



**AMENDMENT IN THE NATURE OF A SUBSTITUTE**  
**TO H.R. \_\_\_\_\_**  
**OFFERED BY MR. BUYER OF INDIANA**

Strike all after the enacting clause and insert the following:

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

2 (a) SHORT TITLE.—This Act may be cited as the  
3 “Youth Prevention and Tobacco Harm Reduction Act”.

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

- Sec. 1. Short title; table of contents.
- Sec. 2. Findings.
- Sec. 3. Purpose.
- Sec. 4. Scope and effect.
- Sec. 5. Severability.
- Sec. 6. Effective date.

**TITLE I—AUTHORITY OF THE TOBACCO HARM REDUCTION  
CENTER**

- Sec. 100. Definitions.
- Sec. 101. Center authority over tobacco products.
- Sec. 102. Exclusion of other regulatory programs.
- Sec. 103. Existing Federal statutes maintained.
- Sec. 104. Proceedings in the name of the united states; subpoenas; preemption  
of State and local law; no private right of action.
- Sec. 105. Illicit trade.
- Sec. 106. Adulterated tobacco products.
- Sec. 107. Misbranded tobacco products.
- Sec. 108. Submission of health information to the Administrator.
- Sec. 109. Registration and listing.
- Sec. 110. General provisions respecting control of tobacco products.
- Sec. 111. Smoking article standards.
- Sec. 112. Notification and other remedies.
- Sec. 113. Records and reports on tobacco products.
- Sec. 114. Application for review of certain smoking articles.
- Sec. 115. Modified risk tobacco products.
- Sec. 116. Judicial review.

- Sec. 117. Jurisdiction of and coordination with the federal trade commission.
- Sec. 118. Regulation requirement.
- Sec. 119. Preservation of state and local authority.
- Sec. 120. Tobacco Products Scientific Advisory Committee.
- Sec. 121. Drug products used to treat tobacco dependence.
- Sec. 122. Advertising and Marketing of tobacco products.

TITLE II—TOBACCO PRODUCTS WARNINGS; CONSTITUENT AND  
SMOKE CONSTITUENT DISCLOSURE

- Sec. 201. Cigarette label and advertising warnings.
- Sec. 202. Smokeless tobacco labels and advertising warnings.

TITLE III—PUBLIC DISCLOSURES BY TOBACCO PRODUCTS  
MANUFACTURERS

- Sec. 301. Disclosures on packages of tobacco products.
- Sec. 302. Disclosures on packages of smokeless tobacco.
- Sec. 303. Public disclosure of ingredients.

TITLE IV—PREVENTION OF ILLICIT TRADE IN TOBACCO  
PRODUCTS

- Sec. 401. Study and report on illicit Trade.
- Sec. 402. Amendment to section 1926 of the Public Health Service Act.
- Sec. 403. Establishment of rankings.

TITLE V—ENFORCEMENT PROVISIONS

- Sec. 501. Prohibited acts.
- Sec. 502. Injunction proceedings.
- Sec. 503. Penalties.
- Sec. 504. Seizure.
- Sec. 505. Report of minor violations.
- Sec. 506. Inspection.
- Sec. 507. Effect of compliance.
- Sec. 508. Imports.
- Sec. 509. tobacco products for export.

TITLE VI—MISCELLANEOUS PROVISIONS

- Sec. 601. Use of payments under the master settlement agreement and individual state settlement agreements.
- Sec. 602. Preemption of State Laws Implementing Fire Safety Standard for Cigarettes.
- Sec. 603. Inspection by the alcohol and tobacco tax trade bureau of records of certain cigarette and smokeless tobacco sellers.
- Sec. 604. Severability.

TITLE VII—TOBACCO GROWER PROTECTION

- Sec. 701. Tobacco grower protection.

**1 SEC. 2. FINDINGS.**

**2** The Congress finds the following:

1           (1) Cigarette smoking is a leading cause of pre-  
2           ventable deaths in the United States. Cigarette  
3           smoking significantly increases the risk of developing  
4           lung cancer, heart disease, chronic bronchitis, em-  
5           physema and other serious diseases with adverse  
6           health conditions.

7           (2) The risk for serious diseases is significantly  
8           affected by the type of tobacco product and the fre-  
9           quency, duration and manner of use.

10          (3) No tobacco product has been shown to be  
11          safe and without risks. The health risks associated  
12          with cigarettes are significantly greater than those  
13          associated with the use of smoke-free tobacco and  
14          nicotine products.

15          (4) Nicotine in tobacco products is addictive but  
16          is not considered a significant threat to health.

17          (5) It is the smoke inhaled from burning to-  
18          bacco which poses the most significant risk of seri-  
19          ous diseases.

20          (6) Quitting cigarette smoking significantly re-  
21          duces the risk for serious diseases.

22          (7) Adult tobacco consumers have a right to be  
23          fully and accurately informed about the risks of seri-  
24          ous diseases, the significant differences in the com-  
25          parative risks of different tobacco and nicotine-based

1 products, and the benefits of quitting. This informa-  
2 tion should be based on sound science.

3 (8) Governments, public health officials, tobacco  
4 manufacturers and others share a responsibility to  
5 provide adult tobacco consumers with accurate infor-  
6 mation about the various health risks and compara-  
7 tive risks associated with the use of different tobacco  
8 and nicotine products.

9 (9) Tobacco products should be regulated in a  
10 manner that is designed to achieve significant and  
11 measurable reductions in the morbidity and mor-  
12 tality associated with tobacco use. Regulations  
13 should enhance the information available to adult  
14 consumers to permit them to make informed choices,  
15 and encourage the development of tobacco and nico-  
16 tine products with lower risks than cigarettes cur-  
17 rently sold in the United States.

18 (10) The form of regulation should be based on  
19 the risks and comparative risks of tobacco and nico-  
20 tine products and their respective product categories.

21 (11) The regulation of marketing of tobacco  
22 products should be consistent with constitutional  
23 protections and enhance an adult consumer's ability  
24 to make an informed choice by providing accurate

1 information on the risks and comparative risks of to-  
2 bacco products.

3 (12) Reducing the diseases and deaths associ-  
4 ated with the use of cigarettes serves public health  
5 goals and is in the best interest of consumers and  
6 society. Harm reduction should be the critical ele-  
7 ment of any comprehensive public policy surrounding  
8 the health consequences of tobacco use.

9 (13) Significant reductions in the harm associ-  
10 ated with the use of cigarettes can be achieved by  
11 providing accurate information regarding the com-  
12 parative risks of tobacco products to adult tobacco  
13 consumers, thereby encouraging smokers to migrate  
14 to the use of smoke-free tobacco and nicotine prod-  
15 ucts, and by developing new smoke-free tobacco and  
16 nicotine products and other actions.

17 (14) Governments, public health officials, man-  
18 ufacturers, tobacco producers and consumers should  
19 support the development, production, and commer-  
20 cial introduction of tobacco leaf, and tobacco and  
21 nicotine-based products that are scientifically shown  
22 to reduce the risks associated with the use of exist-  
23 ing tobacco products, particularly cigarettes.

1           (15) Adult tobacco consumers should have ac-  
2           cess to a range of commercially viable tobacco and  
3           nicotine-based products.

4           (16) There is substantial scientific evidence  
5           that selected smokeless tobacco products can satisfy  
6           the nicotine addiction of inveterate smokers while  
7           eliminating most, if not all, risk of pulmonary and  
8           cardiovascular complications of smoking and while  
9           reducing the risk of cancer by more than 95 percent.

10          (17) Transitioning smokers to selected smoke-  
11          less tobacco products will eliminate environmental  
12          tobacco smoke and fire-related hazards.

13          (18) Current “abstain, quit, or die” tobacco  
14          control policies in the United States may have  
15          reached their maximum possible public health ben-  
16          efit because of the large number of cigarette smok-  
17          ers either unwilling or unable to discontinue their  
18          addiction to nicotine.

19          (19) There is evidence that harm reduction  
20          works and can be accomplished in a way that will  
21          not increase initiation or impede smoking cessation.

22          (20) Health-related agencies and organizations,  
23          both within the United States and abroad have al-  
24          ready gone on record endorsing Harm Reduction as

1 an approach to further reducing tobacco related ill-  
2 ness and death.

3 (21) Current Federal policy requires tobacco  
4 product labeling that leaves the incorrect impression  
5 that all tobacco product present equal risk.

6 **SEC. 3. PURPOSE.**

7 The purposes of this Act are—

8 (1) to provide authority to the Tobacco Harm  
9 Reduction Center by recognizing it as the primary  
10 Federal regulatory authority with respect to tobacco  
11 products as provided for in this Act;

12 (2) to ensure that the Center has the authority  
13 to address issues of particular concern to public  
14 health officials, especially the use of tobacco by  
15 young people and dependence on tobacco;

16 (3) to authorize the Center to set national  
17 standards controlling the manufacture of tobacco  
18 products and the identity, public disclosure, and  
19 amount of ingredients used in such products;

20 (4) to provide new and flexible enforcement au-  
21 thority to ensure that there is effective oversight of  
22 the tobacco industry's efforts to develop, introduce,  
23 and promote less harmful tobacco products;

1           (5) to vest the Center with the authority to reg-  
2           ulate the levels of tar, nicotine, and other harmful  
3           components of tobacco products;

4           (6) to ensure that consumers are better in-  
5           formed regarding the relative risks for death and  
6           disease between categories of tobacco products;

7           (7) to continue to allow the sale of tobacco  
8           products to adults in conjunction with measures to  
9           ensure that they are not sold or accessible to under-  
10          age purchasers;

11          (8) to impose appropriate regulatory controls on  
12          the tobacco industry;

13          (9) to promote prevention, cessation, and harm  
14          reduction policies and regulations to reduce disease  
15          risk and the social costs associated with tobacco-re-  
16          lated diseases;

17          (10) to provide authority to the Department of  
18          Health and Human Services to regulate tobacco  
19          products;

20          (11) to establish national policies that effec-  
21          tively reduce disease and death associated with ciga-  
22          rette smoking and other tobacco use;

23          (12) to establish national policies that encour-  
24          age prevention, cessation, and harm reduction meas-  
25          ures regarding the use of tobacco products;

1           (13) to encourage current cigarette smokers  
2 who will not quit to use noncombustible tobacco or  
3 nicotine products that have significantly less risk  
4 than cigarettes;

5           (14) to establish national policies that accu-  
6 rately and consistently inform adult tobacco con-  
7 sumers of significant differences in risk between re-  
8 spective tobacco products;

9           (15) to establish national policies that encour-  
10 age and assist the development and awareness of  
11 noncombustible tobacco and nicotine products;

12           (16) to coordinate national and State preven-  
13 tion, cessation, and harm reduction programs;

14           (17) to impose measures to ensure tobacco  
15 products are not sold or accessible to underage pur-  
16 chasers; and

17           (18) to strengthen Federal and State legislation  
18 to prevent illicit trade in tobacco products.

19 **SEC. 4. SCOPE AND EFFECT.**

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

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

1           (2) affect any action pending in Federal, State,  
2           or Tribal court, or any agreement, consent decree, or  
3           contract of any kind; or

4           (3) be applicable to tobacco products or compo-  
5           nent parts manufactured in the United States for  
6           export.

7           (b) **AGRICULTURAL ACTIVITIES.**—The provisions of  
8           this Act (or an amendment made by this Act) which au-  
9           thorize the Administrator to take certain actions with re-  
10          gard to tobacco and tobacco products shall not be con-  
11          strued to affect any authority of the Secretary of Agri-  
12          culture under existing law regarding the growing, cultiva-  
13          tion, or curing of raw tobacco.

14          (c) **REVENUE ACTIVITIES.**—The provisions of this  
15          Act (or an amendment made by this Act) which authorize  
16          the Administrator to take certain actions with regard to  
17          tobacco products shall not be construed to affect any au-  
18          thority of the Secretary of the Treasury under chapter 52  
19          of the Internal Revenue Code of 1986.

20          **SEC. 5. SEVERABILITY.**

21          If any provision of this Act, the amendments made  
22          by this Act, or the application of any provision of this Act  
23          to any person or circumstance is held to be invalid, the  
24          remainder of this Act, the amendments made by this Act,  
25          and the application of the provisions of this Act to any

1 other person or circumstance shall not be affected and  
2 shall continue to be enforced to the fullest extent possible.

3 **SEC. 6. EFFECTIVE DATE.**

4 Except as otherwise specifically provided, the effec-  
5 tive date of this Act shall be the date of its enactment.

6 **TITLE I—AUTHORITY OF THE TO-**  
7 **BACCO HARM REDUCTION**  
8 **CENTER**

9 **SEC. 100. DEFINITIONS.**

10 In this Act:

11 (1) The term “Administrator” means the chief  
12 executive of the Tobacco Harm Reduction Center.

13 (2) The term “adult” means any individual who  
14 has attained the minimum age under applicable  
15 State law to be an individual to whom tobacco prod-  
16 ucts may lawfully be sold.

17 (3) The term “adult-only facility” means a fa-  
18 cility or restricted area, whether open-air or en-  
19 closed, where the operator ensures, or has a reason-  
20 able basis to believe, that no youth is present. A fa-  
21 cility or restricted area need not be permanently re-  
22 stricted to adults in order to constitute an adult-only  
23 facility, if the operator ensures, or has a reasonable  
24 basis to believe, that no youth is present during any  
25 period of operation as an adult-only facility.

1           (4) The term “affiliate” means a person that  
2 directly or indirectly owns or controls, is owned or  
3 controlled by, or is under common ownership or con-  
4 trol with, another person. The terms “owns,” “is  
5 owned”, and “ownership” refer to ownership of an  
6 equity interest, or the equivalent thereof, of 50 per-  
7 cent or more.

8           (5) The term “annual report” means a tobacco  
9 product manufacturer’s annual report to the Center,  
10 which provides ingredient information and nicotine  
11 yield ratings for each brand style that tobacco prod-  
12 uct manufacturer manufactures for commercial dis-  
13 tribution domestically.

14           (6) The term “brand name” means a brand  
15 name of a tobacco product distributed or sold do-  
16 mestically, alone, or in conjunction with any other  
17 word, trademark, logo, symbol, motto, selling mes-  
18 sage, recognizable pattern of colors, or any other in-  
19 dicium of product identification identical or similar  
20 to, or identifiable with, those used for any domestic  
21 brand of tobacco product. The term shall not include  
22 the corporate name of any tobacco product manufac-  
23 turer that does not, after the effective date of this  
24 Act, sell a brand style of tobacco product in the  
25 United States that includes such corporate name.

1           (7) The term “brand style” means a tobacco  
2           product having a brand name, and distinguished by  
3           the selection of the tobacco, ingredients, structural  
4           materials, format, configuration, size, package, prod-  
5           uct descriptor, amount of tobacco, or yield of “tar”  
6           or nicotine.

7           (8) The term “Center” means the Tobacco  
8           Harm Reduction Center.

9           (9) The term “cigar” has the meaning assigned  
10          that term by the Alcohol and Tobacco Tax and  
11          Trade Bureau in section 40.11 of title 27, Code of  
12          Federal Regulations.

13          (10) The term “cigarette” means—

14                (A) any roll of tobacco wrapped in paper  
15                or in any substance not containing tobacco; or

16                (B) any roll of tobacco wrapped in any  
17                substance containing tobacco which, because of  
18                the appearance of the roll of tobacco, the type  
19                of tobacco used in the filler, or its package or  
20                labeling, is likely to be offered to, or purchased  
21                by, consumers as a cigarette described in para-  
22                graph (1).

23          (11) The term “competent and reliable sci-  
24          entific evidence” means evidence based on tests,  
25          analyses, research, or studies, conducted and evalu-

1       ated in an objective manner by individuals qualified  
2       to do so, using procedures generally accepted in the  
3       relevant scientific disciplines to yield accurate and  
4       reliable results.

5           (12) The term “distributor” means any person  
6       who furthers the distribution of tobacco products,  
7       whether domestic or imported, at any point from the  
8       original place of manufacture to the person who sells  
9       or distributes the tobacco product to individuals for  
10      personal consumption. Common carriers, retailers,  
11      and those engaged solely in advertising are not con-  
12      sidered distributors for purposes of this Act.

13          (13) The terms “domestic” and “domestically”  
14      mean within the United States, including activities  
15      within the United States involving advertising, mar-  
16      keting, distribution, or sale of tobacco products that  
17      are intended for consumption within the United  
18      States.

19          (14) The term “illicit tobacco product” means  
20      any tobacco product intended for use by consumers  
21      in the United States—

22            (A) as to which not all applicable duties or  
23            taxes have been paid in full;

24            (B) that has been stolen, smuggled, or is  
25            otherwise contraband;

1 (C) that is counterfeit; or

2 (D) that has or had a label, labeling, or  
3 packaging stating, or that stated, that the prod-  
4 uct is or was for export only, or that it is or  
5 was at any time restricted by section 5704 of  
6 title 26, United States Code.

7 (15) The term “illicit trade” means any trans-  
8 fer, distribution, or sale in interstate commerce of  
9 any illicit tobacco product.

10 (16) The term “immediate container” does not  
11 include package liners.

12 (17) The term “Indian tribe” has the meaning  
13 assigned that term in section 4(e) of the Indian Self  
14 Determination and Education Assistance Act.

15 (18) The term “ingredient” means tobacco and  
16 any substance added to tobacco to have an effect in  
17 the final tobacco product or when the final tobacco  
18 product is used by a consumer.

19 (19) The term “International Organization for  
20 Standardization (ISO) testing regimen” means the  
21 methods for measuring cigarette smoke yields, as set  
22 forth in the most recent version of ISO 3308, enti-  
23 tled “Routine analytical cigarette-smoking machine  
24 – Definition of standard conditions”; ISO 4387, en-  
25 titled “Cigarettes – Determination of total and nico-

1       tine-free dry particulate matter using a routine ana-  
2       lytical smoking machine”; ISO 10315, entitled  
3       “Cigarettes – Determination of nicotine in smoke  
4       condensates – Gas-chromatographic method”; ISO  
5       10362–1, entitled “Cigarettes – Determination of  
6       water in smoke condensates – Part 1: Gas-  
7       chromatographic method”; and ISO 8454, entitled  
8       “Cigarettes – Determination of carbon monoxide in  
9       the vapour phase of cigarette smoke – NDIR meth-  
10      od”. A cigarette that does not burn down in accord-  
11      ance with the testing regimen standards may be  
12      measured under the same puff regimen using the  
13      number of puffs that such a cigarette delivers before  
14      it extinguishes, plus an additional three puffs, or  
15      with such other modifications as the Administrator  
16      may approve.

17           (20) The term “interstate commerce” means all  
18      trade, traffic, or other commerce—

19                   (A) within the District of Columbia, or any  
20      territory or possession of the United States;

21                   (B) between any point in a State and any  
22      point outside thereof;

23                   (C) between points within the same State  
24      through any place outside such State; or

1 (D) over which the United States has ju-  
2 risdiction.

3 (21) The term “label” means a display of writ-  
4 ten, printed, or graphic matter upon or applied se-  
5 curely to the immediate container of a tobacco prod-  
6 uct.

7 (22) The term “labeling” means all labels and  
8 other written, printed, or graphic matter (1) upon or  
9 applied securely to any tobacco product or any of its  
10 containers or wrappers, or (2) accompanying a to-  
11 bacco product.

12 (23) The term “little cigar” has the meaning  
13 assigned that term by the Alcohol and Tobacco Tax  
14 and Trade Bureau in section 40.11 of title 27, Code  
15 of Federal Regulations.

16 (24) The term “loose tobacco” means any form  
17 of tobacco, alone or in combination with any other  
18 ingredient or material, that, because of its appear-  
19 ance, form, type, packaging, or labeling, is suitable  
20 for use and likely to be offered to, or purchased by,  
21 consumers as tobacco for making or assembling  
22 cigarettes, incorporation into pipes, or otherwise  
23 used by consumers to make any tobacco product.

24 (25) The term “manufacture” means to design,  
25 manufacture, fabricate, assemble, process, package,

1 or repackage, label, or relabel, import, or hold or  
2 store in a commercial quantity, but does not in-  
3 clude—

4 (A) the growing, curing, de-stemming, or  
5 aging of tobacco; or

6 (B) the holding, storing or transporting of  
7 a tobacco product by a common carrier for hire,  
8 a public warehouse, a testing laboratory, a dis-  
9 tributor, or a retailer.

10 (26) The term “nicotine-containing product”  
11 means a product, other than a tobacco product, that  
12 contains added nicotine, whether or not in the form  
13 of a salt or solvate, that has been—

14 (A) synthetically produced, or

15 (B) obtained from tobacco or other source  
16 of nicotine.

17 (27) The term “package” means a pack, box,  
18 carton, pouch, or container of any kind in which a  
19 tobacco product or tobacco products are offered for  
20 sale, sold, or otherwise distributed to consumers.  
21 The term “package” does not include an outer con-  
22 tainer used solely for shipping one or more packages  
23 of a tobacco product or tobacco products.

24 (28) The term “person” means any individual,  
25 partnership, corporation, committee, association, or-

1 organization or group of persons, or other legal or  
2 business entity.

3 (29) The term “proof of age” means a driver’s  
4 license or other form of identification that is issued  
5 by a governmental authority and includes a photo-  
6 graph and a date of birth of the individual.

7 (30) The term “raw tobacco” means tobacco in  
8 a form that is received by a tobacco product manu-  
9 facturer as an agricultural commodity, whether in a  
10 form that is natural, stem, or leaf, cured or aged,  
11 or as parts or pieces, but not in a reconstituted  
12 form, extracted pulp form, or extract form.

13 (31) The term “reduced-exposure claim” means  
14 a statement in advertising or labeling intended for  
15 one or more consumers of tobacco products, that a  
16 tobacco product provides a reduced exposure of  
17 users of that tobacco product to one or more toxi-  
18 cants, as compared to an appropriate reference to-  
19 bacco product or category of tobacco products. A  
20 statement or representation that a tobacco product  
21 or the tobacco in a tobacco product contains “no ad-  
22 ditives” or is “natural” or that uses a substantially  
23 similar term is not a reduced-exposure claim if the  
24 advertising or labeling that contains such statement

1 or representation also contains the disclosure re-  
2 quired by section 108(h) of this Act.

3 (32) The term “reduced-risk claim” means a  
4 statement in advertising or labeling intended for one  
5 or more consumers of smoking articles, that a smok-  
6 ing article provides to users of that product a re-  
7 duced risk of morbidity or mortality resulting from  
8 one or more chronic diseases or serious adverse  
9 health conditions associated with tobacco use, as  
10 compared to an appropriate reference smoking arti-  
11 cle or category of smoking articles, even if it is not  
12 stated, represented, or implied that all health risks  
13 associated with using that smoking article have been  
14 reduced or eliminated. A statement or representation  
15 that a smoking article or the tobacco in a smoking  
16 article contains “no additives,” or is “natural,” or  
17 that uses a substantially similar term is not a re-  
18 duced-risk claim if the advertising or labeling that  
19 contains such statement or representation also con-  
20 tains the disclosure required by section 108(h).

21 (33) The term “retailer” means any person  
22 that—

23 (A) sells tobacco products to individuals  
24 for personal consumption; or

1 (B) operates a facility where the sale of to-  
2 bacco products to individuals for personal con-  
3 sumption is permitted.

4 (34) The term “small business” means a to-  
5 bacco product manufacturer that—

6 (A) has 150 or fewer employees; and

7 (B) during the 3-year period prior to the  
8 current calendar year, had an average annual  
9 gross revenue from tobacco products that did  
10 not exceed \$40,000,000.

11 (35) The term “smokeless tobacco product”  
12 means any form of finely cut, ground, powdered, re-  
13 constituted, processed or shaped tobacco, leaf to-  
14 bacco, or stem tobacco, whether or not combined  
15 with any other ingredient, whether or not in extract  
16 or extracted form, and whether or not incorporated  
17 within any carrier or construct, that is intended to  
18 be placed in the oral or nasal cavity, including dry  
19 snuff, moist snuff, and chewing tobacco.

20 (36) The term “smoking article” means any to-  
21 bacco-containing article that is intended, when used  
22 by a consumer, to be burned or otherwise to employ  
23 heat to produce a vapor, aerosol or smoke that—

24 (A) incorporates components of tobacco or  
25 derived from tobacco; and

1 (B) is intended to be inhaled by the user.

2 (37) The term “State” means any State of the  
3 United States and, except as otherwise specifically  
4 provided, includes any Indian tribe or tribal organi-  
5 zation, the District of Columbia, the Commonwealth  
6 of Puerto Rico, Guam, the Virgin Islands, American  
7 Samoa, Wake Island, Midway Island, Kingman Reef,  
8 Johnston Atoll, the Northern Marianas, and any  
9 other trust territory or possession of the United  
10 States.

11 (38) The term “tar” means nicotine-free dry  
12 particulate matter as defined in ISO 4387, entitled  
13 “Cigarettes – Determination of total and nicotine-  
14 free dry particulate matter using a routine analytical  
15 smoking machine”.

16 (39) The term “tobacco” means a tobacco plant  
17 or any part of a harvested tobacco plant intended for  
18 use in the production of a tobacco product, including  
19 leaf, lamina, stem, or stalk, whether in green, cured,  
20 or aged form, whether in raw, treated, or processed  
21 form, and whether or not combined with other mate-  
22 rials, including any by-product, extract, extracted  
23 pulp material, or any other material (other than pu-  
24 rified nicotine) derived from a tobacco plant or any  
25 component thereof, and including strip, filler, stem,

1 powder, and granulated, blended, or reconstituted  
2 forms of tobacco.

3 (40) The term “tobacco product” means—

4 (A) the singular of “tobacco products” as  
5 defined in section 5702(e) of the Internal Rev-  
6 enue Code of 1986;

7 (B) any other product that contains to-  
8 bacco as a principal ingredient and that, be-  
9 cause of its appearance, type, or the tobacco  
10 used in the product, or its packaging and label-  
11 ing, is likely to be offered to, or purchased by,  
12 consumers as a tobacco product as described in  
13 subparagraph (A); and

14 (C) any form of tobacco or any construct  
15 incorporating tobacco, intended for human con-  
16 sumption, whether by—

17 (i) placement in the oral or nasal cav-  
18 ity;

19 (ii) inhalation of vapor, aerosol, or  
20 smoke; or

21 (iii) any other means.

22 (41) The term “tobacco product category”  
23 means a type of tobacco product characterized by its  
24 composition, components, and intended use, and in-  
25 cludes tobacco products classified as cigarettes, loose

1 tobacco for roll-your-own tobacco products, little ci-  
2 gars, cigars, pipe tobacco, moist snuff, dry snuff,  
3 chewing tobacco, and other forms of tobacco prod-  
4 ucts (which are treated in this Act collectively as a  
5 single category).

