

111TH CONGRESS
1ST SESSION

S. 579

To establish a comprehensive Federal tobacco product regulatory program, to create a Tobacco Regulatory Agency, to prevent use of tobacco products by youth, and to provide protections for adult tobacco product users through the regulation of the tobacco products manufacturing industry.

IN THE SENATE OF THE UNITED STATES

MARCH 12, 2009

Mr. BURR (for himself and Mrs. HAGAN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To establish a comprehensive Federal tobacco product regulatory program, to create a Tobacco Regulatory Agency, to prevent use of tobacco products by youth, and to provide protections for adult tobacco product users through the regulation of the tobacco products manufacturing industry.

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

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

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Federal Tobacco Act of 2009”.

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

- Sec. 1. Short title; table of contents.
- Sec. 2. Purposes.
- Sec. 3. Definitions.

TITLE I—GENERAL PROVISIONS

- Sec. 101. Establishment of the Tobacco Regulatory Agency.
- 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. Advisory committees.
- Sec. 106. Illicit trade.
- Sec. 107. Adulterated tobacco products.
- Sec. 108. Misbranded tobacco products.
- Sec. 109. Registration and listing.
- Sec. 110. Effective date.

TITLE II—RESTRICTIONS ON YOUTH ACCESS TO TOBACCO PRODUCTS AND EXPOSURE OF YOUTH TO TOBACCO PRODUCT MARKETING AND ADVERTISING

- Sec. 201. Prohibitions on youth targeting.
- Sec. 202. State law regarding sale of tobacco products to individuals under age of 18.
- Sec. 203. Restrictions on descriptors used in marketing of cigarettes.

TITLE III—REDUCED-EXPOSURE AND REDUCED-RISK CLAIMS FOR TOBACCO PRODUCTS, AND RANKING OF TOBACCO PRODUCT CATEGORIES

- Sec. 301. Prohibition of unapproved reduced-exposure and reduced-risk claims.
- Sec. 302. Applications for approval of reduced-exposure and reduced-risk claims.
- Sec. 303. Standards for approval of applications for reduced-exposure or reduced-risk claims.
- Sec. 304. General provisions.
- Sec. 305. Establishment of rankings.
- Sec. 306. Compulsory licensing.
- Sec. 307. Moist snuff warnings.

TITLE IV—DISCLOSURES TO THE AGENCY REGARDING TOBACCO PRODUCTS

- Sec. 401. Confidential disclosures to the agency.
- Sec. 402. Nicotine reporting requirements for cigarettes.
- Sec. 403. Nicotine reporting requirements for smokeless tobacco products.

TITLE V—TAR AND NICOTINE YIELDS

- Sec. 501. Determination of tar and nicotine yields of cigarettes.
- Sec. 502. Cigarette tar limits.
- Sec. 503. Prohibition of smoking article yield terms.

- Sec. 504. Disclosure of tar and nicotine yields of cigarettes.
 Sec. 505. Evaluation of tobacco smoke toxicants.

TITLE VI—PUBLIC DISCLOSURES BY TOBACCO PRODUCT
 MANUFACTURERS

- Sec. 601. Disclosures on packages of smoking articles.
 Sec. 602. Disclosures on packages of chewing tobacco and dry snuff.
 Sec. 603. Public disclosure of ingredients.
 Sec. 604. Cigarette label and advertising warnings.

TITLE VII—ENFORCEMENT PROVISIONS

- Sec. 701. Prohibited acts.
 Sec. 702. Injunction proceedings.
 Sec. 703. Penalties.
 Sec. 704. Seizure.
 Sec. 705. Report of minor violations.
 Sec. 706. Inspection.
 Sec. 707. Effect of compliance.
 Sec. 708. Imports.
 Sec. 709. Tobacco products for export.

TITLE VIII—MISCELLANEOUS PROVISIONS

- Sec. 801. Use of payments under the master settlement agreement and individual State settlement agreements.
 Sec. 802. User fees.
 Sec. 803. Fire safety standards for cigarettes.
 Sec. 804. Inspection by the alcohol and tobacco tax trade bureau of records of certain cigarette and smokeless tobacco sellers.
 Sec. 805. Tobacco grower protection.
 Sec. 806. Severability.

