will fit within  
7 such area.

8 “(4) MARKETING REQUIREMENTS.—

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

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

1           “(C) The Secretary shall review each plan  
2           submitted under subparagraph (B) and approve  
3           it if the plan—

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

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

13           (b) **REPEAL OF PROHIBITION ON STATE RESTRIC-**  
14 **TION.**—Section 5 of the Federal Cigarette Labeling and  
15 Advertising Act (15 U.S.C. 1334) is amended—

16                   (1) by striking “(a) **ADDITIONAL STATE-**  
17 **MENTS.—**” in subsection (a); and

18                   (2) by striking subsection (b).

19 **SEC. 202. AUTHORITY TO REVISE CIGARETTE WARNING**  
20 **LABEL STATEMENTS.**

21           Section 4 of the Federal Cigarette Labeling and Ad-  
22 vertising Act ( 15 U.S.C. 1333), as amended by section  
23 301 of this title, is further amended by adding at the end  
24 the following:

1       “(c) CHANGE IN REQUIRED STATEMENTS.—The Sec-  
2 retary may, by a rulemaking conducted under section 553  
3 of title 5, United States Code, adjust the format, type size,  
4 and text of any of the warning label statements required  
5 by subsection (a) of this section, or establish the format,  
6 type size, and text of any other disclosures required under  
7 the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301  
8 et seq.), if the Secretary finds that such a change would  
9 promote greater public understanding of the risks associ-  
10 ated with the use of smokeless tobacco products.”.

11 **SEC. 203. SMOKELESS TOBACCO LABELS AND ADVERTISING**  
12 **WARNINGS.**

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

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

17       “(a) GENERAL RULE.—

18               “(1) It shall be unlawful for any person to man-  
19 ufacture, package, or import for sale or distribution  
20 within the United States any smokeless tobacco  
21 product unless the product package bears, in accord-  
22 ance with the requirements of this Act, one of the  
23 following labels:

24       “WARNING: This product can cause mouth cancer”

1 “WARNING: This product can cause gum disease  
2 and tooth loss”

3 “WARNING: This product is not a safe alternative  
4 to cigarettes”

5 “WARNING: Smokeless tobacco is addictive”

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

8 “(A) located on the 2 principal display  
9 panels of the package, and each label statement  
10 shall comprise at least 25 percent of each such  
11 display panel; and

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

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

6           “(4) The provisions of this subsection do not  
7           apply to a tobacco product manufacturer or dis-  
8           tributor of any smokeless tobacco product that does  
9           not manufacture, package, or import smokeless to-  
10          bacco products for sale or distribution within the  
11          United States.

12          “(b) REQUIRED LABELS.—

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

20                 “(2) Each label statement required by sub-  
21                 section (a) in smokeless tobacco advertising shall  
22                 comply with the standards set forth in this para-  
23                 graph. For press and poster advertisements, each  
24                 such statement and (where applicable) any required

1 statement relating to tar, nicotine, or other con-  
2 stituent yield shall—

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

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

14 “(3)(A) The label statements specified in sub-  
15 section (a)(1) shall be randomly displayed in each  
16 12-month period, in as equal a number of times as  
17 is possible on each brand of the product and be ran-  
18 domly distributed in all areas of the United States  
19 in which the product is marketed in accordance with  
20 a plan submitted by the tobacco product manufac-  
21 turer, importer, distributor, or retailer and approved  
22 by the Secretary.

23 “(B) The label statements specified in sub-  
24 section (a)(1) shall be rotated quarterly in alter-  
25 nating sequence in advertisements for each brand of

1 smokeless tobacco product in accordance with a plan  
 2 submitted by the tobacco product manufacturer, im-  
 3 porter, distributor, or retailer to, and approved by,  
 4 the Secretary.

5 “(C) The Secretary shall review each plan sub-  
 6 mitted under subparagraph (B) and approve it if the  
 7 plan—

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

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

15 “(c) TELEVISION AND RADIO ADVERTISING.—It is  
 16 unlawful to advertise smokeless tobacco on any medium  
 17 of electronic communications subject to the jurisdiction of  
 18 the Federal Communications Commission.”.

19 **SEC. 204. AUTHORITY TO REVISE SMOKELESS TOBACCO**  
 20 **PRODUCT WARNING LABEL STATEMENTS.**

21 Section 3 of, as amended by section 303 of this title,  
 22 is further amended by adding at the end the following:

23 “(d) AUTHORITY TO REVISE WARNING LABEL  
 24 STATEMENTS.—The Secretary may, by a rulemaking con-  
 25 ducted under section 553 of title 5, United States Code,

1 adjust the format, type size, and text of any of the warn-  
2 ing label statements required by subsection (a) of this sec-  
3 tion, or establish the format, type size, and text of any  
4 other disclosures required under the Federal Food, Drug,  
5 and Cosmetic Act (21 U.S.C. 301 et seq.), if the Secretary  
6 finds that such a change would promote greater public un-  
7 derstanding of the risks associated with the use of smoke-  
8 less tobacco products.”.

9 **SEC. 205. TAR, NICOTINE, AND OTHER SMOKE CON-**  
10 **STITUENT DISCLOSURE TO THE PUBLIC.**

11 Section 4(a) of the Federal Cigarette Labeling and  
12 Advertising Act (15 U.S.C. 1333 (a)), as amended by sec-  
13 tion 301 of this title, is further amended by adding at  
14 the end the following:

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

1 type size requirements of subsection (b) of this sec-  
2 tion, and shall appear within the area specified in  
3 subsection (b) of this section.

4 “(B) Any differences between the requirements  
5 established by the Secretary under subparagraph (A)  
6 and tar and nicotine yield reporting requirements es-  
7 tablished by the Federal Trade Commission shall be  
8 resolved by a memorandum of understanding be-  
9 tween the Secretary and the Federal Trade Commis-  
10 sion.

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

1       bacco product package or advertisement insert, or by  
2       any other means under the Federal Food, Drug, and  
3       Cosmetic Act (21 U.S.C. 301 et seq.).”.

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