6 (42) The term “tobacco product communica-  
7 tion” means any means, medium, or manner for pro-  
8 viding information relating to any tobacco product,  
9 including face-to-face interaction, mailings by postal  
10 service or courier to an individual who is an ad-  
11 dressee, and electronic mail to an individual who is  
12 an addressee.

13 (43) The term “tobacco product manufacturer”  
14 means an entity that directly—

15 (A) manufactures anywhere a tobacco  
16 product that is intended to be distributed com-  
17 mercially in the United States, including a to-  
18 bacco product intended to be distributed com-  
19 mercially in the United States through an im-  
20 porter;

21 (B) is the first purchaser for resale in the  
22 United States of tobacco products manufac-  
23 tured outside the United States for distribution  
24 commercially in the United States; or

1 (C) is a successor or assign of any of the  
2 foregoing.

3 (44) The term “toxicant” means a chemical or  
4 physical agent that produces an adverse biological  
5 effect.

6 (45) The term “tribal organization” has the  
7 meaning assigned that term in section 4(1) of the  
8 Indian Self Determination and Education Assistance  
9 Act.

10 (46) The term “United States” means the sev-  
11 eral States, as defined in this Act.

12 (47) The term “youth” means any individual  
13 who is not an adult.

14 **SEC. 101. CENTER AUTHORITY OVER TOBACCO PRODUCTS.**

15 (a) IN GENERAL.—Tobacco products, including  
16 modified risk tobacco products for which an order has  
17 been issued in accordance with section 117, shall be regu-  
18 lated by the Administrator under this Act.

19 (b) APPLICABILITY.—This Act shall apply to all ciga-  
20 rettes, cigarette tobacco, roll-your-own tobacco, and  
21 smokeless tobacco and to any other tobacco products that  
22 the Administrator by regulation deems to be subject to  
23 this Act.

24 (c) CENTER.—The Secretary of Health and Human  
25 Services shall establish within the Department of Health

1 and Human Services the Tobacco Harm Reduction Cen-  
2 ter. The head of the Center shall be an Administrator,  
3 who shall assume the statutory authority conferred by this  
4 Act, perform the functions that relate to the subject mat-  
5 ter of this Act, and have the authority to promulgate regu-  
6 lations for the efficient enforcement of this Act. In pro-  
7 mulgating any regulations under such authority, in whole  
8 or in part or any regulation that is likely to have an an-  
9 nual effect on the economy of \$50,000,000 or more or  
10 have a material adverse effect on adult users of tobacco  
11 products, tobacco product manufacturers, distributors, or  
12 retailers, the Administrator shall—

13           (1) determine the technological and economic  
14           ability of parties that would be required to comply  
15           with the regulation to comply with it;

16           (2) consider experience gained under any rel-  
17           evantly similar regulations at the Federal or State  
18           level;

19           (3) determine the reasonableness of the rela-  
20           tionship between the costs of complying with such  
21           regulation and the public health benefits to be  
22           achieved by such regulation;

23           (4) determine the reasonable likelihood of meas-  
24           urable and substantial reductions in morbidity and  
25           mortality among individual tobacco users;

1           (5) determine the impact to United States to-  
2           bacco producers and farm operations;

3           (6) determine the impact on the availability and  
4           use of tobacco products by minors; and

5           (7) determine the impact on illicit trade of to-  
6           bacco products.

7           (d) LIMITATION OF AUTHORITY.—

8           (1) IN GENERAL.—The provisions of this Act  
9           shall not apply to tobacco leaf that is not in the pos-  
10          session of a manufacturer of tobacco products, or to  
11          the producers of tobacco leaf, including tobacco  
12          growers, tobacco warehouses, and tobacco grower co-  
13          operatives, nor shall any employee of the Center  
14          have any authority to enter onto a farm owned by  
15          a producer of tobacco leaf without the written con-  
16          sent of such producer.

17          (2) EXCEPTION.—Notwithstanding paragraph  
18          (1), if a producer of tobacco leaf is also a tobacco  
19          product manufacturer or controlled by a tobacco  
20          product manufacturer, the producer shall be subject  
21          to this Act in the producer's capacity as a manufac-  
22          turer. The exception in this subparagraph shall not  
23          apply to a producer of tobacco leaf who grows to-  
24          bacco under a contract with a tobacco product man-

1 manufacturer and who is not otherwise engaged in the  
2 manufacturing process.

3 (3) RULE OF CONSTRUCTION.—Nothing in this  
4 Act shall be construed to grant the Administrator  
5 authority to promulgate regulations on any matter  
6 that involves the production of tobacco leaf or a pro-  
7 ducer thereof.

8 (e) RULEMAKING PROCEDURES.—Each rulemaking  
9 under this Act shall be in accordance with chapter 5 of  
10 title 5, United States Code.

11 (f) CONSULTATION PRIOR TO RULEMAKING.—Prior  
12 to promulgating rules under this Act, the Administrator  
13 shall endeavor to consult with other Federal agencies as  
14 appropriate.

15 **SEC. 102. EXCLUSION OF OTHER REGULATORY PROGRAMS.**

16 (a) EXCLUSION OF TOBACCO PRODUCTS AND NICO-  
17 TINE-CONTAINING PRODUCTS FROM THE FEDERAL  
18 FOOD, DRUG, AND COSMETIC ACT.—No tobacco product  
19 and no nicotine-containing product shall be regulated as  
20 a food, drug, or device in accordance with section 201 (f),  
21 (g) or (h) or Chapter IV or V of the Federal Food, Drug,  
22 and Cosmetic Act, except that any tobacco product com-  
23 mercially distributed domestically and any nicotine-con-  
24 taining product commercially distributed domestically  
25 shall be subject to Chapter V of the Federal Food, Drug,

1 and Cosmetic Act if the manufacturer or a distributor of  
2 such product markets it with an explicit claim that the  
3 product is intended for use in the cure, mitigation, treat-  
4 ment, or prevention of disease in man or other animals,  
5 within the meaning of section 201(g)(1)(C) or section  
6 201(h)(2) of that Act.

7 (b) LIMITATION ON EFFECT OF THIS ACT.—Nothing  
8 in this Act shall be construed to—

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

12 (2) affect any action pending in any Federal,  
13 State, or Tribal court, or any agreement, consent de-  
14 cree, or contract of any kind.

15 (c) EXCLUSIONS FROM AUTHORITY OF ADMINIS-  
16 TRATOR.—The authority granted to the Administrator  
17 under this Act shall not apply to—

18 (1) raw tobacco that is not in the possession or  
19 control of a tobacco product manufacturer;

20 (2) raw tobacco that is grown for a tobacco  
21 product manufacturer by a grower, and that is in  
22 the possession of that grower or of a person that is  
23 not a tobacco product manufacturer and is within  
24 the scope of subparagraphs (A) through(F) of para-  
25 graph (3); or

1           (3) the activities, materials, facilities, or prac-  
2           tices of persons that are not tobacco product manu-  
3           facturers and that are—

4                   (A) producers of raw tobacco, including to-  
5           bacco growers;

6                   (B) tobacco warehouses, and other persons  
7           that receive raw tobacco from growers;

8                   (C) tobacco grower cooperatives;

9                   (D) persons that cure raw tobacco;

10                  (E) persons that process raw tobacco; and

11                  (F) persons that store raw tobacco for  
12           aging.

13           If a producer of raw tobacco is also a tobacco prod-  
14           uct manufacturer, an affiliate of a tobacco product  
15           manufacturer, or a person producing raw tobacco for  
16           a tobacco product manufacturer, then that producer  
17           shall be subject to this Act only to the extent of that  
18           producer's capacity as a tobacco product manufac-  
19           turer.

20 **SEC. 103. EXISTING FEDERAL STATUTES MAINTAINED.**

21           Except as amended or repealed by this Act, all Fed-  
22           eral statutes in effect as of the effective date of this Act  
23           that regulate tobacco, tobacco products, or tobacco prod-  
24           uct manufacturers shall remain in full force and effect.  
25           Such statutes include, without limitation—

1           (1) the Federal Cigarette Labeling and Adver-  
2           tising Act, sections 1331–1340 of title 15, United  
3           States Code, except that section 1335 of title 15,  
4           United States Code, is repealed;

5           (2) the Comprehensive Smokeless Tobacco  
6           Health Education Act of 1986, sections 4401–4408  
7           of title 15, United States Code, except that section  
8           4402(f) of title 15, United States Code, is repealed;

9           (3) section 300x-26 of title 42, United States  
10          Code; and

11          (4) those statutes authorizing regulation of to-  
12          bacco, tobacco products, or tobacco product manu-  
13          facturers by the Federal Trade Commission, the De-  
14          partment of Agriculture, the Environmental Protec-  
15          tion Agency, the Internal Revenue Service, and the  
16          Alcohol and Tobacco Tax and Trade Bureau of the  
17          Department of the Treasury.

18 **SEC. 104. PROCEEDINGS IN THE NAME OF THE UNITED**  
19                                   **STATES; SUBPOENAS; PREEMPTION OF STATE**  
20                                   **AND LOCAL LAW; NO PRIVATE RIGHT OF AC-**  
21                                   **TION.**

22          In furtherance of this Act:

23           (1) All proceedings for the enforcement, or to  
24           restrain violations, of this Act shall be by and in the  
25           name of the United States. Subpoenas for witnesses

1 who are required to attend a court of the United  
2 States, in any district, may run into any other dis-  
3 trict in any proceeding under this section. No State,  
4 or political subdivision thereof, may proceed or inter-  
5 vene in any Federal or State court under this Act  
6 or under any regulation promulgated under it, or al-  
7 lege any violation thereof except a violation by the  
8 Administrator. Nothing in this Act shall be con-  
9 strued to create a right of action by any private per-  
10 son for any violation of any provision of this Act or  
11 of any regulation promulgated under it.

12 (2) With respect to any subject matter ad-  
13 dressed by this Act or by any regulation promul-  
14 gated under it, no requirement or prohibition shall  
15 be imposed under State or local law upon any to-  
16 bacco product manufacturer or distributor.

17 (3) Paragraph (2) shall not apply to any re-  
18 quirement or prohibition imposed under State or  
19 local law before the date of introduction of the bill  
20 that was enacted as this Act.

21 **SEC. 105. ILLICIT TRADE.**

22 The Administrator shall not promulgate any regula-  
23 tion or take any other action that has the effect of—

24 (1) increasing illicit trade involving tobacco or  
25 any tobacco product, or

1           (2) making affected tobacco products unaccept-  
2           able to a substantial number of then current users  
3           of such products, thereby creating a substantial risk  
4           that such users will resort to illicit tobacco products,  
5           or tobacco products that are otherwise noncompliant  
6           or unlawful.

7   **SEC. 106. ADULTERATED TOBACCO PRODUCTS.**

8           A tobacco product shall be deemed to be adulter-  
9   ated—

10           (1) if it bears or contains any poisonous or del-  
11           eterious substance other than—

12                   (A) tobacco;

13                   (B) a substance naturally present in to-  
14           bacco;

15                   (C) a pesticide or fungicide chemical res-  
16           idue in or on tobacco if such pesticide or fun-  
17           gicide chemical is registered by the Environ-  
18           mental Protection Agency for use on tobacco in  
19           the United States; or

20                   (D) in the case of imported tobacco, a res-  
21           idue of a pesticide or fungicide chemical that—

22                           (i) is approved for use in the country  
23                           of origin of the tobacco; and

24                           (ii) has not been banned, and the reg-  
25                           istration of which has not been canceled,

1 by the Environmental Protection Agency  
2 for use on tobacco in the United States)  
3 that may render it injurious to health; but,  
4 in case the substance is not an added sub-  
5 stance, such tobacco product shall not be  
6 considered adulterated under this sub-  
7 section if the quantity of such substance in  
8 such tobacco product does not ordinarily  
9 render it injurious to health;

10 (2) if there is significant scientific agreement  
11 that, as a result of the tobacco it contains, the to-  
12 bacco product presents a risk to human health that  
13 is materially higher than the risk presented by—

14 (A) such product on the effective date of  
15 this Act; or

16 (B) if such product was not distributed  
17 commercially domestically on that date, by com-  
18 parable tobacco products of the same style and  
19 within the same category that were commer-  
20 cially distributed domestically on that date.

21 (3) if it has been prepared, packed, or held  
22 under unsanitary conditions whereby it may have be-  
23 come contaminated with filth;

1 (4) if its package is composed, in whole or in  
2 part, of any poisonous or deleterious substance that  
3 may render the contents injurious to health; or

4 (5) if its “tar” yield is in violation of section  
5 111.

6 **SEC. 107. MISBRANDED TOBACCO PRODUCTS.**

7 A tobacco product shall be deemed to be mis-  
8 branded—

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

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

13 (A) an identification of the type of product  
14 it is, by the common or usual name of such  
15 type of product;

16 (B) an accurate statement of the quantity  
17 of the contents in the package in terms of  
18 weight, measure, or numerical count, except  
19 that reasonable variations shall be permitted,  
20 and exemptions as to small packages shall be  
21 established by regulations promulgated by the  
22 Administrator;

23 (C) the name and place of business of the  
24 tobacco product manufacturer, packer, or dis-  
25 tributor; and

1 (D) the information required by section  
2 201(c) and (e) or section 202(c) and (e), as ap-  
3 plicable;

4 (3) if any word, statement, or other information  
5 required by or under authority of this Act to appear  
6 on the label, labeling, or advertising is not promi-  
7 nently placed thereon with such conspicuousness (as  
8 compared with other words, statements, or designs  
9 on the label, labeling, or advertising, as applicable)  
10 and in such terms as to render it reasonably likely  
11 to be read and understood by the ordinary individual  
12 under customary conditions of purchase and use;

13 (4) if any word, statement, or other information  
14 is required by or under this Act to appear on the  
15 label, unless such word, statement, or other informa-  
16 tion also appears on the outside container or wrap-  
17 per, if any, of the retail package of such tobacco  
18 product, or is easily legible through the outside con-  
19 tainer or wrapper;

20 (5) if it was manufactured, prepared, or proc-  
21 essed in an establishment not duly registered under  
22 section 109, if it was not included in a list required  
23 by section 109, or if a notice or other information  
24 respecting it was not provided as required by section  
25 109;

1           (6) if its packaging, labeling, or advertising is  
2           in violation of this Act or of an applicable regulation  
3           promulgated in accordance with this Act;

4           (7) if it contains tobacco or another ingredient  
5           as to which a required disclosure under this Act was  
6           not made;

7           (8) if it is labeled or advertised, or the tobacco  
8           contained in it is advertised, as—

9                   (A) containing “no additives,” or any sub-  
10                   stantially similar term, unless the labeling or  
11                   advertising, as applicable, also contains, clearly  
12                   and prominently, the following disclosure: “No  
13                   additives in our tobacco does NOT mean  
14                   safer.”; or

15                   (B) being “natural,” or any substantially  
16                   similar term, unless the labeling or advertising,  
17                   as applicable, also contains, clearly and promi-  
18                   nently, the following disclosure: “Natural does  
19                   NOT mean safer.” ;

20           (9) if in its labeling or advertising a term de-  
21           scriptive of the tobacco in the tobacco product is  
22           used otherwise than in accordance with a sanction or  
23           approval granted by a Federal agency;

24           (10) if with respect to such tobacco product a  
25           disclosure required by section 603 was not made;

1 (11) if with respect to such tobacco product a  
2 certification required by section 803 was not sub-  
3 mitted or is materially false or misleading; or

4 (12) if its manufacturer or distributor made  
5 with respect to it a claim prohibited by section 115.

6 **SEC. 108. SUBMISSION OF HEALTH INFORMATION TO THE**  
7 **ADMINISTRATOR.**

8 (a) REQUIREMENT.—Each tobacco product manufac-  
9 turer or importer, or agents thereof, shall submit to the  
10 Administrator the following information:

11 (1) Not later than 18 months after the date of  
12 enactment of the Act, a listing of all ingredients, in-  
13 cluding tobacco, substances, compounds, and addi-  
14 tives that are, as of such date, added by the manu-  
15 facturer to the tobacco, paper, filter, or other part  
16 of each tobacco product by brand and by quantity in  
17 each brand and brand style.

18 (2) A description of the content, delivery, and  
19 form of nicotine in each tobacco product measured  
20 in milligrams of nicotine in accordance with regula-  
21 tions promulgated by the Administrator in accord-  
22 ance with section 4(e) of the Federal Cigarette La-  
23 beling and Advertising Act.

24 (3) Beginning 4 years after the date of enact-  
25 ment of this Act, a listing of all constituents, includ-

1       ing smoke constituents as applicable, identified by  
2       the Administrator as harmful to health in each to-  
3       bacco product, and as applicable in the smoke of  
4       each tobacco product, by brand and by quantity in  
5       each brand and subbrand.

6       (b) DATA SUBMISSION.—At the request of the Ad-  
7       ministrators, each tobacco product manufacturer or im-  
8       porter of tobacco products, or agents thereof, shall submit  
9       the following:

10           (1) Any or all documents (including underlying  
11           scientific information) relating to research activities,  
12           and research findings, conducted, supported, or pos-  
13           sessed by the manufacturer (or agents thereof) on  
14           the health, toxicological, or physiologic effects of to-  
15           bacco products and their constituents (including  
16           smoke constituents), ingredients, components, and  
17           additives.

18           (2) Any or all documents (including underlying  
19           scientific information) relating to research activities,  
20           and research findings, conducted, supported, or pos-  
21           sessed by the manufacturer (or agents thereof) that  
22           relate to the issue of whether a significant reduction  
23           in risk to health from tobacco products can occur  
24           upon the employment of technology available to the  
25           manufacturer.

1 An importer of a tobacco product not manufactured in the  
2 United States shall supply the information required of a  
3 tobacco product manufacturer under this subsection.

4 (c) DATA LIST.—

5 (1) IN GENERAL.—Not later than 4 years after  
6 the date of enactment of the Act, and annually  
7 thereafter, the Administrator shall publish in a for-  
8 mat that is understandable and not misleading to a  
9 lay person, and place on public display (in a manner  
10 determined by the Administrator) the list established  
11 under subsection (d).

12 (2) CONSUMER RESEARCH.—The Administrator  
13 shall conduct periodic consumer research to ensure  
14 that the list published under paragraph (1) is not  
15 misleading to lay persons. Not later than 5 years  
16 after the date of enactment of the Act, the Adminis-  
17 trator shall submit to the appropriate committees of  
18 Congress a report on the results of such research,  
19 together with recommendations on whether such  
20 publication should be continued or modified.

21 (d) DATA COLLECTION.—Not later than 36 months  
22 after the date of enactment of this Act, the Administrator  
23 shall establish, and periodically revise as appropriate, a  
24 list of harmful constituents, including smoke constituents,

1 to health in each tobacco product by brand and by quan-  
2 tity in each brand and subbrand.

3 **SEC. 109. REGISTRATION AND LISTING.**

4 (a) DEFINITIONS.—As used in this section:

5 (1) The term “manufacture, preparation, or  
6 processing” shall include repackaging or otherwise  
7 changing the container, wrapper, or label of any to-  
8 bacco product package other than the carton in fur-  
9 therance of the distribution of the tobacco product  
10 from the original place of manufacture to the person  
11 that makes final delivery or sale to the ultimate con-  
12 sumer or user, but shall not include the addition of  
13 a tax marking or other marking required by law to  
14 an already packaged tobacco product.

15 (2) The term “name” shall include in the case  
16 of a partnership the name of the general partner  
17 and, in the case of a privately held corporation, the  
18 name of the chief executive officer of the corporation  
19 and the State of incorporation.

20 (b) ANNUAL REGISTRATION.—Commencing one year  
21 after enactment, on or before December 31 of each year,  
22 every person that owns or operates any establishment in  
23 any State engaged in the manufacture, preparation, or  
24 processing of a tobacco product or products for commer-  
25 cial distribution domestically shall register with the Ad-

1    ministrator its name, places of business, and all such es-  
2    tablishments.

3           (c) NEW PRODUCERS.—Every person upon first en-  
4    gaging, for commercial distribution domestically, in the  
5    manufacture, preparation, or processing of a tobacco prod-  
6    uct or products in any establishment that it owns or oper-  
7    ates in any State shall immediately register with the Ad-  
8    ministrator its name, places of business, and such estab-  
9    lishment.

10          (d) REGISTRATION OF FOREIGN ESTABLISH-  
11    MENTS.—

12           (1) Commencing one year after enactment of  
13    this Act, on or before December 31 of each year, the  
14    person that, within any foreign country, owns or op-  
15    erates any establishment engaged in the manufac-  
16    ture, preparation, or processing of a tobacco product  
17    that is imported or offered for import into the  
18    United States shall, through electronic means or  
19    other means permitted by the Administrator, reg-  
20    ister with the Administrator the name and place of  
21    business of each such establishment, the name of the  
22    United States agent for the establishment, and the  
23    name of each importer of such tobacco product in  
24    the United States that is known to such person.

1           (2) Such person also shall provide the informa-  
2           tion required by subsection (j), including sales made  
3           by mail, or through the Internet, or other electronic  
4           means.

5           (3) The Administrator is authorized to enter  
6           into cooperative arrangements with officials of for-  
7           eign countries to ensure that adequate and effective  
8           means are available for purposes of determining,  
9           from time to time, whether tobacco products manu-  
10          factured, prepared, or processed by an establishment  
11          described in paragraph (1), if imported or offered  
12          for import into the United States, shall be refused  
13          admission on any of the grounds set forth in section  
14          708.

15          (e) **ADDITIONAL ESTABLISHMENTS.**—Every person  
16          duly registered in accordance with the foregoing sub-  
17          sections of this section shall immediately register with the  
18          Administrator any additional establishment that it owns  
19          or operates and in which it begins the manufacture, prepa-  
20          ration, or processing of a tobacco product or products for  
21          commercial distribution domestically or for import into the  
22          United States.

23          (f) **EXCLUSIONS FROM APPLICATION OF THIS SEC-**  
24          **TION.**—The foregoing subsections of this section shall not  
25          apply to—

1           (1) persons that manufacture, prepare, or proc-  
2           ess tobacco products solely for use in research,  
3           teaching, chemical or biological analysis, or export;  
4           or

5           (2) such other classes of persons as the Admin-  
6           istrator may by regulation exempt from the applica-  
7           tion of this section upon a finding that registration  
8           by such classes of persons in accordance with this  
9           section is not necessary for the protection of the  
10          public health.

11          (g) INSPECTION OF PREMISES.—Every establishment  
12          registered with the Administrator pursuant to this section  
13          shall be subject to inspection pursuant to section 706; and  
14          every such establishment engaged in the manufacture,  
15          preparation, or processing of a tobacco product or prod-  
16          ucts shall be so inspected by one or more officers or em-  
17          ployees duly designated by the Administrator at least once  
18          in the two-year period beginning with the date of registra-  
19          tion of such establishment pursuant to this section and  
20          at least once in every successive two-year period there-  
21          after, except that inspection of establishments outside the  
22          United States may be conducted by other personnel pursu-  
23          ant to a cooperative arrangement under subsection (d)(3).

1 (h) FILING OF LISTS OF TOBACCO PRODUCTS MANU-  
2 FACTURED, PREPARED, OR PROCESSED BY REGISTRANTS;  
3 STATEMENTS; ACCOMPANYING DISCLOSURES.—

4 (1) Every person that registers with the Admin-  
5 istrator under subsection (b), (c), (d), or (e) shall,  
6 at the time of registration under any such sub-  
7 section, file with the Administrator a list of all  
8 brand styles (with each brand style in each list listed  
9 by the common or usual name of the tobacco prod-  
10 uct category to which it belongs and by any propri-  
11 etary name) that are being manufactured, prepared,  
12 or processed by such person for commercial distribu-  
13 tion domestically or for import into the United  
14 States, and that such person has not included in any  
15 list of tobacco products filed by such person with the  
16 Administrator under this paragraph or paragraph  
17 (2) before such time of registration. Such list shall  
18 be prepared in such form and manner as the Admin-  
19 istrator may prescribe, and shall be accompanied by  
20 the label for each such brand style and a representa-  
21 tive sampling of any other labeling and advertising  
22 for each;

23 (2) Each person that registers with the Admin-  
24 istrator under this section shall report to the Admin-  
25 istrator each August for the preceding six-month pe-

1       riod from January through June, and each February  
2       for the preceding six-month period from July  
3       through December, following information:

4               (A) A list of each brand style introduced  
5       by the registrant for commercial distribution  
6       domestically or for import into the United  
7       States that has not been included in any list  
8       previously filed by such registrant with the Ad-  
9       ministrators under this subparagraph or para-  
10      graph (1). A list under this subparagraph shall  
11      list a brand style by the common or usual name  
12      of the tobacco product category to which it be-  
13      longs and by any proprietary name, and shall  
14      be accompanied by the other information re-  
15      quired by paragraph (1).

16              (B) If since the date the registrant last  
17      made a report under this paragraph (or if such  
18      registrant has not previously made a report  
19      under this paragraph, since the effective date of  
20      this Act) such registrant has discontinued the  
21      manufacture, preparation, or processing for  
22      commercial distribution domestically or for im-  
23      port into the United States of a brand style in-  
24      cluded in a list filed by such registrant under  
25      subparagraph (A) or paragraph (1), notice of

1 such discontinuance, the date of such dis-  
2 continuance, and the identity (by the common  
3 or usual name of the tobacco product category  
4 to which it belongs and by any proprietary  
5 name) of such tobacco product.

6 (C) If, since the date the registrant re-  
7 ported pursuant to subparagraph (B) a notice  
8 of discontinuance of a tobacco product, the reg-  
9 istrant has resumed the manufacture, prepara-  
10 tion, or processing for commercial distribution  
11 domestically or for import into the United  
12 States of that brand style, notice of such re-  
13 sumption, the date of such resumption, the  
14 identity of such brand style (by the common or  
15 usual name of the tobacco product category to  
16 which it belongs and by any proprietary name),  
17 and the other information required by para-  
18 graph (1), unless the registrant has previously  
19 reported such resumption to the Administrator  
20 pursuant to this subparagraph.

21 (D) Any material change in any informa-  
22 tion previously submitted pursuant to this para-  
23 graph (2) or paragraph (1).

24 (i) ELECTRONIC REGISTRATION.—Registrations  
25 under subsections (b), (c), (d), and (e) (including the sub-

1 mission of updated information) shall be submitted to the  
2 Administrator by electronic means, unless the Adminis-  
3 trator grants a request for waiver of such requirement be-  
4 cause use of electronic means is not reasonable for the  
5 person requesting such waiver.