1 **SEC. 2. PURPOSES.**

2 The purposes of this Act are—

3 (1) to provide Federal authority and an appropriate administrative body designed specifically to
 4 regulate tobacco products, including smoking articles
 5 and smokeless tobacco products;
 6

7 (2) to affirm the lawfulness of tobacco products
 8 and to ensure the ability of private manufacturers to
 9 compete for the business of adult users of tobacco
 10 products, including smokers and users of smokeless
 11 tobacco, in a free enterprise system;

1 (3) to confirm that cigarettes and other tobacco
2 products, as customarily marketed, are not subject
3 to regulation under the Federal Food, Drug, and
4 Cosmetic Act (21 U.S.C. 201 et seq.), but instead
5 are subject to regulation under this and other appro-
6 priate Acts;

7 (4) to ensure that existing Federal laws regu-
8 lating certain aspects of tobacco and tobacco product
9 production, as well as tobacco product taxation, test-
10 ing, marketing, promotion, and advertising remain
11 in full force and effect, except as repealed or amend-
12 ed by this Act;

13 (5) to ensure that tobacco products sold in the
14 United States conform with all applicable laws and
15 regulations;

16 (6) to strengthen enforcement against illegal
17 sales of tobacco products, including the smuggling of
18 illegal cigarettes and other tobacco products into the
19 United States;

20 (7) to restrict access to tobacco products on the
21 part of individuals younger than the minimum age
22 established by State law for the purchase of tobacco
23 products, and to limit the exposure of such individ-
24 uals to tobacco product advertising, marketing, and
25 promotion;

1 (8) to continue to permit the sale of tobacco
2 products to adults in conjunction with measures to
3 ensure that tobacco products are not sold or acces-
4 sible to those who have not attained the minimum
5 age established by State law for the purchase of to-
6 bacco products;

7 (9) to allow tobacco product manufacturers to
8 communicate truthful and nonmisleading informa-
9 tion, in advertising and otherwise, concerning to-
10 bacco products to adult users of tobacco products,
11 including smokers and users of smokeless tobacco;

12 (10) to ensure that tobacco products sold in the
13 United States do not present adults who choose to
14 use those products with additional health risks be-
15 yond those inherent in tobacco use;

16 (11) to establish principles and policies gov-
17 erning tobacco products to promote reductions in
18 morbidity and mortality associated with tobacco
19 products, to inform adult users of tobacco products
20 about the relative risks of chronic diseases and seri-
21 ous adverse health conditions associated with to-
22 bacco use presented by different categories of to-
23 bacco products, and to encourage manufacturers of
24 tobacco products to develop and introduce tobacco
25 products that present reduced exposure of tobacco

1 product users to toxicants in tobacco or in tobacco
2 smoke and tobacco products that present a reduced
3 risk of chronic diseases and serious adverse health
4 conditions associated with tobacco use;

5 (12) to promote the ability of adult consumers
6 of tobacco products to obtain truthful and nonmis-
7 leading health-related information regarding the to-
8 bacco products that those consumers choose to use,
9 while protecting the trade secrets of tobacco product
10 manufacturers; and

11 (13) to establish a comprehensive Federal pro-
12 gram to deal with tobacco, including the subject
13 matters addressed in paragraphs (1) through (12),
14 such that commerce and the national economy may
15 be—

16 (A) protected to the maximum extent; and

17 (B) not impeded by diverse, nonuniform,

18 and confusing requirements or prohibitions.

19 **SEC. 3. DEFINITIONS.**

20 In this Act:

21 (1) ADMINISTRATOR.—The term “Adminis-
22 trator” means the chief executive of the Tobacco
23 Regulatory Agency established under section 101.

24 (2) ADULT.—The term “adult” means any indi-
25 vidual who has attained the minimum age under ap-

1 plicable State law to be an individual to whom to-
2 bacco products may lawfully be sold.