6 **SEC. 110. GENERAL PROVISIONS RESPECTING CONTROL OF**  
7 **TOBACCO PRODUCTS.**

8 (a) IN GENERAL.—Any requirement established by or  
9 under section 106, 107, or 113 applicable to a tobacco  
10 product shall apply to such tobacco product until the ap-  
11 plicability of the requirement to the tobacco product has  
12 been changed by action taken under section 111, section  
13 114, section 115, or subsection (d) of this section, and  
14 any requirement established by or under section 106, 107,  
15 or 113 which is inconsistent with a requirement imposed  
16 on such tobacco product under section 111, section 114,  
17 section 115, or subsection (d) of this section shall not  
18 apply to such tobacco product.

19 (b) INFORMATION ON PUBLIC ACCESS AND COM-  
20 MENT.—Each notice of proposed rulemaking or other noti-  
21 fication under section 111, 112, 113, 114, or 115 or under  
22 this section, any other notice which is published in the  
23 Federal Register with respect to any other action taken  
24 under any such section and which states the reasons for  
25 such action, and each publication of findings required to

1 be made in connection with rulemaking under any such  
2 section shall set forth—

3 (1) the manner in which interested persons may  
4 examine data and other information on which the  
5 notice or findings is based; and

6 (2) the period within which interested persons  
7 may present their comments on the notice or find-  
8 ings (including the need therefore) orally or in writ-  
9 ing, which period shall be at least 60 days but may  
10 not exceed 90 days unless the time is extended by  
11 the Administrator by a notice published in the Fed-  
12 eral Register stating good cause therefore.

13 (c) LIMITED CONFIDENTIALITY OF INFORMATION.—  
14 Any information reported to or otherwise obtained by the  
15 Administrator or the Administrator's representative under  
16 section 107, 108, 111, 112, 113, 114, 115, or 504, or  
17 under subsection (e) or (f) of this section, which is exempt  
18 from disclosure under subsection (a) of section 552 of title  
19 5, United States Code, by reason of subsection (b)(4) of  
20 that section shall be considered confidential and shall not  
21 be disclosed, except that the information may be disclosed  
22 to other officers or employees concerned with carrying out  
23 this Act, or when relevant in any proceeding under this  
24 Act.

25 (d) RESTRICTIONS.—

1           (1) IN GENERAL.—The Administrator may  
2           issue regulations, consistent with this Act, regarding  
3           tobacco products if the Administrator determines  
4           that such regulation would be appropriate for the  
5           protection of the public health. The finding as to  
6           whether such regulation would be appropriate for  
7           the protection of the public health shall be deter-  
8           mined with respect to the risks and benefits to the  
9           users of the tobacco product, and taking into ac-  
10          count that the standard is reasonably likely to result  
11          in measurable and substantial reductions in mor-  
12          bidly and mortality among individual tobacco users.

13          (2) LABEL STATEMENTS.—The label of a to-  
14          bacco product shall bear such appropriate state-  
15          ments of the restrictions required by a regulation  
16          under subsection (a) as the Administrator may in  
17          such regulation prescribe.

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

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

22                    (A) IN GENERAL.—In applying manufac-  
23                    turing restrictions to tobacco, the Administrator  
24                    shall, in accordance with subparagraph (B),  
25                    prescribe regulations (which may differ based

1           on the type of tobacco product involved) requir-  
2           ing that the methods used in, and the facilities  
3           and controls used for, the manufacture,  
4           preproduction design validation (including a  
5           process to assess the performance of a tobacco  
6           product), packing, and storage of a tobacco  
7           product conform to current good manufacturing  
8           practice, or hazard analysis and critical control  
9           point methodology, as prescribed in such regu-  
10          lations to assure that the public health is pro-  
11          tected and that the tobacco product is in com-  
12          pliance with this Act. Such regulations may  
13          provide for the testing of raw tobacco for pes-  
14          ticide chemical residues after a tolerance for  
15          such chemical residues has been established.

16                (B) REQUIREMENTS.—The Administrator  
17          shall—

18                       (i) before promulgating any regulation  
19                       under subparagraph (A), afford the To-  
20                       bacco Products Scientific Advisory Com-  
21                       mittee an opportunity to submit rec-  
22                       ommendations with respect to the regula-  
23                       tion proposed to be promulgated;

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

4 (iii) provide the Tobacco Products  
5 Scientific Advisory Committee a reasonable  
6 time to make its recommendation with re-  
7 spect to proposed regulations under sub-  
8 paragraph (A); and

9 (iv) in establishing the effective date  
10 of a regulation promulgated under this  
11 subsection, take into account the dif-  
12 ferences in the manner in which the dif-  
13 ferent types of tobacco products have his-  
14 torically been produced, the financial re-  
15 sources of the different tobacco product  
16 manufacturers, and the state of their exist-  
17 ing manufacturing facilities, and shall pro-  
18 vide for a reasonable period of time for  
19 such manufacturers to conform to good  
20 manufacturing practices but no earlier  
21 than four years from date of enactment.

22 (C) ADDITIONAL SPECIAL RULE.—A to-  
23 bacco product manufactured in or imported into  
24 the United States shall not contain foreign-  
25 grown flue-cured or burley tobacco that—

1 (i) was knowingly grown or processed  
2 using a pesticide chemical that is not ap-  
3 proved under applicable Federal law for  
4 use in domestic tobacco farming and proc-  
5 essing; or

6 (ii) in the case of a pesticide chemical  
7 that is so approved, was grown or proc-  
8 essed using the pesticide chemical in a  
9 manner inconsistent with the approved la-  
10 beling for use of the pesticide chemical in  
11 domestic tobacco farming and processing.

12 (D) EXCLUSION.—Subparagraph (C)(ii)  
13 shall not apply to tobacco products manufac-  
14 tured with foreign-grown flue-cured or burley  
15 tobacco so long as that foreign grown tobacco  
16 was either—

17 (i) in the inventory of a manufacturer  
18 prior to the effective date, or

19 (ii) planted by the farmer prior to the  
20 effective date of this Act and utilized by  
21 the manufacturer no later than 3 years  
22 after the effective date.

23 (E) SETTING OF MAXIMUM RESIDUE LIM-  
24 ITS.—The Administrator shall adopt the fol-  
25 lowing pesticide residue standards:

1 Pesticide residue standards

2 The maximum concentration of residues of the fol-  
3 lowing pesticides allowed in flue-cured or burley tobacco,  
4 expressed as parts by weight of the residue per one million  
5 parts by weight of the tobacco (PPM) are:

6 CHLORDANE.....3.0

7 DIBROMOCHLOROPROPANE (DBCP).....1.0

8 DICAMBA (Temporary).... 5.0

9 ENDRIN....0.1

10 ETHYLENE DIBROMIDE (EDB)....0.1

11 FORMOTHION.....0.5

12 HEXACHLOROBENZENE (HCB)....0.1

13 METHOXYCHLOR.....0.1

14 TOXAPHENE.....0.3

15 2,4-D (Temporary).....5.0

16 2,4,5-T.....0.1

17 Sum of ALDRIN and DIELDRIN.....0.1

18 Sum of CYPERMETHRIN and PERMETHRIN  
19 (Temporary).....3.0

20 Sum of DDT, TDE (DDD), and DDE .....0.4

21 Sum of HEPTACHLOR and HEPTACHLOR EP-  
22 OXIDE.....0.1

23 (F) MAXIMUM RESIDUE LIMITS.—The Ad-  
24 ministrator shall adopt regulations within one  
25 year of the effective date of this Act to establish

1 maximum residue limits for pesticides identified  
2 under subparagraph (E) but not included in the  
3 table of such subparagraph to account for the  
4 fact that weather and agronomic conditions will  
5 cause pesticides identified in subparagraph (E)  
6 to be detected in foreign-grown tobacco even  
7 where the farmer has not knowingly added such  
8 pesticide.

9 (2) EXEMPTIONS; VARIANCES.—

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

23 (ii) in the case of a petition for a vari-  
24 ance from a requirement, set forth the  
25 methods proposed to be used in, and the

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

6 (iii) contain such other information as  
7 the Administrator shall prescribe.

8 (B) REFERRAL TO THE TOBACCO PROD-  
9 UCTS SCIENTIFIC ADVISORY COMMITTEE.—The  
10 Administrator may refer to the Tobacco Prod-  
11 ucts Scientific Advisory Committee any petition  
12 submitted under subparagraph (A). The To-  
13 bacco Products Scientific Advisory Committee  
14 shall report its recommendations to the Admin-  
15 istrator with respect to a petition referred to it  
16 within 60 days after the date of the petition's  
17 referral. Within 60 days after—

18 (i) the date the petition was submitted  
19 to the Administrator under subparagraph  
20 (A); or

21 (ii) the day after the petition was re-  
22 ferred to the Tobacco Products Scientific  
23 Advisory Committee,

24 whichever occurs later, the Administrator shall  
25 by order either deny the petition or approve it.

1 (C) APPROVAL.—The Administrator may  
2 approve—

3 (i) a petition for an exemption for a  
4 tobacco product from a requirement if the  
5 Administrator determines that compliance  
6 with such requirement is not required to  
7 assure that the tobacco product will be in  
8 compliance with this Act; and

9 (ii) a petition for a variance for a to-  
10 bacco product from a requirement if the  
11 Administrator determines that the methods  
12 to be used in, and the facilities and con-  
13 trols to be used for, the manufacture,  
14 packing, and storage of the tobacco prod-  
15 uct in lieu of the methods, facilities, and  
16 controls prescribed by the requirement are  
17 sufficient to assure that the tobacco prod-  
18 uct will be in compliance with this Act.

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

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

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

7           (3) COMPLIANCE.—Compliance with require-  
8           ments under this subsection shall not be required be-  
9           fore the end of the 3-year period following the date  
10          of enactment of this Act.

11          (f) RESEARCH AND DEVELOPMENT.—The Adminis-  
12         trator may enter into contracts for research, testing, and  
13         demonstrations respecting tobacco products and may ob-  
14         tain tobacco products for research, testing, and dem-  
15         onstration purposes.

16         **SEC. 111. SMOKING ARTICLE STANDARDS.**

17           (a) IN GENERAL.—

18           (1) RESTRICTIONS ON DESCRIPTORS USED IN  
19           MARKETING OF CIGARETTES.—

20           (A) IN GENERAL.—Except as provided in  
21           subparagraph (B), no person shall use, with re-  
22           spect to any cigarette brand style commercially  
23           distributed domestically, on the portion of the  
24           package of such cigarette brand style that cus-  
25           tomarily is visible to consumers before pur-

1 chase, or in advertising of such cigarette brand  
2 style any of the following as a descriptor of any  
3 cigarette brand style—

4 (i) the name of any candy or fruit;

5 (ii) the word “candy,” “citrus,”  
6 “cream,” “fruit,” “sugar,” “sweet,”  
7 “tangy,” or “tart,”; or

8 (iii) any extension or variation of any  
9 of the words “candy,” “citrus,” “cream,”  
10 “fruit,” “sugar,” “sweet,” “tangy,” or  
11 “tart,” including but not limited to  
12 “creamy,” or “fruity.”

13 (B) LIMITATION.—Subparagraph (A) shall  
14 not apply to the use of the following words or  
15 to any extension or variation of any of them:  
16 “coffee,” “mint,” and “menthol”.

17 (C) SCENTED MATERIALS.—No person  
18 shall use, in the advertising or labeling of any  
19 cigarette commercially distributed domestically,  
20 any scented materials, except in an adult-only  
21 facility.

22 (D) DEFINITIONS.—In this section:

23 (i) The term “candy” means a confec-  
24 tion made from sugar or sugar substitute,  
25 including any confection identified generi-

1 cally or by brand, and shall include the  
2 words “cacao,” “chocolate,” “cinnamon,”  
3 “cocoa,” “honey,” “licorice,” “maple,”  
4 “mocha,” and “vanilla.”

5 (ii) The term “fruit” means any fruit  
6 identified by generic name, type, or vari-  
7 ety, including but not limited to “apple,”  
8 “banana,” “cherry,” and “orange.” The  
9 term “fruit” does not include words that  
10 identify seeds, nuts or peppers, or types or  
11 varieties thereof or words that are exten-  
12 sions or variations of such words.

13 (2) SMOKING ARTICLE STANDARDS.—

14 (A) IN GENERAL.—The Administrator may  
15 adopt smoking article standards in addition to  
16 those in paragraph (1) if the Administrator  
17 finds that a smoking article standard is appro-  
18 priate for the protection of the public health.

19 (B) DETERMINATIONS.—

20 (i) CONSIDERATIONS.—In making a  
21 finding described in subparagraph (A), the  
22 Administrator shall consider scientific evi-  
23 dence concerning—

1 (I) the risks and benefits to the  
2 users of smoking articles of the pro-  
3 posed standard; and

4 (II) that the standard is reason-  
5 ably likely to result in measurable and  
6 substantial reductions in morbidity  
7 and mortality among individual to-  
8 bacco users.

9 (ii) ADDITIONAL CONSIDERATIONS.—

10 In the event that the Administrator makes  
11 a determination, set forth in a proposed  
12 smoking article standard in a proposed  
13 rule, that it is appropriate for the protec-  
14 tion of public health to require the reduc-  
15 tion or elimination of an additive, con-  
16 stituent (including a smoke constituent), or  
17 other component of a smoking article be-  
18 cause the Administrator has found that the  
19 additive, constituent, or other component is  
20 harmful, any party objecting to the pro-  
21 posed standard on the ground that the  
22 proposed standard will not reduce or elimi-  
23 nate the risk of illness or injury may pro-  
24 vide for the Administrator's consideration  
25 scientific evidence that demonstrates that

1           the proposed standard will not reduce or  
2           eliminate the risk of illness or injury.

3           (3) CONTENT OF SMOKING ARTICLE STAND-  
4           ARDS.—A smoking article standard established  
5           under this section for a smoking article—

6           (A) may include provisions that are appro-  
7           priate for the protection of the public health,  
8           including provisions, where appropriate—

9           (i) for “tar” and nicotine yields of the  
10          product;

11          (ii) for the reduction of other constitu-  
12          ents, including smoke constituents, or  
13          harmful components of the product; or

14          (iii) relating to any other requirement  
15          under subparagraph (B); and

16          (B) may, where appropriate for the protec-  
17          tion of the public health, include—

18          (i) provisions respecting the construc-  
19          tion, components, ingredients, additives,  
20          constituents, including smoke constituents,  
21          and properties of the smoking article;

22          (ii) provisions for the testing (on a  
23          sample basis or, if necessary, on an indi-  
24          vidual basis) of the smoking article;

1 (iii) provisions for the measurement of  
2 the smoking article characteristics of the  
3 smoking article; and

4 (iv) provisions requiring that the re-  
5 sults of each or of certain of the tests of  
6 the smoking article required to be made  
7 under clause (ii) show that the smoking ar-  
8 ticle is in conformity with the portions of  
9 the standard for which the test or tests  
10 were required.

11 (4) PERIODIC REEVALUATION OF SMOKING AR-  
12 TICLE STANDARDS.—The Administrator may provide  
13 for periodic evaluation of smoking article standards  
14 established under this section to determine whether  
15 such standards should be changed to reflect new  
16 medical, scientific, or other technological data.

17 (5) CIGARETTE “TAR” LIMITS.—

18 (A) NO INCREASE IN “TAR” YIELDS.—No  
19 cigarette manufacturer shall distribute for sale  
20 domestically a brand style of cigarettes that  
21 generates a “tar” yield greater than the “tar”  
22 yield of that brand style of cigarettes on the  
23 date of introduction of this Act, as determined  
24 by the ISO smoking regimen and its associated  
25 tolerances. The “tar” tolerances for cigarettes

1 with ISO “tar” yields in the range of 1 to 20  
2 milligrams per cigarette, based on variations  
3 arising from sampling procedure, test method,  
4 and sampled product, itself, are the greater of  
5 plus or minus—

6 (i) 15 percent; or

7 (ii) 1 milligram per cigarette.

8 (B) LIMIT ON NEW CIGARETTES.—After  
9 the effective date of this Act, no cigarette man-  
10 ufacturer shall manufacture for commercial dis-  
11 tribution domestically a brand style of ciga-  
12 rettes that both—

13 (i) was not in commercial distribution  
14 domestically on the effective date of this  
15 Act, and

16 (ii) generates a “tar” yield of greater  
17 than 20 milligrams per cigarette as deter-  
18 mined by the ISO smoking regimen and its  
19 associated tolerances.

20 (C) LIMIT ON ALL CIGARETTES.—After  
21 December 31, 2010, no cigarette manufacturer  
22 shall manufacture for commercial distribution  
23 domestically a brand style of cigarettes that  
24 generates a “tar” yield greater than 20 milli-

1           grams per cigarette as determined by the ISO  
2           smoking regimen and its associated tolerances.

3           (D) REVIEW BY ADMINISTRATOR.—After  
4           the effective date of this Act, the Administrator  
5           shall evaluate the available scientific evidence  
6           addressing the potential relationship between  
7           historical “tar” yield values and risk of harm to  
8           smokers. If upon a review of that evidence, and  
9           after consultation with technical experts of the  
10          Tobacco Harm Reduction Center and the Cen-  
11          ters for Disease Control and Prevention and no-  
12          tice and an opportunity for public comment, the  
13          Administrator determines, that a reduction in  
14          “tar” yield may reasonably be expected to pro-  
15          vide a meaningful reduction of the risk or risks  
16          of harm to smokers, the Administrator shall  
17          issue an order that—

18                 (i) provides that no cigarette manu-  
19                 facturer shall manufacture for commercial  
20                 distribution domestically a cigarette that  
21                 generates a “tar” yield that exceeds 14  
22                 milligrams as determined by the ISO  
23                 smoking regimen and its associated toler-  
24                 ances; and

1 (ii) provides a reasonable time for  
2 manufacturers to come into compliance  
3 with such prohibition.

4 (6) INVOLVEMENT OF OTHER AGENCIES; IN-  
5 FORMED PERSONS.—In carrying out duties under  
6 this section, the Administrator shall endeavor to—

7 (A) use personnel, facilities, and other  
8 technical support available in other Federal  
9 agencies;

10 (B) consult with other Federal agencies  
11 concerned with standard setting and other na-  
12 tionally or internationally recognized standard-  
13 setting entities; and

14 (C) invite appropriate participation,  
15 through joint or other conferences, workshops,  
16 or other means, by informed persons represent-  
17 ative of scientific, professional, industry, agri-  
18 cultural, or consumer organizations who in the  
19 Administrator's judgment can make a signifi-  
20 cant contribution.

21 (b) CONSIDERATIONS BY ADMINISTRATOR.—

22 (1) TECHNICAL ACHIEVABILITY.—The Adminis-  
23 trator shall consider information submitted in con-  
24 nection with a proposed standard regarding the tech-  
25 nical achievability of compliance with such standard.

1           (2) OTHER CONSIDERATIONS.—The Adminis-  
2           trator shall consider all other information submitted  
3           in connection with a proposed standard, such as the  
4           creation of a significant demand for contraband or  
5           other tobacco products that do not meet the require-  
6           ments of this Act and the significance of such de-  
7           mand.

8           (c) PROPOSED STANDARDS.—

9           (1) IN GENERAL.—The Administrator shall  
10          publish in the Federal Register a notice of proposed  
11          rulemaking for the establishment, amendment, or  
12          revocation of any smoking article standard.

13          (2) REQUIREMENTS OF NOTICE.—A notice of  
14          proposed rulemaking for the establishment or  
15          amendment of a smoking article standard shall—

16                 (A) set forth a finding with supporting jus-  
17                 tification that the smoking article standard is  
18                 appropriate for the protection of the public  
19                 health;

20                 (B) invite interested persons to submit a  
21                 draft or proposed smoking article standard for  
22                 consideration by the Administrator;

23                 (C) invite interested persons to submit  
24                 comments on structuring the standard so that

1           it does not advantage foreign-grown tobacco  
2           over domestically grown tobacco; and

3           (D) invite the Secretary of Agriculture to  
4           provide any information or analysis which the  
5           Secretary of Agriculture believes is relevant to  
6           the proposed smoking article standard.

7           (3) FINDING.—A notice of proposed rulemaking  
8           for the revocation of a smoking article standard  
9           shall set forth a finding with supporting justification  
10          that the smoking article standard is no longer ap-  
11          propriate for the protection of the public health.

12          (4) COMMENT.—The Administrator shall pro-  
13          vide for a comment period of not less than 90 days.

14          (d) PROMULGATION.—

15          (1) IN GENERAL.—After the expiration of the  
16          period for comment on a notice of proposed rule-  
17          making published under subsection (c) respecting a  
18          standard and after consideration of comments sub-  
19          mitted under subsections (b) and (c) and any report  
20          from the Tobacco Products Scientific Advisory Com-  
21          mittee, if the Administrator determines that the  
22          standard would be appropriate for the protection of  
23          the public health, the Administrator shall—

24                  (A) promulgate a regulation establishing a  
25                  smoking article standard and publish in the

1 Federal Register findings on the matters re-  
2 ferred to in subsection (c); or

3 (B) publish a notice terminating the pro-  
4 ceeding for the development of the standard to-  
5 gether with the reasons for such termination.

6 (2) EFFECTIVE DATE.—A regulation estab-  
7 lishing a smoking article standard shall set forth the  
8 date or dates upon which the standard shall take ef-  
9 fect, but no such regulation may take effect before  
10 1 year after the date of its publication unless the  
11 Administrator determines that an earlier effective  
12 date is necessary for the protection of the public  
13 health. Such date or dates shall be established so as  
14 to minimize, consistent with the public health, eco-  
15 nomic loss to, and disruption or dislocation of, do-  
16 mestic and international trade. In establishing such  
17 effective date or dates, the Administrator shall con-  
18 sider information submitted in connection with a  
19 proposed product standard by interested parties, in-  
20 cluding manufacturers and tobacco growers, regard-  
21 ing the technical achievability of compliance with the  
22 standard, and including information concerning the  
23 existence of patents that make it impossible to com-  
24 ply in the timeframe envisioned in the proposed  
25 standard.

1           (3) LIMITATION ON POWER GRANTED.—Be-  
2           cause of the importance of a decision of the Admin-  
3           istrator to issue a regulation—

4                   (A) banning cigarettes, smokeless smoking  
5                   articles, little cigars, cigars other than little ci-  
6                   gars, pipe tobacco, or roll-your-own smoking ar-  
7                   ticles;

8                   (B) requiring the reduction of “tar” or nic-  
9                   otine yields of a smoking article to zero;

10                   (C) prohibiting the sale of any smoking ar-  
11                   ticle in face-to-face transactions by a specific  
12                   category of retail outlets;

13                   (D) establishing a minimum age of sale of  
14                   smoking articles to any person older than 18  
15                   years of age; or

16                   (E) requiring that the sale or distribution  
17                   of a smoking article be limited to the written or  
18                   oral authorization of a practitioner licensed by  
19                   law to prescribe medical products,  
20           the Administrator is prohibited from taking such ac-  
21           tions under this Act.

22           (4) MATCHBOOKS.—For purposes of any regu-  
23           lations issued by the Administrator under this Act,  
24           matchbooks of conventional size containing not more  
25           than 20 paper matches, and which are customarily

1 given away for free with the purchase of smoking ar-  
2 ticles, shall be considered as adult-written publica-  
3 tions which shall be permitted to contain advertising.

4 (5) AMENDMENT; REVOCATION.—

5 (A) AUTHORITY.—The Administrator,  
6 upon the Administrator's own initiative or upon  
7 petition of an interested person, may by a regu-  
8 lation, promulgated in accordance with the re-  
9 quirements of subsection (c) and paragraph (2),  
10 amend or revoke a smoking article standard.

11 (B) EFFECTIVE DATE.—The Adminis-  
12 trator may declare a proposed amendment of a  
13 smoking article standard to be effective on and  
14 after its publication in the Federal Register and  
15 until the effective date of any final action taken  
16 on such amendment if the Administrator deter-  
17 mines that making it so effective is in the pub-  
18 lic interest.

19 (6) REFERRAL TO ADVISORY COMMITTEE.—

20 (A) IN GENERAL.—The Administrator  
21 shall refer a proposed regulation for the estab-  
22 lishment, amendment, or revocation of a smok-  
23 ing article standard to the Tobacco Products  
24 Scientific Advisory Committee for a report and  
25 recommendation with respect to any matter in-

1           involved in the proposed regulation which requires  
2           the exercise of scientific judgment.

3           (B) INITIATION OF REFERRAL.—The Ad-  
4           ministrators shall make a referral under this  
5           paragraph—

6                   (i) on the Administrator's own initia-  
7                   tive; or

8                   (ii) upon the request of an interested  
9                   person that—

10                           (I) demonstrates good cause for  
11                           the referral; and

12                           (II) is made before the expiration  
13                           of the period for submission of com-  
14                           ments on the proposed regulation.

15           (C) PROVISION OF DATA.—If a proposed  
16           regulation is referred under this paragraph to  
17           the Tobacco Products Scientific Advisory Com-  
18           mittee, the Administrator shall provide the Ad-  
19           visory Committee with the data and information  
20           on which such proposed regulation is based.

21           (D) REPORT AND RECOMMENDATION.—  
22           The Tobacco Products Scientific Advisory Com-  
23           mittee shall, within 90 days after the referral of  
24           a proposed regulation under this paragraph and  
25           after independent study of the data and infor-

1           mation furnished to it by the Administrator and  
2           other data and information before it, submit to  
3           the Administrator a report and recommendation  
4           respecting such regulation, together with all un-  
5           derlying data and information and a statement  
6           of the reason or basis for the recommendation.

7           (E) PUBLIC AVAILABILITY.—The Adminis-  
8           trator shall make a copy of each report and rec-  
9           ommendation under subparagraph (D) publicly  
10          available.

11 **SEC. 112. NOTIFICATION AND OTHER REMEDIES.**

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

14               (1) a tobacco product which is introduced or de-  
15               livered for introduction into interstate commerce for  
16               commercial distribution presents an unreasonable  
17               risk of substantial harm materially above the risk  
18               for death and disease of tobacco products currently  
19               in interstate commerce, to the public health; and

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

1 the Administrator may issue such order as may be nec-  
2 essary to assure that adequate notification is provided in  
3 an appropriate 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 Administrator may order notification  
7 by any appropriate means, including public service an-  
8 nouncements. Before issuing an order under this sub-  
9 section, the Administrator shall consult with the persons  
10 who are to give notice under the order.

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

18 (c) RECALL AUTHORITY.—

19 (1) IN GENERAL.—If the Administrator finds  
20 that there is a reasonable probability that a tobacco  
21 product contains a manufacturing or other defect  
22 not ordinarily contained in tobacco products on the  
23 market that would cause serious, acute adverse  
24 health consequences or death, the Administrator  
25 shall issue an order requiring the appropriate person

1 (including the manufacturers, importers, distribu-  
2 tors, or retailers of the tobacco product) to imme-  
3 diately cease distribution of such tobacco product.  
4 The order shall provide the person subject to the  
5 order with an opportunity for an informal hearing,  
6 to be held not later than 10 days after the date of  
7 the issuance of the order, on the actions required by  
8 the order and on whether the order should be  
9 amended to require a recall of such tobacco product.  
10 If, after providing an opportunity for such a hear-  
11 ing, the Administrator determines that inadequate  
12 grounds exist to support the actions required by the  
13 order, the Administrator shall 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 Administrator determines  
19 that the order should be amended to include a  
20 recall of the tobacco product with respect to  
21 which the order was issued, the Administrator  
22 shall, except as provided in subparagraph (B),  
23 amend the order to require a recall. The Ad-  
24 ministrator shall specify a timetable in which  
25 the tobacco product recall will occur and shall

1           require periodic reports to the Administrator  
2           describing the progress of the recall.

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

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

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

10           In providing the notice required by clause (ii),  
11           the Administrator may use the assistance of re-  
12           tailers and other persons who distributed such  
13           tobacco product. If a significant number of such  
14           persons cannot be identified, the Administrator  
15           shall 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).

19   **SEC. 113. RECORDS AND REPORTS ON TOBACCO PROD-**  
20                   **UCTS.**

21           Every person who is a tobacco product manufacturer  
22           or importer of a tobacco product shall establish and main-  
23           tain such records, make such reports, and provide such  
24           information, as the Administrator may by regulation rea-

1 sonably require to assure that such tobacco product is not  
2 adulterated or misbranded.

3 **SEC. 114. APPLICATION FOR REVIEW OF CERTAIN SMOKING**  
4 **ARTICLES.**

5 (a) IN GENERAL.—

6 (1) NEW SMOKING ARTICLE DEFINED.—For  
7 purposes of this section the term “new smoking arti-  
8 cle” means—

9 (A) any smoking article that was not com-  
10 mercially marketed in the United States as of  
11 the date of enactment of this Act; and

12 (B) any smoking article that incorporates  
13 a significant modification (including changes in  
14 design, component, part, or constituent, includ-  
15 ing a smoke constituent, or in the content, de-  
16 livery or form of nicotine, or other additive or  
17 ingredient) of a smoking article where the  
18 modified product was commercially marketed in  
19 the United States after the date of enactment  
20 of this Act.

21 (2) PREMARKET REVIEW REQUIRED.—

22 (A) NEW PRODUCTS.—An order under  
23 subsection (c)(1)(A) for a new smoking article  
24 is required unless the product—

1 (i) is substantially equivalent to a  
2 smoking article commercially marketed in  
3 the United States as of date of enactment  
4 of this Act; and

5 (ii) is in compliance with the require-  
6 ments of this Act.

7 (B) CONSUMER TESTING.—This section  
8 shall not apply to smoking articles that are pro-  
9 vided to adult tobacco consumers for purposes  
10 of consumer testing. For purposes of this sec-  
11 tion, the term “consumer testing” means an as-  
12 sessment of smoking articles that is conducted  
13 by or under the control and direction of a man-  
14 ufacturer for the purpose of evaluating con-  
15 sumer acceptance of such smoking articles, uti-  
16 lizing only the quantity of cigarettes that is rea-  
17 sonably necessary for such assessment

18 (3) SUBSTANTIALLY EQUIVALENT DEFINED.—

19 (A) IN GENERAL.—In this section, the  
20 term “substantially equivalent” or “substantial  
21 equivalence” means, with respect to the smok-  
22 ing article being compared to the predicate  
23 smoking article, that the Administrator by  
24 order has found that the smoking article—

1 (i) has the same general characteris-  
2 tics as the predicate smoking article; or

3 (ii) has different characteristics and  
4 the information submitted contains infor-  
5 mation, including clinical data if deemed  
6 necessary by the Administrator, that dem-  
7 onstrates that it is not appropriate to reg-  
8 ulate the product under this section be-  
9 cause the product does not raise different  
10 questions of public health for the consumer  
11 of the product.

12 (B) CHARACTERISTICS.—In subparagraph  
13 (A), the term “characteristics” means the mate-  
14 rials, ingredients, design, composition, heating  
15 source, or other features of a smoking article.

16 (C) LIMITATION.—A smoking article may  
17 not be found to be substantially equivalent to a  
18 predicate smoking article that has been re-  
19 moved from the market at the initiative of the  
20 Administrator or that has been determined by  
21 a judicial order to be misbranded or adulter-  
22 ated.

23 (4) HEALTH INFORMATION.—As part of a sub-  
24 mission respecting a smoking article, the person re-  
25 quired to file a premarket notification shall provide

1 an adequate summary of any health information re-  
2 lated to the smoking article or state that such infor-  
3 mation will be made available upon request by any  
4 person.

5 (b) APPLICATION.—

6 (1) CONTENTS.—An application under this sec-  
7 tion shall contain—

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

15 (B) a full statement of the components, in-  
16 gredients, additives, and properties, and of the  
17 principle or principles of operation, of such  
18 smoking article;

19 (C) a full description of the methods used  
20 in, and the facilities and controls used for, the  
21 manufacture, processing, and, when relevant,  
22 packing and installation of, such smoking arti-  
23 cle;

24 (D) an identifying reference to any smok-  
25 ing article standard under section 111 which

1 would be applicable to any aspect of such smok-  
2 ing article, and either adequate information to  
3 show that such aspect of such smoking article  
4 fully meets such smoking article standard or  
5 adequate information to justify any deviation  
6 from such standard;

7 (E) such samples of such smoking article  
8 and of components thereof as the Administrator  
9 may reasonably require;

10 (F) specimens of the labeling proposed to  
11 be used for such smoking article; and

12 (G) such other information relevant to the  
13 subject matter of the application as the Admin-  
14 istrator may require.

15 (2) REFERRAL TO TOBACCO PRODUCTS SCI-  
16 ENTIFIC ADVISORY COMMITTEE.—Upon receipt of an  
17 application meeting the requirements set forth in  
18 paragraph (1), the Administrator—

19 (A) may, on the Administrator's own ini-  
20 tiative; or

21 (B) may, upon the request of an applicant,  
22 refer such application to the Tobacco Products Sci-  
23 entific Advisory Committee for reference and for  
24 submission (within such period as the Administrator  
25 may establish) of a report and recommendation re-

1       specting the application, together with all underlying  
2       data and the reasons or basis for the recommenda-  
3       tion.

4       (c) ACTION ON APPLICATION.—

5           (1) DEADLINE.—As promptly as possible, but  
6       in no event later than 90 days after the receipt of  
7       an application under subsection (b), the Adminis-  
8       trator, after considering the report and rec-  
9       ommendation submitted under subsection (b)(2),  
10      shall—

11           (A) issue an order that the new product  
12      may be introduced or delivered for introduction  
13      into interstate commerce if the Administrator  
14      finds that none of the grounds specified in  
15      paragraph (2) of this subsection applies; or

16           (B) issue an order that the new product  
17      may not be introduced or delivered for introduc-  
18      tion into interstate commerce if the Adminis-  
19      trator finds (and sets forth the basis for such  
20      finding as part of or accompanying such denial)  
21      that 1 or more grounds for denial specified in  
22      paragraph (2) of this subsection apply.

23           (2) DENIAL OF APPLICATION.—The Adminis-  
24      trator shall deny an application submitted under  
25      subsection (b) if, upon the basis of the information

1 submitted to the Administrator as part of the appli-  
2 cation and any other information before the Admin-  
3 istrator with respect to such smoking article, the Ad-  
4 ministrator finds that—

5 (A) there is a lack of a showing that per-  
6 mitting such smoking article to be marketed  
7 would be appropriate for the protection of the  
8 public health;

9 (B) the methods used in, or the facilities  
10 or controls used for, the manufacture, proc-  
11 essing, or packing of such smoking article do  
12 not conform to the requirements of section  
13 110(e);

14 (C) based on a fair evaluation of all mate-  
15 rial facts, the proposed labeling is false or mis-  
16 leading in any particular; or

17 (D) such smoking article is not shown to  
18 conform to a smoking article standard in effect  
19 under section 111, and there is a lack of ade-  
20 quate information to justify the deviation from  
21 such standard.

22 (3) DENIAL INFORMATION.—Any denial of an  
23 application shall, insofar as the Administrator deter-  
24 mines to be practicable, be accompanied by a state-  
25 ment informing the applicant of the measures re-

1        required to remove such application from deniable  
2        form (which measures may include further research  
3        by the applicant in accordance with 1 or more proto-  
4        cols prescribed by the Administrator).

5            (4) BASIS FOR FINDING.—For purposes of this  
6        section, the finding as to whether the commercial in-  
7        troduction of a smoking article for which an applica-  
8        tion has been submitted is appropriate for the pro-  
9        tection of the public health shall be determined with  
10       respect to the risks and benefits to the users of the  
11       smoking article, and taking into account whether  
12       such commercial introduction is reasonably likely to  
13       increase the morbidity and mortality among indi-  
14       vidual tobacco users.

15        (d) WITHDRAWAL AND TEMPORARY SUSPENSION.—

16            (1) IN GENERAL.—The Administrator shall,  
17        upon obtaining, where appropriate, advice on sci-  
18        entific matters from the Tobacco Products Scientific  
19        Advisory Committee, and after due notice and op-  
20        portunity for informal hearing for a smoking article  
21        for which an order was issued under subsection  
22        (c)(1)(A), issue an order withdrawing the order if  
23        the Administrator finds—

1 (A) that the continued marketing of such  
2 smoking article no longer is appropriate for the  
3 protection of the public health;

4 (B) that the application contained or was  
5 accompanied by an untrue statement of a mate-  
6 rial fact;

7 (C) that the applicant—

8 (i) has failed to establish a system for  
9 maintaining records, or has repeatedly or  
10 deliberately failed to maintain records or to  
11 make reports, required by an applicable  
12 regulation under section 113; or

13 (ii) has refused to permit access to, or  
14 copying or verification of, such records as  
15 required by section 110; or

16 (D) on the basis of new information before  
17 the Administrator with respect to such smoking  
18 article, evaluated together with the evidence be-  
19 fore the Administrator when the application  
20 was reviewed, that the methods used in, or the  
21 facilities and controls used for, the manufac-  
22 ture, processing, packing, or installation of such  
23 smoking article do not conform with the re-  
24 quirements of section 110(e) and were not  
25 brought into conformity with such requirements

1           within a reasonable time after receipt of written  
2           notice from the Administrator of noncon-  
3           formity;

4           (E) on the basis of new information before  
5           the Administrator, evaluated together with the  
6           evidence before the Administrator when the ap-  
7           plication was reviewed, that the labeling of such  
8           smoking article, based on a fair evaluation of  
9           all material facts, is false or misleading in any  
10          particular and was not corrected within a rea-  
11          sonable time after receipt of written notice from  
12          the Administrator of such fact; or

13          (F) on the basis of new information before  
14          the Administrator, evaluated together with the  
15          evidence before the Administrator when such  
16          order was issued, that such smoking article is  
17          not shown to conform in all respects to a smok-  
18          ing article standard which is in effect under  
19          section 111, compliance with which was a con-  
20          dition to the issuance of an order relating to  
21          the application, and that there is a lack of ade-  
22          quate information to justify the deviation from  
23          such standard.

24          (2) APPEAL.—The holder of an application sub-  
25          ject to an order issued under paragraph (1) with-

1 drawing an order issued pursuant to subsection  
2 (c)(1)(A) may, by petition filed on or before the  
3 30th day after the date upon which such holder re-  
4 ceives notice of such withdrawal, obtain review there-  
5 of in accordance with section 116.

6 (3) TEMPORARY SUSPENSION.—If, after pro-  
7 viding an opportunity for an informal hearing, the  
8 Administrator determines there is reasonable prob-  
9 ability that the continuation of distribution of a  
10 smoking article under an order would cause serious,  
11 adverse health consequences or death, that is greater  
12 than ordinarily caused by smoking articles on the  
13 market, the Administrator shall by order temporarily  
14 suspend the authority of the manufacturer to mar-  
15 ket the product. If the Administrator issues such an  
16 order, the Administrator shall proceed expeditiously  
17 under paragraph (1) to withdraw such application.

18 (e) SERVICE OF ORDER.—An order issued by the Ad-  
19 ministrator under this section shall be served—

20 (1) in person by any officer or employee of the  
21 department designated by the Administrator; or

22 (2) by mailing the order by registered mail or  
23 certified mail addressed to the applicant at the ap-  
24 plicant's last known address in the records of the  
25 Administrator.

1 (f) RECORDS.—

2 (1) ADDITIONAL INFORMATION.—In the case of  
3 any smoking article for which an order issued pursu-  
4 ant to subsection (c)(1)(A) for an application filed  
5 under subsection (b) is in effect, the applicant shall  
6 establish and maintain such records, and make such  
7 reports to the Administrator, as the Administrator  
8 may by regulation, or by order with respect to such  
9 application, prescribe on the basis of a finding that  
10 such records and reports are necessary in order to  
11 enable the Administrator to determine, or facilitate  
12 a determination of, whether there is or may be  
13 grounds for withdrawing or temporarily suspending  
14 such order.

15 (2) ACCESS TO RECORDS.—Each person re-  
16 quired under this section to maintain records, and  
17 each person in charge of custody thereof, shall, upon  
18 request of an officer or employee designated by the  
19 Administrator, permit such officer or employee at all  
20 reasonable times to have access to and copy and  
21 verify such records.

22 (g) INVESTIGATIONAL SMOKING ARTICLE EXEMP-  
23 TION FOR INVESTIGATIONAL USE.—The Administrator  
24 may exempt smoking articles intended for investigational

1 use from the provisions of this Act under such conditions  
2 as the Administrator may by regulation prescribe.

3 **SEC. 115. MODIFIED RISK TOBACCO PRODUCTS.**

4 (a) IN GENERAL.—No person may introduce or de-  
5 liver for introduction into interstate commerce any modi-  
6 fied risk tobacco product unless an order issued pursuant  
7 to subsection (g) is effective with respect to such product.

8 (b) DEFINITIONS.—In this section:

9 (1) MODIFIED RISK TOBACCO PRODUCT.—The  
10 term “modified risk tobacco product” means any to-  
11 bacco product that is sold or distributed for use to  
12 reduce harm or the risk of tobacco-related disease  
13 associated with commercially marketed tobacco prod-  
14 ucts.

15 (2) SOLD OR DISTRIBUTED.—

16 (A) IN GENERAL.—With respect to a to-  
17 bacco product, the term “sold or distributed for  
18 use to reduce harm or the risk of tobacco-re-  
19 lated disease associated with commercially mar-  
20 keted tobacco products” means a tobacco prod-  
21 uct—

22 (i) the label, labeling, or advertising of  
23 which represents explicitly or implicitly  
24 that—

1 (I) the tobacco product presents  
2 a lower risk of tobacco-related disease  
3 or is less harmful than one or more  
4 other commercially marketed tobacco  
5 products;

6 (II) the tobacco product or its  
7 smoke contains a reduced level of a  
8 substance or presents a reduced expo-  
9 sure to a substance; or

10 (III) the tobacco product or its  
11 smoke does not contain or is free of a  
12 substance;

13 (ii) the label, labeling, or advertising  
14 of which uses the descriptors “light”,  
15 “mild”, “low”, “medium”, “ultra light”,  
16 “low tar” or “ultra low tar”; or

17 (iii) the tobacco product manufacturer  
18 of which has taken any action directed to  
19 consumers through the media or otherwise,  
20 other than by means of the tobacco prod-  
21 uct’s label, labeling, or advertising, after  
22 the date of enactment of the Act, respect-  
23 ing the product that would be reasonably  
24 expected to result in consumers believing  
25 that the tobacco product or its smoke may

1 present a lower risk of disease or is less  
2 harmful than one or more commercially  
3 marketed tobacco products, or presents a  
4 reduced exposure to, or does not contain or  
5 is free of, a substance or substances.

6 (B) LIMITATION.—No tobacco product  
7 shall be considered to be “sold or distributed  
8 for use to reduce harm or the risk of tobacco-  
9 related disease associated with commercially  
10 marketed tobacco products”, except as de-  
11 scribed in subparagraph (A).

12 (C) SMOKELESS TOBACCO PRODUCT.—No  
13 smokeless tobacco product shall be considered  
14 to be “sold or distributed for use to reduce  
15 harm or the risk of tobacco-related disease as-  
16 sociated with commercially marketed tobacco  
17 products”.

18 (3) EFFECTIVE DATE.—The provisions of para-  
19 graph (2)(A)(ii) shall take effect 12 months after  
20 the date of enactment of the Act.

21 (c) TOBACCO DEPENDENCE PRODUCTS.—A product  
22 that is intended to be used for the treatment of tobacco  
23 dependence, including smoking cessation, is not a modified  
24 risk tobacco product under this section if it has been ap-

1 proved as a drug or device by the Center and is subject  
2 to the requirements of chapter V.

3 (d) FILING.—Any person may file with the Adminis-  
4 trator an application for a modified risk tobacco product.  
5 Such application shall include—

6 (1) a description of the proposed product and  
7 any proposed advertising and labeling;

8 (2) the conditions for using the product;

9 (3) the formulation of the product;

10 (4) sample product labels and labeling;

11 (5) all documents (including underlying sci-  
12 entific information) relating to research findings  
13 conducted, supported, or possessed by the tobacco  
14 product manufacturer relating to the effect of the  
15 product on tobacco-related diseases and health-re-  
16 lated conditions, including information both favor-  
17 able and unfavorable to the ability of the product to  
18 reduce risk or exposure and relating to human  
19 health;

20 (6) data and information on how consumers ac-  
21 tually use the tobacco product; and

22 (7) such other information as the Administrator  
23 may require.

24 (e) PUBLIC AVAILABILITY.—The Administrator shall  
25 make the application described in subsection (d) publicly

1 available (except matters in the application which are  
2 trade secrets or otherwise confidential, commercial infor-  
3 mation) and shall request comments by interested persons  
4 on the information contained in the application and on the  
5 label, labeling, and advertising accompanying such appli-  
6 cation.

7 (f) ADVISORY COMMITTEE.—

8 (1) IN GENERAL.—The Administrator shall  
9 refer to the Tobacco Products Scientific Advisory  
10 Committee any application submitted under this sec-  
11 tion.

12 (2) RECOMMENDATIONS.—Not later than 60  
13 days after the date an application is referred to the  
14 Tobacco Products Scientific Advisory Committee  
15 under paragraph (1), the Advisory Committee shall  
16 report its recommendations on the application to the  
17 Administrator.

18 (g) MARKETING.—

19 (1) MODIFIED RISK PRODUCTS.—Except as  
20 provided in paragraph (2), the Administrator shall,  
21 with respect to an application submitted under this  
22 section, issue an order that a modified risk product  
23 may be commercially marketed only if the Adminis-  
24 trator determines that the applicant has dem-

1           onstrated that such product, as it is actually used by  
2           consumers, will—

3                   (A) significantly reduce harm and the risk  
4                   of tobacco-related disease to individual tobacco  
5                   users; and

6                   (B) is reasonably likely to result in meas-  
7                   urable and substantial reductions in morbidity  
8                   and mortality among individual tobacco users.

9           (2) SPECIAL RULE FOR CERTAIN PRODUCTS.—

10                   (A) IN GENERAL.—The Administrator may  
11                   issue an order that a tobacco product may be  
12                   introduced or delivered for introduction into  
13                   interstate commerce, pursuant to an application  
14                   under this section, with respect to a tobacco  
15                   product that may not be commercially marketed  
16                   under paragraph (1) if the Secretary makes the  
17                   findings required under this paragraph and de-  
18                   termines that the applicant has demonstrated  
19                   that—

20                           (i) such order would be appropriate to  
21                           promote the public health;

22                           (ii) any aspect of the label, labeling,  
23                           and advertising for such product that  
24                           would cause the tobacco product to be a  
25                           modified risk tobacco product under sub-

1 section (b) is limited to an explicit or im-  
2 plicit representation that such tobacco  
3 product or its smoke does not contain or is  
4 free of a substance or contains a reduced  
5 level of a substance, or presents a reduced  
6 exposure to a substance in tobacco smoke;

7 (iii) scientific evidence is not available  
8 and, using the best available scientific  
9 methods, cannot be made available without  
10 conducting long-term epidemiological stud-  
11 ies for an application to meet the stand-  
12 ards set forth in paragraph (1); and

13 (iv) the scientific evidence that is  
14 available without conducting long-term epi-  
15 demiological studies demonstrates that a  
16 measurable and substantial reduction in  
17 morbidity or mortality among individual  
18 tobacco users is reasonably likely in subse-  
19 quent studies.

20 (B) ADDITIONAL FINDINGS REQUIRED.—  
21 To issue an order under subparagraph (A) the  
22 Administrator must also find that the applicant  
23 has demonstrated that—

24 (i) the magnitude of the overall reduc-  
25 tions in exposure to the substance or sub-

1 stances which are the subject of the appli-  
2 cation is substantial, such substance or  
3 substances are harmful, and the product as  
4 actually used exposes consumers to the  
5 specified reduced level of the substance or  
6 substances;

7 (ii) the product as actually used by  
8 consumers will not expose them to higher  
9 levels of other harmful substances com-  
10 pared to the similar types of tobacco prod-  
11 ucts then on the market unless such in-  
12 creases are minimal and the reasonably  
13 likely overall impact of use of the product  
14 remains a substantial and measurable re-  
15 duction in overall morbidity and mortality  
16 among individual tobacco users;

17 (iii) testing of actual consumer per-  
18 ception shows that, as the applicant pro-  
19 poses to label and market the product, con-  
20 sumers will not be misled into believing  
21 that the product—

22 (I) is or has been demonstrated  
23 to be significantly less harmful; or

24 (II) presents or has been dem-  
25 onstrated to present significant less of

1 a risk of disease than other commer-  
2 cially marketed tobacco products; and  
3 (iv) issuance of an order with respect  
4 to the application is expected to benefit the  
5 health of users of tobacco products.

6 (3) BASIS.—The determinations under para-  
7 graphs (1) and (2) shall be based on—

8 (A) the scientific evidence submitted by the  
9 applicant; and

10 (B) scientific evidence and other informa-  
11 tion that is made available to the Adminis-  
12 trator.

13 (h) ADDITIONAL CONDITIONS FOR MARKETING.—

14 (1) MODIFIED RISK PRODUCTS.—The Adminis-  
15 trator shall require for the marketing of a product  
16 under this section that any advertising or labeling  
17 concerning modified risk products enable the public  
18 to comprehend the information concerning modified  
19 risk and to understand the relative significance of  
20 such information in the context of total health and  
21 in relation to all of the diseases and health-related  
22 conditions associated with the use of tobacco prod-  
23 ucts.

24 (2) COMPARATIVE CLAIMS.—

1           (A) IN GENERAL.—The Administrator may  
2           require for the marketing of a product under  
3           this subsection that a claim comparing a to-  
4           bacco product to other commercially marketed  
5           tobacco products shall compare the tobacco  
6           product to a commercially marketed tobacco  
7           product that is representative of that type of to-  
8           bacco product on the market (for example the  
9           average value of the top 3 brands of an estab-  
10          lished regular tobacco product).

11          (B) QUANTITATIVE COMPARISONS.—The  
12          Administrator may also require, for purposes of  
13          subparagraph (A), that the percent (or fraction)  
14          of change and identity of the reference tobacco  
15          product and a quantitative comparison of the  
16          amount of the substance claimed to be reduced  
17          shall be stated in immediate proximity to the  
18          most prominent claim.

19          (i) POSTMARKET SURVEILLANCE AND STUDIES.—

20           (1) IN GENERAL.—The Administrator shall re-  
21           quire, with respect to a product for which an appli-  
22           cant obtained an order under subsection (g)(1), that  
23           the applicant conduct postmarket surveillance and  
24           studies for such a tobacco product to determine the  
25           impact of the order issuance on consumer percep-

1       tion, behavior, and health, to enable the Adminis-  
2       trator to review the accuracy of the determinations  
3       upon which the order was based, and to provide in-  
4       formation that the Administrator determines is oth-  
5       erwise necessary regarding the use or health risks  
6       involving the tobacco product. The results of  
7       postmarket surveillance and studies shall be sub-  
8       mitted to the Administrator on an annual basis.

9               (2) SURVEILLANCE PROTOCOL.—Each appli-  
10       cant required to conduct a surveillance of a tobacco  
11       product under paragraph (1) shall, within 30 days  
12       after receiving notice that the applicant is required  
13       to conduct such surveillance, submit, for the ap-  
14       proval of the Administrator, a protocol for the re-  
15       quired surveillance. The Administrator, within 30  
16       days of the receipt of such protocol, shall determine  
17       if the principal investigator proposed to be used in  
18       the surveillance has sufficient qualifications and ex-  
19       perience to conduct such surveillance and if such  
20       protocol will result in collection of the data or other  
21       information designated by the Administrator as nec-  
22       essary to protect the public health.

23               (j) WITHDRAWAL OF AUTHORIZATION.—The Admin-  
24       istrator, after an opportunity for an informal hearing,

1 shall withdraw an order under subsection (g) if the Ad-  
2 ministrator determines that—

3 (1) the applicant, based on new information,  
4 can no longer make the demonstrations required  
5 under subsection (g), or the Administrator can no  
6 longer make the determinations required under sub-  
7 section (g);

8 (2) the application failed to include material in-  
9 formation or included any untrue statement of mate-  
10 rial fact;

11 (3) any explicit or implicit representation that  
12 the product reduces risk or exposure is no longer  
13 valid, including if—

14 (A) a tobacco product standard is estab-  
15 lished pursuant to section 111;

16 (B) an action is taken that affects the  
17 risks presented by other commercially marketed  
18 tobacco products that were compared to the  
19 product that is the subject of the application; or

20 (C) any postmarket surveillance or studies  
21 reveal that the order is no longer consistent  
22 with the protection of the public health;

23 (4) the applicant failed to conduct or submit  
24 the postmarket surveillance and studies required  
25 under subsection (g)(2)(C)(ii) or subsection (i); or

1           (5) the applicant failed to meet a condition im-  
2           posed under subsection (h).

3           (k) CHAPTER IV OR V.—A product for which the Ad-  
4           ministrators has issued an order pursuant to subsection (g)  
5           shall not be subject to chapter IV or V of the Federal  
6           Food, Drug, and Cosmetic Act.