3 (3) ADULT-ONLY FACILITY.—The term “adult-
4 only facility” means a facility or restricted area,
5 whether open-air or enclosed, where the operator en-
6 sures, or has a reasonable basis to believe, that no
7 youth is present. A facility or restricted area need
8 not be permanently restricted to adults in order to
9 constitute an adult-only facility, if the operator en-
10 sures, or has a reasonable basis to believe, that no
11 youth is present during any period of operation as
12 an adult-only facility.

13 (4) ADVERTISING.—The term “advertising”
14 means a communication to the general public by a
15 tobacco product manufacturer, distributor, retailer,
16 or its agents, which identifies a tobacco product by
17 brand name and is intended by such manufacturer,
18 distributor, retailer, or its agents to promote pur-
19 chases of such tobacco product. Such term shall not
20 include—

21 (A) any advertising or other communica-
22 tion in any tobacco trade publication or tobacco
23 trade promotional material;

24 (B) the content of any scientific publica-
25 tion or presentation, or any patent application

1 or other communication to the United States
2 Patent and Trademark Office or any similar of-
3 fice in any foreign country;

4 (C) any corporate or financial report or fi-
5 nancial communication;

6 (D) any communication to a lending insti-
7 tution or to securities holders;

8 (E) any communication not intended for
9 public display or public exposure, except that a
10 direct mailing or direct electronic communica-
11 tion of what otherwise is advertising shall be
12 deemed to be advertising;

13 (F) any communication in, on, or within a
14 factory, office, plant, warehouse, or other facil-
15 ity related to or associated with the develop-
16 ment, manufacture, or storage of tobacco prod-
17 ucts;

18 (G) any communication to any govern-
19 mental agency, body, official, or employee;

20 (H) any communication to any journalist,
21 editor, Internet blogger, or other author;

22 (I) any communication in connection with
23 litigation, including arbitration and similar pro-
24 ceedings; or

1 (J) any editorial advertisement that ad-
2 dresses a public issue.

3 (5) AFFILIATE.—The term “affiliate” means a
4 person that directly or indirectly owns or controls, is
5 owned or controlled by, or is under common owner-
6 ship or control with, another person. The terms
7 “owns”, “is owned”, and “ownership” mean owner-
8 ship of an equity interest, or the equivalent thereof,
9 of 50 percent or more.

10 (6) AGENCY.—The term “Agency” means the
11 Tobacco Regulatory Agency established under sec-
12 tion 101.

13 (7) AGE-VERIFIED ADULT.—The term “age-
14 verified adult” means any individual who is an adult
15 and—

16 (A) who has stated or acknowledged, after
17 being asked, that he or she is an adult and a
18 tobacco product user, and has presented proof
19 of age identifying the individual and verifying
20 that the individual is an adult; or

21 (B) whose status as an adult has been
22 verified by a commercially available database of
23 such information.

24 (8) ANNUAL REPORT.—The term “annual re-
25 port” means a tobacco product manufacturer’s an-

1 nual report to the Agency, which provides ingredient
2 information and nicotine yield ratings for each brand
3 style that the tobacco product manufacturer manu-
4 factures for commercial distribution domestically.

5 (9) BRAND NAME.—The term “brand name”
6 means a brand name of a tobacco product distrib-
7 uted or sold domestically, alone or in conjunction
8 with any other word, trademark, logo, symbol,
9 motto, selling message, recognizable pattern of col-
10 ors, or any other indicium of product identification
11 identical or similar to, or identifiable with, those
12 used for any domestic brand of tobacco product.
13 Such term shall not include the corporate name of
14 any tobacco product manufacturer that does not,
15 after the effective date of this Act, sell a brand style
16 of tobacco product in the United States that in-
17 cludes such corporate name.

18 (10) BRAND NAME SPONSORSHIP.—The term
19 “brand name sponsorship” means an athletic, musi-
20 cal, artistic, or other social or cultural event, series,
21 or tour, as to which payment is made, or other con-
22 sideration is provided, in exchange for use of a
23 brand name or names—

24 (A) as part of the name of the event; or

1 (B) to identify, advertise, or promote such
2 event or an entrant, participant, or team in
3 such event in any other way.

4 (11) BRAND STYLE.—The term “brand style”
5 means a tobacco product having a brand name, and
6 distinguished by the selection of the tobacco, ingredi-
7 ents, structural materials, format, configuration,
8 size, package, product descriptor, amount of tobacco,
9 or yield of tar or nicotine.

10 (12) CARTON.—The term “carton” means a
11 container into which packages of tobacco products
12 are directly placed for distribution or sale (such as
13 a carton containing 10 packages of cigarettes), but
14 does not include cases intended for shipping.

15 (13) CARTOON.—The term “cartoon” means
16 any drawing or other depiction of an object, person,
17 animal, creature or any similar caricature that satis-
18 fies any of the following criteria:

19 (A) The use of comically exaggerated fea-
20 tures.

21 (B) The attribution of human characteris-
22 tics to animals, plants or other objects, or the
23 similar use of anthropomorphic technique.

24 (C) The attribution of unnatural or
25 extrahuman abilities, such as imperviousness to

1 pain or injury, X-ray vision, tunneling at very
2 high speeds, or transformation.

3 Such term shall not include any drawing or other
4 depiction that, on the effective date of this Act, was
5 in use in the United States in any tobacco product
6 manufacturer's corporate logo or in any tobacco
7 product manufacturer's tobacco product packaging.

8 (14) CIGAR.—The term “cigar” has the mean-
9 ing given such term by the Alcohol and Tobacco Tax
10 and Trade Bureau under section 40.11 of title 27,
11 Code of Federal Regulations.

12 (15) CIGARETTE.—The term “cigarette”
13 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 of a cigarette described in sub-
22 paragraph (A).

23 (16) COMPETENT AND RELIABLE SCIENTIFIC
24 EVIDENCE.—The term “competent and reliable sci-
25 entific evidence” means evidence based on tests,

1 analyses, research, or studies, conducted and evalu-
2 ated in an objective manner by individuals qualified
3 to do so, using procedures generally accepted in the
4 relevant scientific disciplines to yield accurate and
5 reliable results.

6 (17) DISTRIBUTOR.—The term “distributor”
7 means any person who furthers the distribution of
8 tobacco products, whether domestic or imported, at
9 any point from the original place of manufacture to
10 the person who sells or distributes the tobacco prod-
11 uct to individuals for personal consumption. Com-
12 mon carriers, retailers, and those engaged solely in
13 advertising are not considered distributors for pur-
14 poses of this Act.

15 (18) DOMESTIC, DOMESTICALLY.—The terms
16 “domestic” and “domestically” mean within the
17 United States, including activities within the United
18 States involving advertising, marketing, distribution,
19 or sale of tobacco products that are intended for
20 consumption within the United States.

21 (19) HUMAN IMAGE.—The term “human
22 image” means any photograph, drawing, silhouette,
23 statue, model, video, likeness, or depiction of the ap-
24 pearance of a human being, or the appearance of
25 any portion of the body of a human being.

1 (20) ILLICIT TOBACCO PRODUCT.—The term
2 “illicit tobacco product” means any tobacco product
3 intended for commercial distribution for use by con-
4 sumers in the United States—

5 (A) with respect to which not all applicable
6 duties or taxes have been paid in full;

7 (B) that has been stolen, smuggled, or is
8 otherwise contraband,

9 (C) that is counterfeit; or

10 (D) that has or had a label, labeling, or
11 packaging stating, or that stated, that the prod-
12 uct is or was for export only, or that it is or
13 was at any time restricted by section 5704 of
14 the Internal Revenue Code of 1986.

15 (21) ILLICIT TRADE.—The term “illicit trade”
16 means any transfer, distribution, or sale in inter-
17 state commerce of any illicit tobacco product.

18 (22) IMMEDIATE CONTAINER.—The term “im-
19 mediate container” shall not include package liners.

20 (23) INDIAN TRIBE.—The term “Indian tribe”
21 has the meaning given such term in section 4(e) of
22 the Indian Self Determination and Education Assist-
23 ance Act (25 U.S.C. 450b(e)).