7           (l) IMPLEMENTING REGULATIONS OR GUIDANCE.—

8           (1) SCIENTIFIC EVIDENCE.—Not later than 2  
9           years after the date of enactment of the Act, the Ad-  
10          ministrators shall issue regulations or guidance (or  
11          any combination thereof) on the scientific evidence  
12          required for assessment and ongoing review of modi-  
13          fied risk tobacco products. Such regulations or guid-  
14          ance shall—

15                 (A) to the extent that adequate scientific  
16                 evidence exists, establish minimum standards  
17                 for scientific studies needed prior to issuing an  
18                 order under subsection (g) to show a reasonable  
19                 likelihood that a substantial reduction in mor-  
20                 bidity or mortality among individual tobacco  
21                 users occurs for products described in sub-  
22                 section (g)(1) or is reasonably likely for prod-  
23                 ucts described in subsection (g)(2);

1 (B) include validated biomarkers, inter-  
2 mediate clinical endpoints, and other feasible  
3 outcome measures, as appropriate;

4 (C) establish minimum standards for  
5 postmarket studies, that shall include regular  
6 and long-term assessments of health outcomes  
7 and mortality, intermediate clinical endpoints,  
8 consumer perception of harm reduction, and the  
9 impact on quitting behavior and new use of to-  
10 bacco products, as appropriate;

11 (D) establish minimum standards for re-  
12 quired postmarket surveillance, including ongo-  
13 ing assessments of consumer perception; and

14 (E) establish a reasonable timetable for the  
15 Administrator to review an application under  
16 this section.

17 (2) CONSULTATION.—The regulations or guid-  
18 ance issued under paragraph (1) may be developed  
19 in consultation with the Institute of Medicine, and  
20 with the input of other appropriate scientific and  
21 medical experts, on the design and conduct of such  
22 studies and surveillance.

23 (3) REVISION.—The regulations or guidance  
24 under paragraph (1) shall be revised on a regular

1 basis as new scientific information becomes avail-  
2 able.

3 (4) NEW TOBACCO PRODUCTS.—Not later than  
4 2 years after the date of enactment of the Act, the  
5 Administrator shall issue a regulation or guidance  
6 that permits the filing of a single application for any  
7 tobacco product that is a new tobacco product under  
8 section 114 and which the applicant seeks to com-  
9 mercially market under this section.

10 **SEC. 116. JUDICIAL REVIEW.**

11 (a) RIGHT TO REVIEW.—

12 (1) IN GENERAL.—Not later than 60 days  
13 after—

14 (A) the promulgation of a regulation under  
15 section 111 establishing, amending, or revoking  
16 a tobacco product standard; or

17 (B) a denial of an application under sec-  
18 tion 114(c),

19 any person adversely affected by such regulation or  
20 denial may file a petition for judicial review of such  
21 regulation or denial with the United States Court of  
22 Appeals for the District of Columbia or for the cir-  
23 cuit in which such person resides or has their prin-  
24 cipal place of business.

25 (2) REQUIREMENTS.—

1 (A) COPY OF PETITION.—A copy of the pe-  
2 tition filed under paragraph (1) shall be trans-  
3 mitted by the clerk of the court involved to the  
4 Administrator.

5 (B) RECORD OF PROCEEDINGS.—On re-  
6 ceipt of a petition under subparagraph (A), the  
7 Administrator shall file in the court in which  
8 such petition was filed—

9 (i) the record of the proceedings on  
10 which the regulation or order was based;  
11 and

12 (ii) a statement of the reasons for the  
13 issuance of such a regulation or order.

14 (C) DEFINITION OF RECORD.—In this sec-  
15 tion, the term “record” means—

16 (i) all notices and other matter pub-  
17 lished in the Federal Register with respect  
18 to the regulation or order reviewed;

19 (ii) all information submitted to the  
20 Administrator with respect to such regula-  
21 tion or order;

22 (iii) proceedings of any panel or advi-  
23 sory committee with respect to such regu-  
24 lation or order;

1 (iv) any hearing held with respect to  
2 such regulation or order; and

3 (v) any other information identified by  
4 the Administrator, in the administrative  
5 proceeding held with respect to such regu-  
6 lation or order, as being relevant to such  
7 regulation or order.

8 (b) STANDARD OF REVIEW.—Upon the filing of the  
9 petition under subsection (a) for judicial review of a regu-  
10 lation or order, the court shall have jurisdiction to review  
11 the regulation or order in accordance with chapter 7 of  
12 title 5, United States Code, and to grant appropriate re-  
13 lief, including interim relief, as provided for in such chap-  
14 ter. A regulation or denial described in subsection (a) shall  
15 be reviewed in accordance with section 706(2)(A) of title  
16 5, United States Code.

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

23 (d) OTHER REMEDIES.—The remedies provided for  
24 in this section shall be in addition to, and not in lieu of,  
25 any other remedies provided by law.

1 (e) REGULATIONS AND ORDERS MUST RECITE BASIS  
2 IN RECORD.—To facilitate judicial review, a regulation or  
3 order issued under section 110, 111, 112, 113, 114, or  
4 119 shall contain a statement of the reasons for the  
5 issuance of such regulation or order in the record of the  
6 proceedings held in connection with its issuance.

7 **SEC. 117. JURISDICTION OF AND COORDINATION WITH THE**  
8 **FEDERAL TRADE COMMISSION.**

9 Except where expressly provided in this Act, nothing  
10 in this Act shall be construed as limiting or diminishing  
11 the authority of the Federal Trade Commission to enforce  
12 the laws under its jurisdiction with respect to the adver-  
13 tising, sale, or distribution of tobacco products.

14 **SEC. 118. REGULATION REQUIREMENT.**

15 (a) TESTING, REPORTING, AND DISCLOSURE.—Not  
16 later than 36 months after the date of enactment of the  
17 Act, the Administrator shall promulgate regulations under  
18 this Act that meet the requirements of subsection (b).

19 (b) CONTENTS OF RULES.—The regulations promul-  
20 gated under subsection (a)—

21 (1) shall require annual testing and reporting of  
22 tobacco product constituents, ingredients, and addi-  
23 tives, including smoke constituents, by brand style  
24 that the Administrator determines should be tested  
25 to protect the public health, provided that, for pur-

1 poses of the testing requirements of this paragraph,  
2 tobacco products manufactured and sold by a single  
3 tobacco product manufacturer that are identical in  
4 all respects except the labels, packaging design, logo,  
5 trade dress, trademark, brand name, or any com-  
6 bination thereof, shall be considered as a single  
7 brand style; and

8 (2) may require that tobacco product manufac-  
9 turers, packagers, or importers make disclosures re-  
10 lating to the results of the testing of tar and nico-  
11 tine through labels or advertising.

12 (c) AUTHORITY.—The Administrator shall have the  
13 authority under this Act to conduct or to require the test-  
14 ing, reporting, or disclosure of tobacco product constitu-  
15 ents, including smoke constituents.

16 (d) JOINT LABORATORY TESTING SERVICES.—The  
17 Administrator shall allow any 2 or more tobacco product  
18 manufacturers to join together to purchase laboratory  
19 testing services required by this section on a group basis  
20 in order to ensure that such manufacturers receive access  
21 to, and fair pricing of, such testing services.

22 (e) EXTENSIONS FOR LIMITED LABORATORY CAPAC-  
23 ITY.—

24 (1) IN GENERAL.—The regulations promulgated  
25 under subsection (a) shall provide that a tobacco

1 product manufacturer shall not be considered to be  
2 in violation of this section before the applicable  
3 deadline, if—

4 (A) the tobacco products of such manufac-  
5 turer are in compliance with all other require-  
6 ments of this Act; and

7 (B) the conditions described in paragraph  
8 (2) are met.

9 (2) CONDITIONS.—Notwithstanding the require-  
10 ments of this section, the Administrator may delay  
11 the date by which a tobacco product manufacturer  
12 must be in compliance with the testing and reporting  
13 required by this section until such time as the test-  
14 ing is reported if, not later than 90 days before the  
15 deadline for reporting in accordance with this sec-  
16 tion, a tobacco product manufacturer provides evi-  
17 dence to the Administrator demonstrating that—

18 (A) the manufacturer has submitted the  
19 required products for testing to a laboratory  
20 and has done so sufficiently in advance of the  
21 deadline to create a reasonable expectation of  
22 completion by the deadline;

23 (B) the products currently are awaiting  
24 testing by the laboratory; and

1           (C) neither that laboratory nor any other  
2           laboratory is able to complete testing by the  
3           deadline at customary, nonexpedited testing  
4           fees.

5           (3) EXTENSION.—The Administrator, taking  
6           into account the laboratory testing capacity that is  
7           available to tobacco product manufacturers, shall re-  
8           view and verify the evidence submitted by a tobacco  
9           product manufacturer in accordance with paragraph  
10          (2). If the Administrator finds that the conditions  
11          described in such paragraph are met, the Adminis-  
12          trator shall notify the tobacco product manufacturer  
13          that the manufacturer shall not be considered to be  
14          in violation of the testing and reporting require-  
15          ments of this section until the testing is reported or  
16          until 1 year after the reporting deadline has passed,  
17          whichever occurs sooner. If, however, the Adminis-  
18          trator has not made a finding before the reporting  
19          deadline, the manufacturer shall not be considered  
20          to be in violation of such requirements until the Ad-  
21          ministrator finds that the conditions described in  
22          paragraph (2) have not been met, or until 1 year  
23          after the reporting deadline, whichever occurs soon-  
24          er.

1           (4) **ADDITIONAL EXTENSION.**—In addition to  
2 the time that may be provided under paragraph (3),  
3 the Administrator may provide further extensions of  
4 time, in increments of no more than 1 year, for re-  
5 quired testing and reporting to occur if the Adminis-  
6 trator determines, based on evidence properly and  
7 timely submitted by a tobacco product manufacturer  
8 in accordance with paragraph (2), that a lack of  
9 available laboratory capacity prevents the manufac-  
10 turer from completing the required testing during  
11 the period described in paragraph (3).

12           (f) **RULE OF CONSTRUCTION.**—Nothing in subsection  
13 (d) or (e) shall be construed to authorize the extension  
14 of any deadline, or to otherwise affect any timeframe,  
15 under any provision of this Act other than this section.

16 **SEC. 119. PRESERVATION OF STATE AND LOCAL AUTHOR-**  
17 **ITY.**

18           (a) **IN GENERAL.**—

19           (1) **PRESERVATION.**—Except as provided in  
20 paragraph (2)(A), nothing in this Act, or rules pro-  
21 mulgated under this Act, shall be construed to limit  
22 the authority of a Federal agency (including the  
23 Armed Forces), a State or political subdivision of a  
24 State, or the government of an Indian tribe to enact,  
25 adopt, promulgate, and enforce any law, rule, regu-

1 lation, or other measure with respect to tobacco  
2 products that is in addition to requirements estab-  
3 lished under this Act, including a law, rule, regula-  
4 tion, or other measure relating to or prohibiting the  
5 sale, distribution, possession, or use of tobacco prod-  
6 ucts by individuals of any age, information reporting  
7 to the State. No provision of this Act shall limit or  
8 otherwise affect any State, Tribal, or local taxation  
9 of tobacco products.

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

12 (A) IN GENERAL.—No State or political  
13 subdivision of a State may establish or continue  
14 in effect with respect to a tobacco product any  
15 requirement which is different from, or in addi-  
16 tion to, any requirement under the provisions of  
17 this Act relating to tobacco product standards,  
18 premarket review, adulteration, misbranding,  
19 labeling, registration, good manufacturing  
20 standards, or modified risk tobacco products.

21 (B) EXCEPTION.—Subparagraph (A) does  
22 not apply to requirements relating to the sale,  
23 distribution, possession, information reporting  
24 to the State, use of, tobacco product by individ-  
25 uals of any age. Information disclosed to a

1 State under subparagraph (A) that is exempt  
2 from disclosure under section 552(b)(4) of title  
3 5, United States Code, shall be treated as a  
4 trade secret and confidential information by the  
5 State.

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

11 **SEC. 120. TOBACCO PRODUCTS SCIENTIFIC ADVISORY COM-**  
12 **MITTEE.**

13 (a) **ESTABLISHMENT.**—Not later than 6 months after  
14 the date of enactment of this Act, the Administrator shall  
15 establish a 16-member advisory committee, to be known  
16 as the Tobacco Products Scientific Advisory Committee  
17 (in this section referred to as the “Advisory Committee”).

18 (b) **MEMBERSHIP.**—

19 (1) **IN GENERAL.**—

20 (A) **MEMBERS.**—The Administrator shall  
21 appoint as members of the Tobacco Harm Re-  
22 duction Advisory Committee individuals who are  
23 technically qualified by training and experience  
24 in medicine, medical ethics, science, or tech-  
25 nology involving the manufacture, evaluation, or

1 use of tobacco products, who are of appro-  
2 priately diversified professional backgrounds.

3 The committee shall be composed of—

4 (i) 6 individuals who are physicians,  
5 dentists, scientists, or health care profes-  
6 sionals practicing in the area of oncology,  
7 pulmonology, cardiology, toxicology, phar-  
8 macology, addiction, or any other relevant  
9 specialty;

10 (ii) 2 individuals who are an officer or  
11 employee of a State or local government or  
12 of the Federal Government;

13 (iii) 2 representatives of the general  
14 public;

15 (iv) 2 representatives of the interests  
16 of the tobacco manufacturing industry;

17 (v) 1 representative of the interests of  
18 the small business tobacco manufacturing  
19 industry, which position may be filled on a  
20 rotating, sequential basis by representa-  
21 tives of different small business tobacco  
22 manufacturers based on areas of expertise  
23 relevant to the topics being considered by  
24 the Advisory Committee;

1 (vi) 1 individual as a representative of  
2 the interests of the tobacco growers; and

3 (vii) 1 individual who is an expert in  
4 illicit trade of tobacco products.

5 (B) CONFLICTS OF INTEREST.—No mem-  
6 bers of the committee, other than members ap-  
7 pointed pursuant to clauses (iv), (v), and (vi) of  
8 subparagraph (A) shall, during the member's  
9 tenure on the committee or for the 18-month  
10 period prior to becoming such a member, re-  
11 ceive any salary, grants, or other payments or  
12 support from any business that manufactures,  
13 distributes, markets, or sells cigarettes or other  
14 tobacco products or government agency with  
15 any form of jurisdiction over tobacco products.

16 (2) LIMITATION.—The Administrator may not  
17 appoint to the Advisory Committee any individual  
18 who is in the regular full-time employ of the To-  
19 bacco Harm Reduction Center or any agency respon-  
20 sible for the enforcement of this Act. The Adminis-  
21 trator may appoint Federal officials as ex officio  
22 members.

23 (3) CHAIRPERSON.—The Administrator shall  
24 designate 1 of the members appointed under clauses

1 (i), (ii), and (iii) of paragraph (1)(A) to serve as  
2 chairperson.

3 (c) DUTIES.—The Tobacco Products Scientific Advi-  
4 sory Committee shall provide advice, information, and rec-  
5 ommendations to the Administrator—

6 (1) as provided in this Act;

7 (2) on the implementation of prevention, ces-  
8 sation, and harm reduction policies;

9 (3) on implementation of policies and programs  
10 to fully inform consumers of the respective risks of  
11 tobacco products; and

12 (4) on its review of other safety, dependence, or  
13 health issues relating to tobacco products as re-  
14 quested by the Administrator.

15 (d) COMPENSATION; SUPPORT; FACA.—

16 (1) COMPENSATION AND TRAVEL.—Members of  
17 the Advisory Committee who are not officers or em-  
18 ployees of the United States, while attending con-  
19 ferences or meetings of the committee or otherwise  
20 engaged in its business, shall be entitled to receive  
21 compensation at rates to be fixed by the Adminis-  
22 trator, which may not exceed the daily equivalent of  
23 the rate in effect under the Senior Executive Sched-  
24 ule under section 5382 of title 5, United States  
25 Code, for each day (including travel time) they are

1 so engaged; and while so serving away from their  
2 homes or regular places of business each member  
3 may be allowed travel expenses, including per diem  
4 in lieu of subsistence, as authorized by section 5703  
5 of title 5, United States Code, for persons in the  
6 Government service employed intermittently.

7 (2) ADMINISTRATIVE SUPPORT.—The Adminis-  
8 trator shall furnish the Advisory Committee clerical  
9 and other assistance.

10 (3) NONAPPLICATION OF FACA.—Section 14 of  
11 the Federal Advisory Committee Act does not apply  
12 to the Advisory Committee.

13 (e) PROCEEDINGS OF ADVISORY PANELS AND COM-  
14 MITTEES.—The Advisory Committee shall make and  
15 maintain a transcript of any proceeding of the panel or  
16 committee. Each such panel and committee shall delete  
17 from any transcript made under this subsection informa-  
18 tion which is exempt from disclosure under section 552(b)  
19 of title 5, United States Code.

20 **SEC. 121. DRUG PRODUCTS USED TO TREAT TOBACCO DE-**  
21 **PENDENCE.**

22 (a) REPORT ON INNOVATIVE PRODUCTS.—

23 (1) IN GENERAL.—Not later than 3 years after  
24 the date of enactment of this Act, the Administrator,  
25 after consultation with recognized scientific, medical,

1 and public health experts (including both Federal  
2 agencies and nongovernmental entities, the Institute  
3 of Medicine of the National Academy of Sciences,  
4 and the Society for Research on Nicotine and To-  
5 bacco), shall submit to the Congress a report that  
6 examines how best to promote, and encourage the  
7 development and use by current tobacco users of in-  
8 novative tobacco and nicotine products and treat-  
9 ments (including nicotine-based and non-nicotine-  
10 based products and treatments) to better achieve, in  
11 a manner that best protects and promotes the public  
12 health—

13 (A) total abstinence from tobacco use;

14 (B) reductions in consumption of tobacco;

15 and

16 (C) reductions in the harm associated with  
17 continued tobacco use by moving current users  
18 to noncombustible tobacco products.

19 (2) RECOMMENDATIONS.—The report under  
20 paragraph (1) shall include the recommendations of  
21 the Administrator on how the Tobacco Harm and  
22 Reduction Center should coordinate and facilitate  
23 the exchange of information on such innovative  
24 products and treatments among relevant offices and  
25 centers within the Center and within the National

1 Institutes of Health, the Centers for Disease Control  
2 and Prevention, and other relevant Federal and  
3 State agencies.

4 **SEC. 122. ADVERTISING AND MARKETING OF TOBACCO**  
5 **PRODUCTS.**

6 (a) Within 18 months of enactment of the Act, the  
7 Administrator shall report to Congress on the benefits to  
8 public health of imposing restrictions or prohibitions on  
9 the advertising and marketing, consistent with or in addi-  
10 tion to such restrictions or prohibitions contained in the  
11 Master Settlement Agreement, on tobacco products.

12 (b) The Administrator shall specify in the report con-  
13 stitutional free speech implications for each recommended  
14 restriction or prohibition.

15 (c) The Administrator shall also specify the class of  
16 tobacco products to which the prohibition or restriction  
17 would be applicable and the impact of such actions on  
18 harm reduction policies, practices, and accurate informa-  
19 tion available to tobacco users.

20 (d) The Administrator shall establish and consult  
21 with an advisory committee consisting of experts in con-  
22 stitutional law, harm reduction policies, marketing prac-  
23 tices, and consumer behavior in preparing this report.

1 **TITLE II—TOBACCO PRODUCTS**  
2 **WARNINGS; CONSTITUENT**  
3 **AND SMOKE CONSTITUENT**  
4 **DISCLOSURE**

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

6 (a) AMENDMENT.—Section 4 of the Federal Ciga-  
7 rette Labeling and Advertising Act (15 U.S.C. 1333) is  
8 amended to read as follows:

9 **“SEC. 4. LABELING.**

10 “(a) LABEL REQUIREMENTS.—

11 “(1) IN GENERAL.—It shall be unlawful for any  
12 person to manufacture, package, sell, offer to sell,  
13 distribute, or import for sale or distribution within  
14 the United States any cigarettes the package of  
15 which fails to bear, in accordance with the require-  
16 ments of this section, one of the following labels:

17 “WARNING: Cigarettes are addictive.

18 “WARNING: Tobacco smoke can harm  
19 your children.

20 “WARNING: Cigarettes cause fatal lung  
21 disease.

22 “WARNING: Cigarettes cause cancer.

23 “WARNING: Cigarettes cause strokes and  
24 heart disease.

1           “WARNING: Smoking during pregnancy  
2           can harm your baby.

3           “WARNING: Smoking can kill you.

4           “WARNING: Tobacco smoke causes fatal  
5           lung disease in nonsmokers.

6           “WARNING: Quitting smoking now great-  
7           ly reduces serious risks to your health.

8           “(2) PLACEMENT; TYPOGRAPHY; ETC.—Each  
9           label statement required by paragraph (1) shall be  
10          located in the lower portion of the front panel of the  
11          package, directly on the package underneath the cel-  
12          lophane or other clear wrapping. Each label state-  
13          ment shall comprise at least the bottom 25 percent  
14          of the front panel of the package. The word  
15          ‘WARNING’ shall appear in capital letters and all  
16          text shall be in conspicuous and legible 17-point  
17          type, unless the text of the label statement would oc-  
18          cupy more than 70 percent of such area, in which  
19          case the text may be in a smaller conspicuous and  
20          legible type size, provided that at least 60 percent of  
21          such area is occupied by required text. The text shall  
22          be black on a white background, or white on a black  
23          background, in a manner that contrasts, by typog-  
24          raphy, layout, or color, with all other printed mate-

1       rial on the package, in an alternating fashion under  
2       the plan submitted under subsection (c).

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

9           “(4) APPLICABILITY TO RETAILERS.—A retailer  
10       of cigarettes shall not be in violation of this subsection for packaging that—

12           “(A) contains a warning label;

13           “(B) is supplied to the retailer by a  
14       license- or permit-holding smoking article manufacturer, importer, or distributor; and

16           “(C) is not altered by the retailer in a way  
17       that is material to the requirements of this subsection.  
18       section.

19       “(b) ADVERTISING REQUIREMENTS.—

20           “(1) IN GENERAL.—It shall be unlawful for any  
21       tobacco product manufacturer, importer, distributor,  
22       or retailer of cigarettes to advertise or cause to be  
23       advertised within the United States any cigarette  
24       unless its advertising bears, in accordance with the

1 requirements of this section, one of the labels speci-  
2 fied in subsection (a).

3 “(2) TYPOGRAPHY, ETC.—Each label statement  
4 required by subsection (a) in cigarette advertising  
5 shall comply with the standards set forth in this  
6 paragraph. For press and poster advertisements,  
7 each such statement and (where applicable) any re-  
8 quired statement relating to tar, nicotine, or other  
9 constituent (including a smoke constituent) yield  
10 shall comprise at least 20 percent of the area of the  
11 advertisement and shall appear in a conspicuous and  
12 prominent format and location at the bottom of each  
13 advertisement within the trim area. The word  
14 ‘WARNING’ shall appear in capital letters, and each  
15 label statement shall appear in conspicuous and leg-  
16 ible type. The text of the label statement shall be  
17 black if the background is white and white if the  
18 background is black, under the plan submitted under  
19 subsection (c). The label statements shall be en-  
20 closed by a rectangular border that is the same color  
21 as the letters of the statements and that is the width  
22 of the first downstroke of the capital ‘W’ of the word  
23 ‘WARNING’ in the label statements. The text of  
24 such label statements shall be in a typeface pro rata  
25 to the following requirements: 45-point type for a

1 whole-page broadsheet newspaper advertisement; 39-  
2 point type for a half-page broadsheet newspaper ad-  
3 vertisement; 39-point type for a whole-page tabloid  
4 newspaper advertisement; 27-point type for a half-  
5 page tabloid newspaper advertisement; 31.5-point  
6 type for a double page spread magazine or whole-  
7 page magazine advertisement; 22.5-point type for a  
8 28 centimeter by 3 column advertisement; and 15-  
9 point type for a 20 centimeter by 2 column adver-  
10 tisement. The label statements shall be in English,  
11 except that—

12 “(A) in the case of an advertisement that  
13 appears in a newspaper, magazine, periodical,  
14 or other publication that is not in English, the  
15 statements shall appear in the predominant lan-  
16 guage of the publication; and

17 “(B) in the case of any other advertise-  
18 ment that is not in English, the statements  
19 shall appear in the same language as that prin-  
20 cipally used in the advertisement.

21 “(3) MATCHBOOKS.—Notwithstanding para-  
22 graph (2), for matchbooks (defined as containing not  
23 more than 20 matches) customarily given away with  
24 the purchase of smokeless tobacco products, each

1 label statement required by subsection (a) may be  
2 printed on the inside cover of the matchbook.

3 “(c) MARKETING REQUIREMENTS.—

4 “(1) RANDOM DISPLAY.—The label statements  
5 specified in subsection (a)(1) shall be randomly dis-  
6 played in each 12-month period, in as equal a num-  
7 ber of times as is possible on each brand of the  
8 product and be randomly distributed in all areas of  
9 the United States in which the product is marketed  
10 in accordance with a plan submitted by the smoke-  
11 less tobacco product manufacturer, importer, dis-  
12 tributor, or retailer and approved by the Secretary.

13 “(2) ROTATION.—The label statements speci-  
14 fied in subsection (a)(1) shall be rotated quarterly in  
15 alternating sequence in advertisements for each  
16 brand of cigarettes in accordance with a plan sub-  
17 mitted by the smokeless tobacco product manufac-  
18 turer, importer, distributor, or retailer to, and ap-  
19 proved by, the Secretary.

20 “(3) REVIEW.—The Secretary shall review each  
21 plan submitted under paragraph (2) and approve it  
22 if the plan—

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

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

5           “(4) APPLICABILITY TO RETAILERS.—This sub-  
6           section and subsection (b) apply to a retailer only if  
7           that retailer is responsible for or directs the label  
8           statements required under this section except that  
9           this paragraph shall not relieve a retailer of liability  
10          if the retailer displays, in a location open to the pub-  
11          lic, an advertisement that does not contain a warn-  
12          ing label or has been altered by the retailer in a way  
13          that is material to the requirements of this sub-  
14          section and subsection (b).”.

15          (b) EFFECTIVE DATE.—The amendment made by  
16          subsection (a) shall take effect 24 months after the date  
17          of enactment of this Act. Such effective date shall be with  
18          respect to the date of manufacture, provided that, in any  
19          case, beginning 30 days after such effective date, a manu-  
20          facturer shall not introduce into the domestic commerce  
21          of the United States any product, irrespective of the date  
22          of manufacture, that is not in conformance with section  
23          4 of the Federal Cigarette Labeling and Advertising Act  
24          (15 U.S.C. 1333), as amended by subsection (a).

1 **SEC. 202. SMOKELESS TOBACCO LABELS AND ADVERTISING**  
2 **WARNINGS.**

3 (a) AMENDMENT.—Section 3 of the Comprehensive  
4 Smokeless Tobacco Health Education Act of 1986 (15  
5 U.S.C. 4402) is amended to read as follows:

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

7 “(a) GENERAL RULE.—

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

14 “WARNING: This product can cause  
15 mouth cancer.

16 “WARNING: This product can cause gum  
17 disease and tooth loss.

18 “WARNING: This product has signifi-  
19 cantly lower risks for diseases associated with  
20 cigarettes.

21 “WARNING: Smokeless tobacco is addict-  
22 ive.

23 “(2) The label statements required by para-  
24 graph (1) shall be introduced by each smokeless to-  
25 bacco product manufacturer, packager, importer,  
26 distributor, or retailer of smokeless tobacco products

1 concurrently into the distribution chain of such  
2 products.

3 “(3) The provisions of this subsection do not  
4 apply to a smokeless tobacco product manufacturer  
5 or distributor of any smokeless tobacco product that  
6 does not manufacture, package, or import smokeless  
7 tobacco products for sale or distribution within the  
8 United States.

9 “(4) A retailer of smokeless tobacco products  
10 shall not be in violation of this subsection for pack-  
11 aging that—

12 “(A) contains a warning label;

13 “(B) is supplied to the retailer by a  
14 license- or permit-holding smokeless tobacco  
15 product manufacturer, importer, or distributor;  
16 and

17 “(C) is not altered by the retailer in a way  
18 that is material to the requirements of this sub-  
19 section.

20 “(b) REQUIRED LABELS.—

21 “(1) It shall be unlawful for any smokeless to-  
22 bacco product manufacturer, packager, importer,  
23 distributor, or retailer of smokeless tobacco products  
24 to advertise or cause to be advertised within the  
25 United States any smokeless tobacco product unless

1 its advertising bears, in accordance with the require-  
2 ments of this section, one of the labels specified in  
3 subsection (a).

4 “(2)(A) Each label statement required by sub-  
5 section (a) in smokeless tobacco advertising shall  
6 comply with the standards set forth in this para-  
7 graph.

8 “(B) For press and poster advertisements, each  
9 such statement and (where applicable) any required  
10 statement relating to nicotine, or other constituent  
11 yield shall comprise at least 20 percent of the area  
12 of the advertisement.

13 “(C) The word ‘WARNING’ shall appear in  
14 capital letters, and each label statement shall appear  
15 in conspicuous and legible type.

16 “(D) The text of the label statement shall be  
17 black on a white background, or white on a black  
18 background, in an alternating fashion under the  
19 plan submitted under paragraph (3).

20 “(E) The label statements shall be enclosed by  
21 a rectangular border that is the same color as the  
22 letters of the statements and that is the width of the  
23 first downstroke of the capital ‘W’ of the word  
24 ‘WARNING’ in the label statements.

1           “(F) The text of such label statements shall be  
2           in a typeface pro rata to the following requirements:  
3           45-point type for a whole-page broadsheet newspaper  
4           advertisement; 39-point type for a half-page  
5           broadsheet newspaper advertisement; 39-point type  
6           for a whole-page tabloid newspaper advertisement;  
7           27-point type for a half-page tabloid newspaper ad-  
8           vertisement; 31.5-point type for a double page  
9           spread magazine or whole-page magazine advertise-  
10          ment; 22.5-point type for a 28 centimeter by 3 col-  
11          umn advertisement; and 15-point type for a 20 cen-  
12          timeter by 2 column advertisement.

13           “(G) The label statements shall be in English,  
14          except that—

15                   “(i) in the case of an advertisement that  
16                   appears in a newspaper, magazine, periodical,  
17                   or other publication that is not in English, the  
18                   statements shall appear in the predominant lan-  
19                   guage of the publication; and

20                   “(ii) in the case of any other advertisement  
21                   that is not in English, the statements shall ap-  
22                   pear in the same language as that principally  
23                   used in the advertisement.

24           “(3)(A) The label statements specified in sub-  
25          section (a)(1) shall be randomly displayed in each

1 12-month period, in as equal a number of times as  
2 is possible on each brand of the product and be ran-  
3 domly distributed in all areas of the United States  
4 in which the product is marketed in accordance with  
5 a plan submitted by the smokeless tobacco product  
6 manufacturer, importer, distributor, or retailer and  
7 approved by the Secretary.

8 “(B) The label statements specified in sub-  
9 section (a)(1) shall be rotated quarterly in alter-  
10 nating sequence in advertisements for each brand of  
11 smokeless tobacco product in accordance with a plan  
12 submitted by the smokeless tobacco product manu-  
13 facturer, importer, distributor, or retailer to, and ap-  
14 proved by, the Secretary.

15 “(C) The Secretary shall review each plan sub-  
16 mitted under subparagraphs (A) and (B) and ap-  
17 prove it if the plan—

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

21 “(ii) assures that all of the labels required  
22 under this section will be displayed by the  
23 smokeless tobacco product manufacturer, im-  
24 porter, distributor, or retailer at the same time.

1           “(D) This paragraph applies to a retailer only  
2           if that retailer is responsible for or directs the label  
3           statements under this section, unless the retailer dis-  
4           plays, in a location open to the public, an advertise-  
5           ment that does not contain a warning label or has  
6           been altered by the retailer in a way that is material  
7           to the requirements of this subsection.

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

12          (b) EFFECTIVE DATE.—The amendment made by  
13          subsection (a) shall take effect 24 months after the date  
14          of enactment of this Act. Such effective date shall be with  
15          respect to the date of manufacture, provided that, in any  
16          case, beginning 30 days after such effective date, a manu-  
17          facturer shall not introduce into the domestic commerce  
18          of the United States any product, irrespective of the date  
19          of manufacture, that is not in conformance with section  
20          3 of the Comprehensive Smokeless Tobacco Health Edu-  
21          cation Act of 1986 (15 U.S.C. 4402), as amended by sub-  
22          section (a).

1 **TITLE III—PUBLIC DISCLOSURES**  
2 **BY TOBACCO PRODUCTS**  
3 **MANUFACTURERS**

4 **SEC. 301. DISCLOSURES ON PACKAGES OF TOBACCO PROD-**  
5 **UCTS.**

6 (a) **BACK FACE FOR REQUIRED DISCLOSURES.**—For  
7 purposes of this section—

8 (1) the principal face of a package of a tobacco  
9 product is the face that has the largest surface area  
10 or, for faces with identical surface areas, any of the  
11 faces that have the largest surface area; a package  
12 shall not be characterized as having more than 2  
13 principal faces;

14 (2) the front face shall be the principal face of  
15 the package;

16 (3) if the front and back faces are of different  
17 sizes in terms of area, then the larger face shall be  
18 the front face;

19 (4) the back face shall be the principal face of  
20 a package that is opposite the front face of the pack-  
21 age;

22 (5) the bottom 50 percent of the back face of  
23 the package shall be allocated for required package  
24 disclosures in accordance with this section; and

1           (6) if a package of a tobacco product is cylin-  
2           drical, a contiguous area constituting 30 percent of  
3           the total surface area of the cylinder shall be deemed  
4           the back face.

5           (b) REQUIRED INFORMATION ON BACK FACE.—Not  
6           later than 24 months after the effective date of this Act,  
7           the bottom 50 percent of the back face of a package of  
8           a tobacco product shall be available solely for disclosures  
9           required by or under this Act, the Federal Cigarette La-  
10          beling and Advertising Act, sections 1331–1340 of title  
11          15, United States Code, and any other Federal statute.  
12          Such disclosures shall include—

13           (1) the printed name and address of the manu-  
14           facturer, packer, or distributor, and any other iden-  
15           tification associated with the manufacturer, packer,  
16           or distributor or with the tobacco product that the  
17           Administrator may require;

18           (2) a list of ingredients as required by sub-  
19           section (e); and

20           (3) the appropriate tax registration number.

21          (c) PACKAGE DISCLOSURE OF INGREDIENTS.—Not  
22          later than 24 months after the effective date of this Act,  
23          the package of a tobacco product shall bear a list of the  
24          common or usual names of the ingredients present in the  
25          tobacco product in an amount greater than 0.1 percent

1 of the total dry weight of the tobacco (including all ingre-  
2 dients), that shall comply with the following:

3 (1) Such listing of ingredients shall appear  
4 under, or be conspicuously accompanied by, the  
5 heading “Tobacco and principal tobacco ingredi-  
6 ents”.

7 (2) Tobacco may be listed as “tobacco,” and  
8 shall be the first listed ingredient.

9 (3) After tobacco, the ingredients shall be listed  
10 in descending order of predominance, by weight.

11 (4) Spices and natural and artificial flavors  
12 may be listed, respectively, as “spices” and “natural  
13 and artificial flavors” without naming each.

14 (5) Preservatives may be listed as “preserva-  
15 tives” without naming each.

16 (6) The disclosure of any ingredient in accord-  
17 ance with this section may, at the option of the to-  
18 bacco product manufacturer, designate the  
19 functionality or purpose of that ingredient.

20 (7) The package say state “Not for sale to mi-  
21 nors”.

22 (8) In the case of a package of cigarettes, the  
23 package shall state that smokeless tobacco has sig-  
24 nificantly lower risks for disease and death than  
25 cigarettes.

1 **SEC. 302. DISCLOSURES ON PACKAGES OF SMOKELESS TO-**  
2 **BACCO.**

3 (a) **BACK FACE FOR REQUIRED DISCLOSURES.**—For  
4 purposes of this section—

5 (1) the principal face of a package of smokeless  
6 tobacco is the face that has the largest surface area  
7 or, for faces with identical surface areas, any of the  
8 faces that have the largest surface area; a package  
9 shall not be characterized as having more than two  
10 principal faces;

11 (2) the front or top face shall be the principal  
12 face of the package;

13 (3) if the front or top and back or bottom faces  
14 are of different sizes in terms of area, then the larg-  
15 er face shall be the front or top face;

16 (4) the back or bottom face of the package shall  
17 be the principal face of a package that is opposite  
18 the front or top face of the package;

19 (5) beginning 24 months after the effective date  
20 of this Act, 50 percent of the back or bottom face  
21 of the package shall be allocated for required pack-  
22 age disclosures in accordance with this section; and

23 (6) if the package is cylindrical, a contiguous  
24 area constituting 30 percent of the total surface  
25 area of the cylinder shall be deemed the back face.

1           (b) REQUIRED INFORMATION ON BACK OR BOTTOM  
2 FACE.—50 percent of the back or bottom face of a pack-  
3 age of smokeless tobacco shall be available solely for dis-  
4 closures required by or under this Act, the Comprehensive  
5 Smokeless Tobacco Health Education Act of 1986, sec-  
6 tions 4401–4408 of title 15, United States Code, and any  
7 other Federal statute. Such disclosures shall include a list  
8 of ingredients as required by subsection (e).

9           (c) PACKAGE DISCLOSURE OF INGREDIENTS.—Com-  
10 mencing 24 months after the effective date of this Act,  
11 a package of smokeless tobacco shall bear a list of the  
12 common or usual names of the ingredients present in the  
13 smokeless tobacco in an amount greater than 0.1 percent  
14 of the total dry weight of the tobacco (including all ingre-  
15 dients).

16           (1) Such listing of ingredients shall appear  
17 under, or be conspicuously accompanied by, the  
18 heading “Tobacco and principal tobacco ingredi-  
19 ents”.

20           (2) Tobacco may be listed as “tobacco,” and  
21 shall be the first listed ingredient.

22           (3) After tobacco, the ingredients shall be listed  
23 in descending order of predominance, by weight.

1 (4) Spices and natural and artificial flavors  
2 may be listed, respectively, as “spices” and “natural  
3 and artificial flavors” without naming each.

4 (5) Preservatives may be listed as “preserva-  
5 tives” without naming each.

6 (6) The disclosure of any ingredient in accord-  
7 ance with this section may, at the option of the to-  
8 bacco product manufacturer, designate the  
9 functionality or purpose of that ingredient.

10 (7) Not for sale to minors.

11 **SEC. 303. PUBLIC DISCLOSURE OF INGREDIENTS.**

12 (a) REGULATIONS.—Not later than 24 months after  
13 the effective date of this Act, the Administrator shall, by  
14 regulation, establish standards under which each tobacco  
15 product manufacturer shall disclose publicly, and update  
16 at least annually—

17 (1) a list of the ingredients it uses in each  
18 brand style it manufactures for commercial distribu-  
19 tion domestically, as provided in subsection (b); and

20 (2) a composite list of all the ingredients it uses  
21 in any of the brand styles it manufactures for com-  
22 mercial distribution domestically, as provided in sub-  
23 section (c).

24 (b) INGREDIENTS TO BE DISCLOSED AS TO EACH  
25 BRAND STYLE.—

1           (1) IN GENERAL.—With respect to the public  
2 disclosure required by subsection (a)(1), as to each  
3 brand style, the tobacco product manufacture shall  
4 disclose the common or usual name of each ingre-  
5 dient present in the brand style in an amount great-  
6 er than 0.1 percent of the total dry weight of the to-  
7 bacco (including all ingredients).

8           (2) REQUIREMENTS.—Disclosure under para-  
9 graph (1) shall comply with the following:

10           (A) Tobacco may be listed as “tobacco,”  
11 and shall be the first listed ingredient.

12           (B) After tobacco, the ingredients shall be  
13 listed in descending order of predominance, by  
14 weight.

15           (C) Spices and natural and artificial fla-  
16 vors may be listed, respectively, as “spices” and  
17 “natural and artificial flavors” without naming  
18 each.

19           (D) Preservatives may be listed as “pre-  
20 servatives” without naming each.

21           (E) The disclosure of any ingredient in ac-  
22 cordance with this section may, at the option of  
23 the tobacco product manufacturer, designate  
24 the functionality or purpose of that ingredient.

25           (c) AGGREGATE DISCLOSURE OF INGREDIENTS.—

1           (1) IN GENERAL.—The public disclosure re-  
2           quired of a tobacco product manufacturer by sub-  
3           section (a)(2) shall consist of a single list of all in-  
4           gredients used in any brand style a tobacco product  
5           manufacturer manufactures for commercial distribu-  
6           tion domestically, without regard to the quantity  
7           used, and including, separately, each spice, each nat-  
8           ural or artificial flavoring, and each preservative.

9           (2) LISTING.—The ingredients shall be listed by  
10          their respective common or usual names in descend-  
11          ing order of predominance by the total weight used  
12          annually by the tobacco product manufacturer in  
13          manufacturing tobacco products for commercial dis-  
14          tribution domestically.

15          (d) NO REQUIRED DISCLOSURE OF QUANTITIES.—  
16          The Administrator shall not require any public disclosure  
17          of quantitative information about any ingredient in a to-  
18          bacco product.

19          (e) DISCLOSURE ON WEBSITE.—The public disclo-  
20          sures required by subsection (a) of this section may be  
21          by posting on an Internet-accessible website, or other loca-  
22          tion electronically accessible to the public, which is identi-  
23          fied on all packages of a tobacco product manufacturer's  
24          tobacco products.

1 (f) TIMING OF INITIAL REQUIRED DISCLOSURES.—  
2 No disclosure pursuant to this section shall be required  
3 to commence until the regulations under subsection (a)  
4 have been in effect for not less than 1 year.

5 **TITLE IV—PREVENTION OF IL-**  
6 **LICIT TRADE IN TOBACCO**  
7 **PRODUCTS**

8 **SEC. 401. STUDY AND REPORT ON ILLICIT TRADE.**

9 (a) The Administrator shall, after consultation with  
10 other relevant agencies including Customs and Tobacco  
11 Tax Bureau, conduct a study of trade in tobacco products  
12 that involves passage of tobacco products either between  
13 the states or from or to any other country across any bor-  
14 der of the United States to—

15 (1) collect data on such trade in tobacco prod-  
16 ucts, including illicit trade involving tobacco prod-  
17 ucts, and make recommendations on the monitoring  
18 and enforcement of such trade;

19 (2) collect data on any advertising intended to  
20 be broadcast, transmitted, or distributed from or to  
21 the United States from or to another country and  
22 make recommendations on how to prevent or elimi-  
23 nate, and what technologies could help facilitate the  
24 elimination of, such advertising; and

1           (3) collect data on such trade in tobacco prod-  
2           ucts by person that is not—

3                   (A) a participating manufacturer (as that  
4                   term is defined in section II(jj) of the Master  
5                   Settlement Agreement of November 23, 1998,  
6                   between certain of the States and certain to-  
7                   bacco product manufacturers); or

8                   (B) an affiliate or subsidiary of a partici-  
9                   pating manufacturer.

10          (b) Not later than 18 months after the effective date  
11 of this Act, the Administrator shall submit to the Sec-  
12 retary, and committees of relevant jurisdiction in Con-  
13 gress, a report the recommendations of the study con-  
14 ducted under subsection (a).

15 **SEC. 402. AMENDMENT TO SECTION 1926 OF THE PUBLIC**  
16 **HEALTH SERVICE ACT.**

17          Section 1926 of the Public Health Service Act (42  
18 U.S.C. § 300x-26) is amended by adding at the end there-  
19 of the following:

20          “(e)(1) Subject to paragraphs (2) and (3), for the  
21 first fiscal year after enactment and each subsequent fiscal  
22 year, the Secretary shall reduce, as provided in subsection  
23 (h), the amount of any grant under section 300x-21 of  
24 this title for any State that does not have in effect a stat-  
25 ute with substantially the following provisions:

1 **“SEC. 1. DISTRIBUTION TO MINORS.**

2 “(a) No person shall distribute a tobacco product  
3 to an individual under 18 years of age or a different min-  
4 imum age established under State law. A person who vio-  
5 lates this subsection is liable for a civil money penalty of  
6 not less than \$25 nor more than \$125 for each violation  
7 of this subsection;

8 “(b) The employer of an employee who has violated  
9 subsection (a) twice while in the employ of such employer  
10 is liable for a civil money penalty of \$125 for each subse-  
11 quent violation by such employee.

12 “(c) It shall be a defense to a charge brought under  
13 subsection (a) that—

14 “(1) the defendant—

15 “(A) relied upon proof of age that ap-  
16 peared on its face to be valid in accordance with  
17 the Federal Tobacco Act of 2007; or

18 “(B) had complied with the requirements  
19 of section 5 and, if applicable, section 7;

20 “(C) relied upon a commercially available  
21 electronic age verification service to confirm  
22 that the person was an age-verified adult; or

23 “(2) the individual to whom the tobacco prod-  
24 uct was distributed was at the time of the distribu-  
25 tion used in violation of subsection 8(b).

1 **“SEC. 2. PURCHASE, RECEIPT, OR POSSESSION BY MINORS**  
2 **PROHIBITED.**

3 ““(a) An individual under 18 years of age or a dif-  
4 ferent minimum age established under State law shall not  
5 purchase or attempt to purchase, receive or attempt to re-  
6 ceive, possess or attempt to possess, a tobacco product.  
7 An individual who violates this subsection is liable for a  
8 civil money penalty of not less than \$25 nor more than  
9 \$125 for each such violation, and shall be required to per-  
10 form not less than four hours nor more than ten hours  
11 of community service. Upon the second or each subsequent  
12 violation of this subsection, such individual shall be re-  
13 quired to perform not less than eight hours nor more than  
14 twenty hours of community service.

15 ““(b) A law enforcement agency, upon determining  
16 that an individual under 18 years of age or a different  
17 minimum age established under State law allegedly pur-  
18 chased, received, possessed, or attempted to purchase, re-  
19 ceive, or possess, a tobacco product in violation of sub-  
20 section (a) shall notify the individual’s parent or parents,  
21 custodian, or guardian as to the nature of the alleged vio-  
22 lation if the name and address of a parent or parents,  
23 guardian, or custodian is reasonably ascertainable by the  
24 law enforcement agency. The notice required by this sub-  
25 section shall be made not later than 48 hours after the  
26 individual who allegedly violated subsection (a) is cited by

1 such agency for the violation. The notice may be made  
2 by any means reasonably calculated to give prompt actual  
3 notice, including notice in person, by telephone, or by first-  
4 class mail.

5 ““(c) Subsection (a) does not prohibit an individual  
6 under 18 years of age or a different minimum age estab-  
7 lished under State law from possessing a tobacco product  
8 during regular working hours and in the course of such  
9 individual’s employment if the tobacco product is not pos-  
10 sessed for such individual’s consumption.

11 **“SEC. 3. OUT-OF-PACKAGE DISTRIBUTION.**

12 ““It shall be unlawful for any person to distribute  
13 cigarettes or a smokeless tobacco product other than in  
14 an unopened package that complies in full with section  
15 108 of the Federal Tobacco Act of 2007. A person who  
16 distributes a cigarette or a smokeless tobacco product in  
17 violation of this section is liable for a civil money penalty  
18 of not less than \$25 nor more than \$125 for each such  
19 violation.

20 **“SEC. 4. SIGNAGE.**

21 ““It shall be unlawful for any person who sells to-  
22 bacco products over-the-counter to fail to post conspicu-  
23 ously on the premises where such person sells tobacco  
24 products over-the-counter a sign communicating that—

1           “(1) the sale of tobacco products to individuals  
2           under 18 years of age or a different minimum age  
3           established under State law is prohibited by law;

4           “(2) the purchase of tobacco products by indi-  
5           viduals under 18 years of age or a different min-  
6           imum age established under State law is prohibited  
7           by law; and

8           “(3) proof of age may be demanded before to-  
9           bacco products are sold.

10          A person who fails to post a sign that complies fully with  
11          this section is liable for a civil money penalty of not less  
12          than \$25 nor more than \$125.

13          **“SEC. 5. NOTIFICATION OF EMPLOYEES.**

14          “(a) Within 180 days of the effective date of the  
15          Youth Prevention and Tobacco Harm Reduction Act,  
16          every person engaged in the business of selling tobacco  
17          products at retail shall implement a program to notify  
18          each employee employed by that person who sells tobacco  
19          products at retail that—

20                 “(1) the sale or other distribution of tobacco  
21                 products to any individual under 18 years of age or  
22                 a different minimum age established under State  
23                 law, and the purchase, receipt, or possession of to-  
24                 bacco products in a place open to the public by any  
25                 individual under 18 years of age or a different min-

1       imum age established under State law, is prohibited;  
2       and

3               “(2) out-of-package distribution of cigarettes  
4       and smokeless tobacco products is prohibited.

5 Any employer failing to provide the required notice to any  
6 employee shall be liable for a civil money penalty of not  
7 less than \$25 nor more than \$125 for each such violation.

8       “(b) It shall be a defense to a charge that an em-  
9 ployer violated subsection (a) of this section that the em-  
10 ployee acknowledged receipt, either in writing or by elec-  
11 tronic means, prior to the alleged violation, of a statement  
12 in substantially the following form:

13       “I understand that State law prohibits the distribu-  
14 tion of tobacco products to individuals under 18 years of  
15 age or a different minimum age established under State  
16 law and out-of-package distribution of cigarettes and  
17 smokeless tobacco products, and permits a defense based  
18 on evidence that a prospective purchaser’s proof of age  
19 was reasonably relied upon and appeared on its face to  
20 be valid. I understand that if I sell, give, or voluntarily  
21 provide a tobacco product to an individual under 18 years  
22 of age or a different minimum age established under State  
23 law, I may be found responsible for a civil money penalty  
24 of not less than \$25 nor more than \$125 for each viola-  
25 tion. I promise to comply with this law.’”

1       “(c) If an employer is charged with a violation of  
2 subsection (a) and the employer uses as a defense to such  
3 charge the defense provided by subsection (b), the em-  
4 ployer shall be deemed to be liable for such violation if  
5 such employer pays the penalty imposed on the employee  
6 involved in such violation or in any way reimburses the  
7 employee for such penalty.

8       **“SEC. 6. SELF-SERVICE DISPLAYS.**

9       “(a) It shall be unlawful for any person who sells  
10 tobacco products over-the-counter at retail to maintain  
11 packages of such products in any location accessible to  
12 customers that is not under the control of a cashier or  
13 other employee during regular business hours. This sub-  
14 section does not apply to any adult-only facility.

15       “(b) Any person who violates subsection (a) is liable  
16 for a civil money penalty of not less than \$25 nor more  
17 than \$125 for each such violation, except that no person  
18 shall be responsible for more than one violation per day  
19 at any one retail store.

20       **“SEC. 7. DISTRIBUTION BY MAIL OR COURIER.**

21       “(a) It shall be unlawful to distribute or sell tobacco  
22 products directly to consumers by mail or courier, unless  
23 the person receiving purchase requests for tobacco prod-  
24 ucts takes reasonable action to prevent delivery to individ-  
25 uals who are not adults by—



1       “(b) The State may engage an individual under 18  
2 years of age or a different minimum age established under  
3 State law to test compliance with this Act, except that  
4 such an individual may be used to test compliance with  
5 this Act only if the testing is conducted under the fol-  
6 lowing conditions:

7           “(1) Prior to use of any individual under 18  
8 years of age or a different minimum age established  
9 under State law in a random, unannounced inspec-  
10 tion, written consent shall be obtained from a par-  
11 ent, custodian, or guardian of such individual;

12           “(2) An individual under 18 years of age or a  
13 different minimum age established under State law  
14 shall act solely under the supervision and direction  
15 of the State Police or a local law enforcement au-  
16 thority duly designated by the State Police during a  
17 random, unannounced inspection;

18           “(3) An individual under 18 years of age or a  
19 different minimum age established under State law  
20 used in random, unannounced inspections shall not  
21 be used in any such inspection at a store in which  
22 such individual is a regular customer; and

23           “(4) If an individual under 18 years of age or  
24 a different minimum age established under State law  
25 participating in random, unannounced inspections is

1       questioned during such an inspection about such in-  
2       dividual's age, such individual shall state his or her  
3       actual age and shall present a true and correct proof  
4       of age if requested at any time during the inspection  
5       to present it.

6       “(c) Any person who uses any individual under 18  
7       years of age or a different minimum age established under  
8       State law, other than as permitted by subsection (b), to  
9       test compliance with this Act, is liable for a civil money  
10      penalty of not less than \$25 nor more than \$125 for each  
11      such violation.

12      “(d) Civil money penalties collected for violations of  
13      this Act and fees collected under section 9 shall be used  
14      only to defray the costs of administration and enforcement  
15      of this Act.

16      **“SEC. 9. LICENSURE.**

17      “(a) Each person engaged in the over-the-counter  
18      distribution at retail of tobacco products shall hold a li-  
19      cense issued under this section. A separate license shall  
20      be required for each place of business where tobacco prod-  
21      ucts are distributed at retail. A license issued under this  
22      section is not assignable and is valid only for the person  
23      in whose name it is issued and for the place of business  
24      designated in the license.

1       “(b) The annual license fee is \$25 for each place  
2 of business where tobacco products are distributed at re-  
3 tail.

4       “(c) Every application for a license, including re-  
5 newal of a license, under this section shall be made upon  
6 a form provided by the appropriate State agency or de-  
7 partment, and shall set forth the name under which the  
8 applicant transacts or intends to transact business, the lo-  
9 cation of the place of business for which the license is to  
10 be issued, the street address to which all notices relevant  
11 to the license are to be sent (in this Act referred to as  
12 “notice address”), and any other identifying information  
13 that the appropriate State agency or department may re-  
14 quire.

15       “(d) The appropriate State agency or department  
16 shall issue or renew a license or deny an application for  
17 a license or the renewal of a license within 30 days of  
18 receiving a properly completed application and the license  
19 fee. The appropriate State agency or department shall  
20 provide notice to an applicant of action on an application  
21 denying the issuance of a license or refusing to renew a  
22 license.

23       “(e) Every license issued by the appropriate State  
24 agency or department pursuant to this section shall be  
25 valid for 1 year from the date of issuance and shall be

1 renewed upon application except as otherwise provided in  
2 this Act.

3 ““(f) Upon notification of a change of address for a  
4 place of business for which a license has been issued, a  
5 license shall be reissued for the new address without the  
6 filing of a new application.

7 ““(g) The appropriate State agency or department  
8 shall notify every person in the State who is engaged in  
9 the distribution at retail of tobacco products of the license  
10 requirements of this section and of the date by which such  
11 person should have obtained a license.

12 ““(h)(1) Except as provided in paragraph (2), any  
13 person who engages in the distribution at retail of tobacco  
14 products without a license required by this section is liable  
15 for a civil money penalty in an amount equal to (i) two  
16 times the applicable license fee, and (ii) \$50 for each day  
17 that such distribution continues without a license.

18 ““(2) Any person who engages in the distribu-  
19 tion at retail of tobacco products after a license  
20 issued under this section has been suspended or re-  
21 voked is liable for a civil money penalty of \$100 per  
22 day for each day on which such distribution con-  
23 tinues after the date such person received notice of  
24 such suspension or revocation.



1 pend a license is initiated, the appropriate State agency  
2 or department shall immediately notify the licensee in  
3 writing at the notice address of the initiation of the action  
4 and the reasons therefor and permit the licensee an oppor-  
5 tunity, at least 30 days after written notice is served per-  
6 sonally or by registered mail upon the licensee, to show  
7 why suspension of the license would be unwarranted or  
8 unjust.

9 ““(c) The appropriate State agency or department  
10 may initiate an administrative action to revoke a license  
11 that previously has been suspended under subsection (b)  
12 if, after the suspension and during the one-year period for  
13 which the license was issued, the licensee committed a fur-  
14 ther violation of this Act, at the same place of business  
15 for which the license was issued. If an administrative ac-  
16 tion to revoke a license is initiated, the appropriate State  
17 agency or department shall immediately notify the licensee  
18 in writing at the notice address of the initiation of the  
19 action and the reasons therefor and permit the licensee  
20 an opportunity, at least 30 days after written notice is  
21 served personally or by registered mail upon the licensee,  
22 to show why revocation of the license would be unwar-  
23 ranted or unjust.

24 ““(d) A person whose license has been suspended or  
25 revoked with respect to a place of business pursuant to

1 this section shall pay a fee of \$50 for the renewal or  
2 reissuance of the license at that same place of business,  
3 in addition to any applicable annual license fees.

4 ““(e) Revocation of a license under subsection (c)  
5 with respect to a place of business shall not be grounds  
6 to deny an application by any person for a new license  
7 with respect to such place of business for more than 12  
8 months subsequent to the date of such revocation. Revoca-  
9 tion or suspension of a license with respect to a particular  
10 place of business shall not be grounds to deny an applica-  
11 tion for a new license, to refuse to renew a license, or to  
12 revoke or suspend an existing license at any other place  
13 of business.

14 ““(f) A licensee may seek judicial review of an action  
15 of the appropriate State agency or department sus-  
16 pending, revoking, denying, or refusing to renew a license  
17 under this section by filing a complaint in a court of com-  
18 petent jurisdiction. Any such complaint shall be filed with-  
19 in 30 days after the date on which notice of the action  
20 is received by the licensee. The court shall review the evi-  
21 dence de novo.

22 ““(g) The State shall not report any action sus-  
23 pending, revoking, denying, or refusing to renew a license  
24 under this section to the Federal Secretary of Health and  
25 Human Services, unless the opportunity for judicial review

1 of the action pursuant to subsection (f), if any, has been  
2 exhausted or the time for seeking such judicial review has  
3 expired.

4 **“SEC. 11. NO PRIVATE RIGHT OF ACTION.**

5 “‘Nothing in this Act shall be construed to create  
6 a right of action by any private person for any violation  
7 of any provision of this Act.

8 **“SEC. 12. JURISDICTION AND VENUE.**

9 “‘Any action alleging a violation of this Act may be  
10 brought only in a court of general jurisdiction in the city  
11 or county where the violation is alleged to have occurred.

12 **“SEC. 13. REPORT.**

13 “‘The appropriate State agency or department shall  
14 prepare for submission annually to the Federal Secretary  
15 of Health and Human Services the report required by sec-  
16 tion 1926 of the Federal Public Health Service Act (42  
17 U.S.C. 300x-26).’”.

18 “(2) In the case of a State whose legislature  
19 does not convene a regular session in fiscal year  
20 2007, and in the case of a State whose legislature  
21 does not convene a regular session in fiscal year  
22 2008, the requirement described in subsection (e)(1)  
23 as a condition of a receipt of a grant under section  
24 300x-21 of this title shall apply only for fiscal year  
25 2009 and subsequent fiscal years.

1           “(3) Subsection (e)(1) shall not affect any  
2           State or local law that (A) was in effect on the date  
3           of introduction of the Federal Tobacco Act of 2007,  
4           and (B) covers the same subject matter as the law  
5           described in subsection (e)(1). Any State law that  
6           meets the conditions of this paragraph shall also be  
7           deemed to meet the requirement described in sub-  
8           section (e)(1) as a condition of a receipt of a grant  
9           under section 300x-21 of this title, if such State law  
10          is at least as stringent as the law described in sub-  
11          section (e)(1).

12          “(f)(1) For the first applicable fiscal year and for  
13          each subsequent fiscal year, a funding agreement for a  
14          grant under section 300x-21 of this title is a funding  
15          agreement under which the State involved will enforce the  
16          law described in subsection (e)(1) of this section in a man-  
17          ner that can reasonably be expected to reduce the extent  
18          to which tobacco products are available to individuals  
19          under the age of 18 or a different minimum age estab-  
20          lished under State law for the purchase of tobacco prod-  
21          ucts.

22          “(2) For the first applicable fiscal year and for each  
23          subsequent fiscal year, a funding agreement for a grant  
24          under section 300x-21 of this title is a funding agreement  
25          under which the State involved will—

1           “(A) conduct random, unannounced inspections  
2           to ensure compliance with the law described in sub-  
3           section (e)(1); and

4           “(B) annually submit to the Secretary a report  
5           describing—

6                   “(i) the activities carried out by the State  
7                   to enforce such law during the fiscal year pre-  
8                   ceding the fiscal year for which the State is  
9                   seeking the grant;

10                   “(ii) the extent of success the State has  
11                   achieved in reducing the availability of tobacco  
12                   products to individuals under 18 years of age or  
13                   a different minimum age established under  
14                   State law, including the results of the inspec-  
15                   tions conducted under subparagraph (A); and

16                   “(iii) the strategies to be utilized by the  
17                   State for enforcing such law during the fiscal  
18                   year for which the grant is sought.

19           “(g) The law specified in subsection (e)(1) may be  
20           administered and enforced by a State using—

21                   “(1) any amounts made available to the State  
22                   through a grant under section 300x-21 of this title;

23                   “(2) any amounts made available to the State  
24                   under section 300w of this title;

1           “(3) any fees collected for licenses issued pursu-  
2           ant to the law described in subsection (e)(1);

3           “(4) any fines or penalties assessed for viola-  
4           tions of the law specified in subsection (e)(1); or

5           “(5) any other funding source that the legisla-  
6           ture of the State may prescribe by statute.

7           “(h) Before making a grant under section 300x-21  
8           of this title to a State for the first applicable fiscal year  
9           or any subsequent fiscal year, the Secretary shall make  
10          a determination of whether the State has maintained com-  
11          pliance with subsections (e) and (f) of this section. If, after  
12          notice to the State and an opportunity for a hearing, the  
13          Secretary determines that the State is not in compliance  
14          with such subsections, the Secretary shall reduce the  
15          amount of the allotment under section 300x-21 of this title  
16          for the State for the fiscal year involved by an amount  
17          equal to—

18               “(1) In the case of the first applicable fiscal  
19               year, 10 percent of the amount determined under  
20               section 300x-33 for the State for the fiscal year;

21               “(2) In the case of the first fiscal year following  
22               such applicable fiscal year, 20 percent of the amount  
23               determined under section 300x-33 for the State for  
24               the fiscal year;

1           “(3) In the case of the second such fiscal year,  
2           30 percent of the amount determined under section  
3           300x-33 for the State for the fiscal year; and

4           “(4) In the case of the third such fiscal year or  
5           any subsequent fiscal year, 40 percent of the amount  
6           determined under section 300x-33 for the State for  
7           the fiscal year.

8           The Secretary shall not have authority or discretion to  
9           grant to any State a waiver of the terms and requirements  
10          of this subsection or subsection (e) or (f).

11          “(i) For the purposes of subsections (e) through (h)  
12          of this section the term ‘first applicable fiscal year’  
13          means—

14                 “(1) fiscal year 2009, in the case of any State  
15                 described in subsection (e)(2) of this section; and

16                 “(2) fiscal year 2008, in the case of any other  
17                 State.

18          “(j) For purposes of subsections (e) through (h) of  
19          this section, references to section 300x-21 shall include  
20          any successor grant programs.’

21          “(k) As required by paragraph (1), and subject to  
22          paragraph (4), an Indian tribe shall satisfy the require-  
23          ments of subsection (e)(1) of this section by enacting a  
24          law or ordinance with substantially the same provisions  
25          as the law described in subsection (e)(1).

1           “(1) An Indian tribe shall comply with sub-  
2           section (e)(1) of this section within 180 days after  
3           the Administrator finds, in accordance with this  
4           paragraph, that—

5                   “(A) the Indian tribe has a governing body  
6                   carrying out substantial governmental powers  
7                   and duties;

8                   “(B) the functions to be exercised by the  
9                   Indian tribe under this Act pertain to activities  
10                  on trust land within the jurisdiction of the  
11                  tribe; and

12                  “(C) the Indian tribe is reasonably ex-  
13                  pected to be capable of carrying out the func-  
14                  tions required under this section.

15           Within 2 years of the date of enactment of the Fed-  
16           eral Tobacco Act of 2007, as to each Indian tribe in  
17           the United States, the Administrator shall make the  
18           findings contemplated by this paragraph or deter-  
19           mine that such findings cannot be made, in accord-  
20           ance with the procedures specified in paragraph (4).

21           “(2) As to Indian tribes subject to subsection  
22           (e)(1) of this section, the Administrator shall pro-  
23           mulgate regulations that—

24                   “(A) provide whether and to what extent,  
25                   if any, the law described in subsection (e)(1)

1           may be modified as adopted by Indian tribes;  
2           and

3                   “(B) ensure, to the extent possible, that  
4           each Indian tribe’s retailer licensing program  
5           under subsection (e)(1) is no less stringent than  
6           the program of the State or States in which the  
7           Indian tribe is located.

8                   “(3) If with respect to any Indian tribe the Ad-  
9           ministrator determines that compliance with the re-  
10          quirements of subsection (e)(1) is inappropriate or  
11          administratively infeasible, the Administrator shall  
12          specify other means for the Indian tribe to achieve  
13          the purposes of the law described in subsection  
14          (e)(1) with respect to persons who engage in the dis-  
15          tribution at retail of tobacco products on tribal  
16          lands.

17                   “(4) The findings and regulations promulgated  
18          under paragraphs (1) and (2) shall be promulgated  
19          in conformance with section 553 of title 5, United  
20          States Code, and shall comply with the following  
21          provisions:

22                           “(A) In making findings as provided in  
23          paragraph (1), and in drafting and promul-  
24          gating regulations as provided in paragraph (2)  
25          (including drafting and promulgating any re-

1           vised regulations), the Administrator shall con-  
2           fer with, and allow for active participation by,  
3           representatives and members of Indian tribes,  
4           and tribal organizations.

5           “(B) In carrying out rulemaking processes  
6           under this subsection, the Administrator shall  
7           follow the guidance of subchapter III of chapter  
8           5 of title 5, United States Code, commonly  
9           known as the ‘Negotiated Rulemaking Act of  
10          1990.’

11          “(C) The tribal participants in the negotia-  
12          tion process referred to in subparagraph (B)  
13          shall be nominated by and shall represent the  
14          groups described in this subsection and shall in-  
15          clude tribal representatives from all geographic  
16          regions.

17          “(D) The negotiations conducted under  
18          this paragraph (4) shall be conducted in a time-  
19          ly manner.

20          “(E) If the Administrator determines that  
21          an extension of the deadlines under subsection  
22          (k)(1) of this section is appropriate, the Sec-  
23          retary may submit proposed legislation to Con-  
24          gress for the extension of such deadlines.

1           “(5) This subsection shall not affect any law or  
2 ordinance that (A) was in effect on tribal lands on  
3 the date of introduction of the Youth Prevention and  
4 Tobacco Harm Reduction Act, and (B) covers the  
5 same subject matter as the law described in sub-  
6 section (e)(1). Any law or ordinance that meets the  
7 conditions of this paragraph shall also be deemed to  
8 meet the requirement described in subsection (k)(1),  
9 if such law or ordinance is at least as stringent as  
10 the law described in subsection (e)(1).

11           “(6) For purposes of this subsection—

12           “(A) ‘Administrator’ means the Adminis-  
13 trator of the Tobacco Harm Reduction Center.

14           “(B) ‘Indian tribe’ has the meaning as-  
15 signed that term in section 4(e) of the Indian  
16 Self Determination and Education Assistance  
17 Act, section 450b(e) of title 25, United States  
18 Code.

19           “(C) ‘Tribal lands’ means all lands within  
20 the exterior boundaries of any Indian reserva-  
21 tion, all lands the title to which is held by the  
22 United States in trust for an Indian tribe, or  
23 lands the title to which is held by an Indian  
24 tribe subject to a restriction by the United

1 States against alienation, and all dependent In-  
2 dian communities.

3 “(D) ‘tribal organization’ has the meaning  
4 assigned that term in section 4(l) of the Indian  
5 Self Determination and Education Assistance  
6 Act, section 450b(l) of title 25, United States  
7 Code.”.

8 **SEC. 403. ESTABLISHMENT OF RANKINGS.**

9 (a) STANDARDS AND PROCEDURES FOR  
10 RANKINGS.—Within 24 months after the effective date of  
11 this Act, the Administrator shall, by regulation, after con-  
12 sultation with an Advisory Committee established for such  
13 purpose, establish the standards and procedures for pro-  
14 mulgating rankings, comprehensible to consumers of to-  
15 bacco products, of the following categories of tobacco  
16 products and also nicotine-containing products on the  
17 basis of the relative risks of serious or chronic tobacco-  
18 related diseases and adverse health conditions those cat-  
19 egories of tobacco products and also nicotine-containing  
20 products respectively present

21 (1) cigarettes;

22 (2) loose tobacco for roll-your-own tobacco  
23 products;

24 (3) little cigars;

25 (4) cigars;

- 1 (5) pipe tobacco;
- 2 (6) moist snuff;
- 3 (7) dry snuff;
- 4 (8) chewing tobacco;
- 5 (9) other forms of tobacco products, including
- 6 pelletized tobacco and compressed tobacco, treated
- 7 collectively as a single category; and
- 8 (10) other nicotine-contain products, treated
- 9 collectively as a single category.

10 The Administrator shall not have authority or discretion  
11 to establish a relative-risk ranking of any category or sub-  
12 category of tobacco products or any category or sub-  
13 category of nicotine-containing products other than the  
14 ten categories specified in this subsection.

15 (b) CONSIDERATIONS IN PROMULGATING REGULA-  
16 TIONS.—In promulgating regulations under this section,  
17 the Administrator

18 (1) shall take into account relevant epidemio-  
19 logic studies and other relevant competent and reli-  
20 able scientific evidence; and

21 (2) in assessing the risks of serious or chronic  
22 tobacco-related diseases and adverse health condi-  
23 tions presented by a particular category, shall con-  
24 sider the range of tobacco products or nicotine-con-  
25 taining products within the category, and shall give

1 appropriate weight to the market shares of the re-  
2 spective products in the category.

3 (c) PROMULGATION OF RANKINGS OF CAT-  
4 EGORIES.—Once the initial regulations required by sub-  
5 section (a) are in effect, the Administrator shall promptly,  
6 by order, after notice and an opportunity for comment,  
7 promulgate to the general public rankings of the cat-  
8 egories of tobacco products and nicotine-containing prod-  
9 ucts in accordance with those regulations. The Adminis-  
10 trator shall promulgate the initial rankings of those cat-  
11 egories of tobacco products and nicotine-containing prod-  
12 ucts to the general public not later than January 1, 2010.  
13 Thereafter, on an annual basis, the Administrator shall,  
14 by order, promulgate to the general public updated  
15 rankings that are (1) in accordance with those regulations,  
16 and (2) reflect the scientific evidence available at the time  
17 of promulgation. The Administrator shall open and main-  
18 tain an ongoing public docket for receipt of data and other  
19 information submitted by any person with respect to such  
20 annual promulgation of rankings.

21 **TITLE V—ENFORCEMENT**  
22 **PROVISIONS**

23 **SEC. 501. PROHIBITED ACTS.**

24 The following acts and the causing thereof are hereby  
25 prohibited—

1           (1) the introduction or delivery for introduction  
2           into interstate commerce of any tobacco product that  
3           is adulterated or misbranded;

4           (2) the adulteration or misbranding of any to-  
5           bacco product in interstate commerce;

6           (3) the receipt in interstate commerce of any  
7           tobacco product that is known to be adulterated or  
8           misbranded, and the delivery or proffered delivery  
9           thereof for pay or otherwise;

10          (4) the failure to establish or maintain any  
11          record, or make any report or other submission, or  
12          to provide any notice required by or under this Act;  
13          or the refusal to permit access to, verification of, or  
14          copying of any record as required by this Act;

15          (5) the refusal to permit entry or inspection as  
16          authorized by this Act;

17          (6) the making to the Administrator of a state-  
18          ment, report, certification or other submission re-  
19          quired by this Act, with knowledge that such state-  
20          ment, report, certification, or other submission is  
21          false in a material aspect;

22          (7) the manufacturing, shipping, receiving, stor-  
23          ing, selling, distributing, possession, or use of any  
24          tobacco product with knowledge that it is an illicit  
25          tobacco product;

1           (8) the forging, simulating without proper per-  
2           mission, falsely representing, or without proper au-  
3           thority using any brand name;

4           (9) the using by any person to his or her own  
5           advantage, or revealing, other than to the Adminis-  
6           trator or officers or employees of the Agency, or to  
7           the courts when relevant in any judicial proceeding  
8           under this Act, any information acquired under au-  
9           thority of this Act concerning any item which as a  
10          trade secret is entitled to protection; except that the  
11          foregoing does not authorize the withholding of in-  
12          formation from either House of Congress or from, to  
13          the extent of matter within its jurisdiction, any com-  
14          mittee or subcommittee of such committee or any  
15          joint committee of Congress or any subcommittee of  
16          such joint committee;

17          (10) the alteration, mutilation, destruction, ob-  
18          literation, or removal of the whole or any part of the  
19          labeling of, or the doing of any other act with re-  
20          spect to, a tobacco product, if such act is done while  
21          such tobacco product is held for sale (whether or not  
22          the first sale) after shipment in interstate commerce,  
23          and results in such tobacco product being adulter-  
24          ated or misbranded;.

1 (11) the importation of any tobacco product  
2 that is adulterated, misbranded, or otherwise not in  
3 compliance with this Act; and

4 (12) the commission of any act prohibited by  
5 section 201 of this Act

6 **SEC. 502. INJUNCTION PROCEEDINGS.**

7 (a) The district courts of the United States shall have  
8 jurisdiction, for cause shown, to restrain violations of this  
9 Act, except for violations of section 701(k).

10 (b) In case of an alleged violation of an injunction  
11 or restraining order issued under this section, which also  
12 constitutes a violation of this Act, trial shall be by the  
13 court, or upon demand of the defendant, by a jury.

14 **SEC. 503. PENALTIES.**

15 (a) CRIMINAL PENALTIES.—Any person who willfully  
16 violates a provision of section 501 of this Act shall be im-  
17 prisoned for not more than one year or fined not more  
18 than \$25,000, or both.

19 (b) CIVIL PENALTIES FOR VIOLATION OF SECTION  
20 803.—

21 (1) Any person who knowingly distributes or  
22 sells, other than through retail sale or retail offer for  
23 sale, any cigarette brand style in violation of section  
24 803(a)—

1 (A) for a first offense shall be liable for a  
2 civil penalty not to exceed \$10,000 for each dis-  
3 tribution or sale, or

4 (B) for a second offense shall be liable for  
5 a civil penalty not to exceed \$25,000 for each  
6 distribution or sale,

7 except that the penalty imposed against any person  
8 with respect to violations during any 30-day period  
9 shall not exceed \$100,000.

10 (2) Any retailer who knowingly distributes, sells  
11 or offers for sale any cigarette brand style in viola-  
12 tion of section 803(a) shall—

13 (A) for a first offense for each sale or offer  
14 for sale of cigarettes, if the total number of  
15 packages of cigarettes sold or offered for sale—

16 (i) does not exceed 50 packages of  
17 cigarettes, be liable for a civil penalty not  
18 to exceed \$500 for each sale or offer for  
19 sale,

20 (ii) exceeds 50 packages of cigarettes,  
21 be liable for a civil penalty not to exceed  
22 \$1,000 for each sale or offer for sale;

23 (B) for each subsequent offense for each  
24 sale or offer for sale of cigarettes, if the total  
25 number of cigarettes sold or offered for sale—

1 (i) does not exceed 50 packages of  
2 cigarettes, be liable for a civil penalty not  
3 to exceed \$2,000 for each sale or offer for  
4 sale, and

5 (ii) exceeds 50 packages of cigarettes,  
6 be liable for a civil penalty not to exceed  
7 \$5,000 for each sale or offer for sale;  
8 except that the penalty imposed against any  
9 person during any 30-day period shall not ex-  
10 ceed \$25,000.

11 **SEC. 504. SEIZURE.**

12 (a) ARTICLES SUBJECT TO SEIZURE.—

13 (1) Any tobacco product that is adulterated or  
14 misbranded when introduced into or while in inter-  
15 state commerce or while held for sale (whether or  
16 not the first sale) after shipment in interstate com-  
17 merce, or which may not, under the provisions of  
18 this Act, be introduced into interstate commerce,  
19 shall be liable to be proceeded against while in inter-  
20 state commerce, or at any time thereafter, on libel  
21 of information and condemned in any district court  
22 of the United States within the jurisdiction of which  
23 the tobacco product is found. No libel for condemna-  
24 tion shall be instituted under this Act for any al-  
25 leged misbranding if there is pending in any court

1 a libel for condemnation proceeding under this Act  
2 based upon the same alleged misbranding, and not  
3 more than one such proceeding shall be instituted if  
4 no such proceeding is so pending, except that such  
5 limitations shall not apply—

6 (A) when such misbranding has been the  
7 basis of a prior judgment in favor of the United  
8 States, in a criminal, injunction, or libel for  
9 condemnation proceeding under this Act, or

10 (B) when the Administrator has probable  
11 cause to believe from facts found, without hear-  
12 ing, by the Administrator or any officer or em-  
13 ployee of the Agency that the misbranded to-  
14 bacco product is dangerous to health beyond  
15 the inherent danger to health posed by tobacco,  
16 or that the labeling of the misbranded tobacco  
17 product is fraudulent, or would be in a material  
18 respect misleading to the injury or damage of  
19 the purchaser or consumer. In any case where  
20 the number of libel for condemnation pro-  
21 ceedings is limited as above provided, the pro-  
22 ceeding pending or instituted shall, on applica-  
23 tion of the claimant, seasonably made, be re-  
24 moved for trial to any district agreed upon by  
25 stipulation between the parties, or, in case of

1 failure to so stipulate within a reasonable time,  
2 the claimant may apply to the court of the dis-  
3 trict in which the seizure has been made, and  
4 such court (after giving the United States at-  
5 torney for such district reasonable notice and  
6 opportunity to be heard) shall by order, unless  
7 good cause to the contrary is shown, specify a  
8 district of reasonable proximity to the claim-  
9 ant's principal place of business, to which the  
10 case shall be removed for trial.

11 (2) The following shall be liable to be proceeded  
12 against at any time on libel of information and con-  
13 demned in any district court of the United States  
14 within the jurisdiction of which they are found—

15 (A) any tobacco product that is an illicit  
16 tobacco product;

17 (B) any container of an illicit tobacco  
18 product;

19 (C) any equipment or thing used in mak-  
20 ing an illicit tobacco product; and

21 (D) any adulterated or misbranded tobacco  
22 product.

23 (3)(A) Except as provided in subparagraph (B),  
24 no libel for condemnation may be instituted under

1 paragraph (1) or (2) against any tobacco product  
2 which—

3 (i) is misbranded under this Act be-  
4 cause of its advertising, and

5 (ii) is being held for sale to the ulti-  
6 mate consumer in an establishment other  
7 than an establishment owned or operated  
8 by a manufacturer, packer, or distributor  
9 of the tobacco product.

10 (B) A libel for condemnation may be insti-  
11 tuted under paragraph (1) or (2) against a to-  
12 bacco product described in subparagraph (A) if  
13 the tobacco product's advertising which resulted  
14 in the tobacco product being misbranded was  
15 disseminated in the establishment in which the  
16 tobacco product is being held for sale to the ul-  
17 timate consumer,—

18 (i) such advertising was disseminated  
19 by, or under the direction of, the owner or  
20 operator of such establishment, or

21 (ii) all or part of the cost of such ad-  
22 vertising was paid by such owner or oper-  
23 ator.

24 (b) PROCEDURES.—The tobacco product, equipment,  
25 or other thing proceeded against shall be liable to seizure

1 by process pursuant to the libel, and the procedure in  
2 cases under this section shall conform, as nearly as may  
3 be, to the procedure in admiralty; except that on demand  
4 of either party any issue of fact joined in any such case  
5 shall be tried by jury. When libel for condemnation pro-  
6 ceedings under this section, involving the same claimant  
7 and the same issues of adulteration or misbranding, are  
8 pending in two or more jurisdictions, such pending pro-  
9 ceedings, upon application of the claimant seasonably  
10 made to the court of one such jurisdiction, shall be consoli-  
11 dated for trial by order of such court, and tried in (1)  
12 any district selected by the claimant where one of such  
13 proceedings is pending; or (2) a district agreed upon by  
14 stipulation between the parties. If no order for consolida-  
15 tion is so made within a reasonable time, the claimant may  
16 apply to the court of one such jurisdiction and such court  
17 (after giving the United States attorney for such district  
18 reasonable notice and opportunity to be heard) shall by  
19 order, unless good cause to the contrary is shown, specify  
20 a district of reasonable proximity to the claimant's prin-  
21 cipal place of business, in which all such pending pro-  
22 ceedings shall be consolidated for trial and tried. Such  
23 order of consolidation shall not apply so as to require the  
24 removal of any case the date for trial of which has been  
25 fixed. The court granting such order shall give prompt no-

1 tification thereof to the other courts having jurisdiction  
2 of the cases covered thereby.

3 (c) SAMPLES AND ANALYSES.—The court at any time  
4 after seizure up to a reasonable time before trial shall by  
5 order allow any party to a condemnation proceeding, the  
6 party's attorney or agent, to obtain a representative sam-  
7 ple of the article seized and a true copy of the analysis,  
8 if any, on which the proceeding is based and the identi-  
9 fying marks or numbers, if any, of the packages from  
10 which the samples analyzed were obtained.

11 (d) DISPOSITION OF CONDEMNED TOBACCO PROD-  
12 UCTS.—(1) Any tobacco product condemned under this  
13 section shall, after entry of the decree, be disposed of by  
14 destruction or sale as the court may, in accordance with  
15 the provisions of this section, direct; and the proceeds  
16 thereof, if sold, less the legal costs and charges, shall be  
17 paid into the Treasury of the United States; but such to-  
18 bacco product shall not be sold under such decree contrary  
19 to the provisions of this Act or the laws of the jurisdiction  
20 in which sold. After entry of the decree and upon the pay-  
21 ment of the costs of such proceedings and the execution  
22 of a good and sufficient bond conditioned that such article  
23 shall not be sold or disposed of contrary to the provisions  
24 of this Act or the laws of any State in which sold, the  
25 court may by order direct that such tobacco product be

1 delivered to the owner thereof to be destroyed or brought  
2 into compliance with the provisions of this Act, under the  
3 supervision of an officer or employee duly designated by  
4 the Administrator; and the expenses of such supervision  
5 shall be paid by the person obtaining release of the tobacco  
6 product under bond. If the tobacco product was imported  
7 into the United States and the person seeking its release  
8 establishes (A) that the adulteration, misbranding, or vio-  
9 lation did not occur after the tobacco product was im-  
10 ported, and (B) that the person seeking the release of the  
11 tobacco product had no cause for believing that it was  
12 adulterated, misbranded, or in violation before it was re-  
13 leased from customs custody, the court may permit the  
14 tobacco product to be delivered to the owner for expor-  
15 tation under section 709 in lieu of destruction upon a  
16 showing by the owner that there is a reasonable certainty  
17 that the tobacco product will not be re-imported into the  
18 United States.

19 (2) The provisions of paragraph (1) of this subsection  
20 shall, to the extent deemed appropriate by the court, apply  
21 to any equipment or other thing which is not otherwise  
22 within the scope of such paragraph and which is referred  
23 to in paragraph (2) of subsection (a).

24 (3) Whenever in any proceeding under this section,  
25 involving paragraph (2) of subsection (a), the condemna-

1 tion of any equipment or thing (other than a tobacco prod-  
2 uct) is decreed, the court shall allow the claim of any  
3 claimant, to the extent of such claimant's interest, for re-  
4 mission or mitigation of such forfeiture if such claimant  
5 proves to the satisfaction of the court (A) that such claim-  
6 ant has not caused the equipment or thing to be within  
7 one of the categories referred to in such paragraph (2)  
8 and has no interest in any tobacco product referred to  
9 therein, (B) that such claimant has an interest in such  
10 equipment or other thing as owner or lienor or otherwise,  
11 acquired by such claimant in good faith, and (C) that such  
12 claimant at no time had any knowledge or reason to be-  
13 lieve that such equipment or other thing was being or  
14 would be used in, or to facilitate, the violation of laws of  
15 the United States relating to any illicit tobacco product.

16 (e) COSTS AND FEES.—When a decree of condemna-  
17 tion is entered against the tobacco product or other article,  
18 court costs and fees, and storage and other proper ex-  
19 penses shall be awarded against the person, if any, inter-  
20 vening as claimant of the tobacco product or other article.

21 (f) REMOVAL FOR TRIAL.—In the case of removal for  
22 trial of any case as provided by subsection (a) or (b)—

23 (1) The clerk of the court from which removal  
24 is made shall promptly transmit to the court in  
25 which the case is to be tried all records in the case

1       necessary in order that such court may exercise ju-  
2       risdiction.

3           (2) The court to which such case was removed  
4       shall have the powers and be subject to the duties,  
5       for purposes of such case, which the court from  
6       which removal was made would have had, or to  
7       which such court would have been subject, if such  
8       case had not been removed.

9       (g) ADMINISTRATIVE DETENTION OF TOBACCO  
10     PRODUCTS.—

11           (1) DETENTION AUTHORITY.—

12           (A) IN GENERAL.—An officer or qualified  
13       employee of the Agency may order the deten-  
14       tion, in accordance with this subsection, of any  
15       tobacco product that is found during an inspec-  
16       tion, examination, or investigation under this  
17       Act conducted by such officer or qualified em-  
18       ployee, if the officer or qualified employee has  
19       credible evidence or information indicating that  
20       such article presents a threat of serious adverse  
21       health consequences beyond those normally in-  
22       herent in the use of tobacco products.

23           (B) ADMINISTRATOR'S APPROVAL.—A to-  
24       bacco product or component thereof may be or-  
25       dered detained under subparagraph (A) if, but

1           only if, the Administrator or an official des-  
2           ignated by the Administrator approves the  
3           order. An official may not be so designated un-  
4           less the official is an officer with supervisory re-  
5           sponsibility for the inspection, examination, or  
6           investigation that led to the order.

7           (2) PERIOD OF DETENTION.—A tobacco prod-  
8           uct may be detained under paragraph (1) for a rea-  
9           sonable period, not to exceed 20 days, unless a  
10          greater period, not to exceed 30 days, is necessary,  
11          to institute an action under subsection (a) or section  
12          702

13          (3) SECURITY OF DETAINED TOBACCO PROD-  
14          UCT.—An order under paragraph (1) may require  
15          that the tobacco product to be detained be labeled  
16          or marked as detained, and shall require that the to-  
17          bacco product be maintained in or removed to a se-  
18          cure facility, as appropriate. A tobacco product sub-  
19          ject to such an order shall not be transferred by any  
20          person from the place at which the tobacco product  
21          is ordered detained, or from the place to which the  
22          tobacco product is so removed, as the case may be,  
23          until released by the Administrator or until the expi-  
24          ration of the detention period applicable under such  
25          order, whichever occurs first. This subsection may

1 not be construed as authorizing the delivery of the  
2 tobacco product pursuant to the execution of a bond  
3 while the tobacco product is subject to the order,  
4 and section 709 does not authorize the delivery of  
5 the tobacco product pursuant to the execution of a  
6 bond while the article is subject to the order.

7 (4) APPEAL OF DETENTION ORDER.—

8 (A) IN GENERAL.—With respect to a to-  
9 bacco product ordered detained under para-  
10 graph (1), any person who would be entitled to  
11 be a claimant of such tobacco product if the to-  
12 bacco product were seized under subsection (a)  
13 may appeal the order to the Administrator.  
14 Within five days after such an appeal is filed,  
15 the Administrator, after providing opportunity  
16 for an informal hearing, shall confirm or termi-  
17 nate the order involved, and such confirmation  
18 by the Administrator shall be considered a final  
19 agency action for purposes of section 702 of  
20 title 5, United States Code. If during such five-  
21 day period the Administrator fails to provide  
22 such an opportunity, or to confirm or terminate  
23 such order, the order is deemed to be termi-  
24 nated.

1                   (B) EFFECT OF INSTITUTING COURT AC-  
2                   TION.—The process under subparagraph (A)  
3                   for the appeal of an order under paragraph (1)  
4                   terminates if the Administrator institutes an  
5                   action under subsection (a) or section 702 re-  
6                   garding the tobacco product involved.

7   **SEC. 505. REPORT OF MINOR VIOLATIONS.**

8           Nothing in this Act shall be construed as requiring  
9           the Administrator to report for prosecution, or for institu-  
10          tion of libel or injunction proceedings, minor violations of  
11          this Act whenever the Administrator believes that the pub-  
12          lic interest will be adequately served by a suitable written  
13          notice or warning.

14   **SEC. 506. INSPECTION.**

15          (a) AUTHORITY TO INSPECT.—The Administrator  
16          shall have the power to inspect the premises of a tobacco  
17          product manufacturer for purposes of determining compli-  
18          ance with this Act, or the regulations promulgated under  
19          it. Officers of the Agency designated by the Administrator,  
20          upon presenting appropriate credentials and a written no-  
21          tice to the person in charge of the premises, are authorized  
22          to enter, at reasonable times, without a search warrant,  
23          any factory, warehouse, or other establishment in which  
24          tobacco products are manufactured, processed, packaged,  
25          or held for domestic distribution. Any such inspection shall

1 be conducted within reasonable limits and in a reasonable  
2 manner, and shall be limited to examining only those  
3 things, including but not limited to records, relevant to  
4 determining whether violations of this Act, or regulations  
5 under it, have occurred. No inspection authorized by this  
6 section shall extend to financial data, sales data other than  
7 shipment data, pricing data, personnel data (other than  
8 data as to qualifications of technical and professional per-  
9 sonnel performing functions subject to this Act), or re-  
10 search data. A separate notice shall be given for each such  
11 inspection, but a notice shall not be required for each  
12 entry made during the period covered by the inspection.  
13 Each such inspection shall be commenced and completed  
14 with reasonable promptness.

15 (b) REPORT OF OBSERVATIONS.—Before leaving the  
16 premises, the officer of the Agency who has supervised or  
17 conducted the inspection shall give to the person in charge  
18 of the premises a report in writing setting forth any condi-  
19 tions or practices that appear to manifest a violation of  
20 this Act, or the regulations under it.

21 (c) SAMPLES.—If the officer has obtained any sample  
22 in the course of inspection, prior to leaving the premises  
23 that officer shall give to the person in charge of the prem-  
24 ises a receipt describing the samples obtained. As to each  
25 sample obtained, the officer shall furnish promptly to the

1 person in charge of the premises a copy of the sample and  
2 of any analysis made upon the sample.

3 **SEC. 507. EFFECT OF COMPLIANCE.**

4 Compliance with the provisions of this Act and the  
5 regulations promulgated under it shall constitute a com-  
6 plete defense to any civil action, including but not limited  
7 to any products liability action, that seeks to recover dam-  
8 ages, whether compensatory or punitive, based upon an  
9 alleged defect in the labeling or advertising of any tobacco  
10 product distributed for sale domestically.

11 **SEC. 508. IMPORTS.**

12 (a) IMPORTS; LIST OF REGISTERED FOREIGN ES-  
13 TABLISHMENTS; SAMPLES FROM UNREGISTERED FOR-  
14 EIGN ESTABLISHMENTS; EXAMINATION AND REFUSAL OF  
15 ADMISSION.—The Secretary of Homeland Security shall  
16 deliver to the Administrator, upon request by the Adminis-  
17 trator, samples of tobacco products that are being im-  
18 ported or offered for import into the United States, giving  
19 notice thereof to the owner or consignee, who may appear  
20 before the Administrator and have the right to introduce  
21 testimony. The Administrator shall furnish to the Sec-  
22 retary of Homeland Security a list of establishments reg-  
23 istered pursuant to subsection (d) of section 109 of this  
24 Act, and shall request that, if any tobacco products manu-  
25 factured, prepared, or processed in an establishment not

1 so registered are imported or offered for import into the  
2 United States, samples of such tobacco products be deliv-  
3 ered to the Administrator, with notice of such delivery to  
4 the owner or consignee, who may appear before the Ad-  
5 ministrator and have the right to introduce testimony. If  
6 it appears from the examination of such samples or other-  
7 wise that (1) such tobacco product is forbidden or re-  
8 stricted in sale in the country in which it was produced  
9 or from which it was exported, or (2) such tobacco product  
10 is adulterated, misbranded, or otherwise in violation of  
11 this Act, then such tobacco product shall be refused ad-  
12 mission, except as provided in subsection (b) of this sec-  
13 tion. The Secretary of Homeland Security shall cause the  
14 destruction of any such tobacco product refused admission  
15 unless such tobacco product is exported, under regulations  
16 prescribed by the Secretary of Homeland Security, within  
17 ninety days of the date of notice of such refusal or within  
18 such additional time as may be permitted pursuant to such  
19 regulations.

20 (b) DISPOSITION OF REFUSED TOBACCO PROD-  
21 UCTS.—Pending decision as to the admission of a tobacco  
22 product being imported or offered for import, the Sec-  
23 retary of Homeland Security may authorize delivery of  
24 such tobacco product to the owner or consignee upon the  
25 execution by such consignee of a good and sufficient bond

1 providing for the payment of such liquidated damages in  
2 the event of default as may be required pursuant to regu-  
3 lations of the Secretary of Homeland Security. If it ap-  
4 pears to the Administrator that a tobacco product in-  
5 cluded within the provisions of clause (3) of subsection  
6 (a) of this section can, by relabeling or other action, be  
7 brought into compliance with this Act or rendered other  
8 than a tobacco product, final determination as to admis-  
9 sion of such tobacco product may be deferred and, upon  
10 filing of timely written application by the owner or con-  
11 signee and the execution by such consignee of a bond as  
12 provided in the preceding provisions of this subsection, the  
13 Administrator may, in accordance with regulations, au-  
14 thorize the applicant to perform such relabeling or other  
15 action specified in such authorization (including destruc-  
16 tion or export of rejected tobacco products or portions  
17 thereof, as may be specified in the Administrator's author-  
18 ization). All such relabeling or other action pursuant to  
19 such authorization shall in accordance with regulations be  
20 under the supervision of an officer or employee of the  
21 Agency designated by the Administrator, or an officer or  
22 employee of the Department of Homeland Security des-  
23 igned by the Secretary of Homeland Security.

24 (c) CHARGES CONCERNING REFUSED TOBACCO  
25 PRODUCTS.—All expenses (including travel, per diem or

1 subsistence, and salaries of officers or employees of the  
2 United States) in connection with the destruction provided  
3 for in subsection (a) of this section and the supervision  
4 of the relabeling or other action authorized under the pro-  
5 visions of subsection (b) of this section, the amount of  
6 such expenses to be determined in accordance with regula-  
7 tions, and all expenses in connection with the storage,  
8 cartage, or labor with respect to any tobacco product re-  
9 fused admission under subsection (a) of this section, shall  
10 be paid by the owner or consignee and, in default of such  
11 payment, shall constitute a lien against any future impor-  
12 tations made by such owner or consignee.

13 **SEC. 509. TOBACCO PRODUCTS FOR EXPORT.**

14 (a) EXEMPTION FOR TOBACCO PRODUCTS EX-  
15 PORTED.—Except as provided in subsection (b), a tobacco  
16 product intended for export shall be exempt from this Act  
17 if

18 (1) it is not in conflict with the laws of the  
19 country to which it is intended fore export, as shown  
20 by either (A) a document issued by the government  
21 of that country or (B) a document provided by a  
22 person knowledgeable with respect to the relevant  
23 laws of that country and qualified by training and  
24 experience to opine on whether the tobacco product  
25 is or is not in conflict with such laws;

1 (2) it is labeled on the outside of the shipping  
2 package that it is intended for export; and

3 (3) the particular units of tobacco product in-  
4 tended for export have not been sold or offered for  
5 sale in domestic commerce.

6 (b) PRODUCTS FOR U.S. ARMED FORCES OVER-  
7 SEAS.—A tobacco product intended for export shall not  
8 be exempt from this Act if it is intended for sale or dis-  
9 tribution to members or units of the armed forces of the  
10 United States located outside of the United States.

11 (c) This Act shall not apply to a person that manu-  
12 factures and/or distributes tobacco products solely for ex-  
13 port under subsection (a), except to the extent such to-  
14 bacco products are subject to subsection (b).

## 15 **TITLE VI—MISCELLANEOUS** 16 **PROVISIONS**

17 **SEC. 601. USE OF PAYMENTS UNDER THE MASTER SETTLE-**  
18 **MENT AGREEMENT AND INDIVIDUAL STATE**  
19 **SETTLEMENT AGREEMENTS.**

20 (a) REDUCTION OF GRANT AMOUNTS.—(1) For fiscal  
21 year 2010 and each subsequent fiscal year, the Secretary  
22 shall reduce, as provided in subsection (b), the amount  
23 of any grant under section 1921 of the Public Health  
24 Service Act (42 U.S.C. § 300x-21) for any State that  
25 spends on tobacco control programs from the funds re-

1 ceived by such State pursuant to the Master Settlement  
2 Agreement, the Florida Settlement Agreement, the Min-  
3 nesota Settlement Agreement, the Mississippi Memo-  
4 randum of Understanding, or the Texas Settlement Agree-  
5 ment, as applicable, less than 20% of the amounts re-  
6 ceived by that State from settlement payments.

7 (2) In the case of a State whose legislature does not  
8 convene a regular session in fiscal year 2009 or 2010, and  
9 in the case of a State whose legislature does not convene  
10 a regular session in fiscal year 2010, the requirement de-  
11 scribed in subsection (a)(1) as a condition of receipt of  
12 a grant under section 1921 of the Public Health Service  
13 Act shall apply only for fiscal year 2009 and subsequent  
14 fiscal years.

15 (b) DETERMINATION OF STATE SPENDING.—Before  
16 making a grant under section 1921 of the Public Health  
17 Service Act, section 300x-21 of title 42, United States  
18 Code, to a State for the first applicable fiscal year or any  
19 subsequent fiscal year, the Secretary shall make a deter-  
20 mination of whether, during the immediately preceding fis-  
21 cal year, the State has spent on tobacco control programs,  
22 from the funds received by such State pursuant to the  
23 Master Settlement Agreement, the Florida Settlement  
24 Agreement, the Minnesota Settlement Agreement, the  
25 Mississippi Memorandum of Understanding, or the Texas

1 Settlement Agreement, as applicable, at least the amount  
2 referenced in (a)(1). If, after notice to the State and an  
3 opportunity for a hearing, the Secretary determines that  
4 the State has spent less than such amount, the Secretary  
5 shall reduce the amount of the allotment under section  
6 300x-21 of title 42, United States Code, for the State for  
7 the fiscal year involved by an amount equal to—

8           (1) in the case of the first applicable fiscal year,  
9           10 percent of the amount determined under section  
10           300x-33 of title 42, United States Code, for the  
11           State for the fiscal year;

12           (2) in the case of the first fiscal year following  
13           such applicable fiscal year, 20 percent of the amount  
14           determined under section 300x-33 of title 42, United  
15           States Code, for the State for the fiscal year;

16           (3) in the case of the second such fiscal year,  
17           30 percent of the amount determined under section  
18           300x-33 of title 42, United States Code, for the  
19           State for the fiscal year; and

20           (4) in the case of the third such fiscal year or  
21           any subsequent fiscal year, 40 percent of the amount  
22           determined under section 300x-33 of title 42, United  
23           States Code, for the State for the fiscal year.

1 The Secretary shall not have authority or discretion to  
2 grant to any State a waiver of the terms and requirements  
3 of this subsection or subsection (a).

4 (c) DEFINITIONS.—For the purposes of this sec-  
5 tion—

6 (1) The term “first applicable fiscal year”  
7 means—

8 (A) fiscal year 2011, in the case of any  
9 State described in subsection (a)(2) of this sec-  
10 tion; and

11 (B) fiscal year 2010, in the case of any  
12 other State.

13 (2) The term “Florida Settlement Agreement”  
14 means the Settlement Agreement, together with the  
15 exhibits thereto, entered into on August 25, 1997,  
16 between the State of Florida and signatory tobacco  
17 product manufacturers, as specified therein.

18 (3) The term “Master Settlement Agreement”  
19 means the Master Settlement Agreement, together  
20 with the exhibits thereto, entered into on November  
21 23, 1998, between the signatory States and signa-  
22 tory tobacco product manufacturers, as specified  
23 therein.

24 (4) The term “Minnesota Settlement Agree-  
25 ment” means the Settlement Agreement, together

1 with the exhibits thereto, entered into on May 8,  
2 1998, between the State of Minnesota and signatory  
3 tobacco product manufacturers, as specified therein.

4 (5) The term “Mississippi Memorandum of Un-  
5 derstanding” means the Memorandum of Under-  
6 standing, together with the exhibits thereto and Set-  
7 tlement Agreement contemplated therein, entered  
8 into on July 2, 1997, between the State of Mis-  
9 sissippi and signatory tobacco product manufactur-  
10 ers, as specified therein.

11 (6) The term “Secretary” means the Secretary  
12 of Health and Human Services.

13 (7) The term “Texas Settlement Agreement”  
14 means the Settlement Agreement, together with the  
15 exhibits thereto, entered into on January 16, 1998,  
16 between the State of Texas and signatory tobacco  
17 product manufacturers, as specified therein.

18 **SEC. 602. PREEMPTION OF STATE LAWS IMPLEMENTING**

19 **FIRE SAFETY STANDARD FOR CIGARETTES.**

20 (a) IN GENERAL.—With respect to fire safety stand-  
21 ards for cigarettes, no State or political subdivision shall—

22 (1) require testing of cigarettes that would be  
23 in addition to, or different from, the testing pre-  
24 scribed in subsection (b); or

1           (2) require a performance standard that is in  
2           addition to, or different from, the performance  
3           standard set forth in subsection (b).

4           (b) TEST METHOD AND PERFORMANCE STAND-  
5           ARD.—

6           (1) To the extent a State or political subdivi-  
7           sion enacts or has enacted legislation or a regulation  
8           setting a fire safety standard for cigarettes, the test  
9           method employed shall be—

10                   (A) the American Society of Testing and  
11                   Materials (“ASTM”) standard E2187–4, enti-  
12                   tled “Standard Test Method for Measuring the  
13                   Ignition Strength of Cigarettes”;

14                   (B) for each cigarette on 10 layers of filter  
15                   paper;

16                   (C) so that a replicate test of 40 cigarettes  
17                   for each brand style of cigarettes comprises a  
18                   complete test trial for that brand style; and

19                   (D) in a laboratory that has been accred-  
20                   ited in accordance with ISO/IEC 17205 of the  
21                   International Organization for Standardization  
22                   (“ISO”) and that has an implemented quality  
23                   control and quality assurance program that in-  
24                   cludes a procedure capable of determining the

1           repeatability of the testing results to a repeat-  
2           ability value that is no greater than 0.19.

3           (2) To the extent a State or political subdivi-  
4           sion enacts or has enacted legislation or a regulation  
5           setting a fire safety standard for cigarettes, the per-  
6           formance standard employed shall be that no more  
7           than 25 percent of the cigarettes of that brand style  
8           tested in a complete test in accordance with para-  
9           graph (1) exhibit full-length burns

10          (c) EXCEPTION TO SUBSECTION (b).—In the event  
11          that a manufacturer of a cigarette that a State or political  
12          subdivision or its respective delegated agency determines  
13          cannot be tested in accordance with the test method pre-  
14          scribed in subsection (b)(1)(A), the manufacturer shall  
15          propose a test method and performance standard for the  
16          cigarette to the State or political subdivision. Upon ap-  
17          proval of the proposed test method and a determination  
18          by the State or political division that the performance  
19          standard proposed by the manufacturer is equivalent to  
20          the performance standard prescribed in subsection (b)(2),  
21          the manufacturer may employ such test method and per-  
22          formance standard to certify such cigarette pursuant to  
23          this subsection notwithstanding subsection (b).

1 **SEC. 603. INSPECTION BY THE ALCOHOL AND TOBACCO**  
2 **TAX TRADE BUREAU OF RECORDS OF CER-**  
3 **TAIN CIGARETTE AND SMOKELESS TOBACCO**  
4 **SELLERS.**

5 (a) **IN GENERAL.**—Any officer of the Bureau of the  
6 Alcohol and Tobacco Tax Trade Bureau may, during nor-  
7 mal business hours, enter the premises of any person de-  
8 scribed in subsection (b) for the purposes of inspecting—

9 (1) any records or information required to be  
10 maintained by such person under the provisions of  
11 law referred to in subsection (d); or

12 (2) any cigarettes or smokeless tobacco kept or  
13 stored by such person at such premises.

14 (b) **COVERED PERSONS.**—Subsection (a) applies to  
15 any person who engages in a delivery sale, and who ships,  
16 sells, distributes, or receives any quantity in excess of  
17 10,000 cigarettes, or any quantity in excess of 500 single-  
18 unit consumer-sized cans or packages of smokeless to-  
19 bacco, within a single month.

20 (c) **RELIEF.**—

21 (1) **IN GENERAL.**—The district courts of the  
22 United States shall have the authority in a civil ac-  
23 tion under this subsection to compel inspections au-  
24 thorized by subsection (a).

25 (2) **VIOLATIONS.**—Whoever violates subsection  
26 (a) or an order issued pursuant to paragraph (1)

1 shall be subject to a civil penalty in an amount not  
2 to exceed \$10,000 for each violation.

3 (d) COVERED PROVISIONS OF LAW.—The provisions  
4 of law referred to in this subsection are—

5 (1) the Act of October 19, 1949 (15 U.S.C.  
6 375; commonly referred to as the “Jenkins Act”);

7 (2) chapter 114 of title 18, United States Code;  
8 and

9 (3) this Act.

10 (e) DELIVERY SALE DEFINED.—In this section, the  
11 term “delivery sale” has the meaning given that term in  
12 2343(e) of title 18, United States Code, as amended by  
13 this Act.

14 **SEC. 604. SEVERABILITY.**

15 If any provision of this Act, the amendments made  
16 by this Act, or the application of any provision of this Act  
17 to any person or circumstance is held to be invalid, the  
18 remainder of this Act, the amendments made by this Act,  
19 and the application of the provisions of this Act to any  
20 other person or circumstance shall not be affected, and  
21 shall continue to be enforced to the fullest extent possible.

1     **TITLE VII—TOBACCO GROWER**  
2                     **PROTECTION**

3     **SEC. 701. TOBACCO GROWER PROTECTION.**

4             No provision in this Act shall allow the Administrator  
5     or any other person to require changes to traditional farm-  
6     ing practices, including standard cultivation practices, cur-  
7     ing processes, seed composition, tobacco type, fertilization,  
8     soil, record keeping, or any other requirement affecting  
9     farming practices.