24 (24) INGREDIENT.—The term “ingredient”
25 means tobacco and any substance added to tobacco

1 to have an effect in the final tobacco product or
2 when the final tobacco product is used by a con-
3 sumer.

4 (25) INTERNATIONAL ORGANIZATION FOR
5 STANDARDIZATION TESTING REGIMEN; ISO TESTING
6 REGIMEN.—

7 (A) IN GENERAL.—The terms “Inter-
8 national Organization for Standardization test-
9 ing regimen” or “ISO testing regimen” mean
10 the methods for measuring cigarette smoke
11 yields, as set forth in the most recent versions
12 of the following:

13 (i) ISO 3308, entitled “Routine ana-
14 lytical cigarette-smoking machine—Defini-
15 tion of standard conditions”.

16 (ii) ISO 4387, entitled “Cigarettes—
17 Determination of total and nicotine-free
18 dry particulate matter using a routine ana-
19 lytical smoking machine”.

20 (iii) ISO 10315, entitled “Ciga-
21 rettes—Determination of nicotine in smoke
22 condensates—Gas-chromatographic meth-
23 od”.

24 (iv) ISO 10362-1, entitled “Ciga-
25 rettes—Determination of water in smoke

1 condensates—Part 1: Gas-chromatographic
2 method”.

3 (v) ISO 8454, entitled “Cigarettes—
4 Determination of carbon monoxide in the
5 vapour phase of cigarette smoke—NDIR
6 method”.

7 (B) CLARIFICATION.—A cigarette that
8 does not burn down in accordance with the test-
9 ing regimen standards described in subpara-
10 graph (A) may be measured under the same
11 puff regimen using the number of puffs that
12 such a cigarette delivers before it extinguishes,
13 plus an additional 3 puffs, or with such other
14 modifications as the Administrator may ap-
15 prove.

16 (26) INTERSTATE COMMERCE.—The term
17 “interstate commerce” means all trade, traffic, or
18 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 (27) LABEL.—The term “label” means a dis-
4 play of written, printed, or graphic matter upon or
5 applied securely to the immediate container of a to-
6 bacco product.

7 (28) LABELING.—The term “labeling” means
8 all labels and other written, printed, or graphic mat-
9 ter—

10 (A) upon or applied securely to any to-
11 bacco product or any of its containers or wrap-
12 pers; or

13 (B) accompanying a tobacco product.

14 (29) LITTLE CIGAR.—The term “little cigar”
15 has the meaning given such term by the Alcohol and
16 Tobacco Tax and Trade Bureau under section 40.11
17 of title 27, Code of Federal Regulations.

18 (30) LOOSE TOBACCO.—The term “loose to-
19 bacco” means any form of tobacco, alone or in com-
20 bination with any other ingredient or material, that,
21 because of its appearance, form, type, packaging, or
22 labeling, is suitable for use and likely to be offered
23 to, or purchased by, consumers as tobacco for mak-
24 ing or assembling cigarettes, incorporation into

1 pipes, or otherwise used by consumers to make any
2 smoking article.

3 (31) MANUFACTURE.—The term “manufac-
4 ture” means to design, manufacture, fabricate, as-
5 semble, process, package or repack, label or
6 relabel, import, or hold or store in a commercial
7 quantity. Such term shall not include—

8 (A) the growing, curing, destemming, or
9 aging of tobacco; or

10 (B) the holding, storing, or transporting of
11 a tobacco product by a common carrier for hire,
12 a public warehouse, a testing laboratory, a dis-
13 tributor, or a retailer.

14 (32) NICOTINE-CONTAINING PRODUCT.—The
15 term “nicotine-containing product” means a product
16 intended for human consumption, other than a to-
17 bacco product, that contains added nicotine, whether
18 or not in the form of a salt or solvate, which nicotine
19 has been—

20 (A) synthetically produced; or

21 (B) obtained from tobacco or other source
22 of nicotine.

23 (33) OUTDOOR ADVERTISING.—

1 (A) IN GENERAL.—Except as provided in
2 subparagraph (B), the term “outdoor adver-
3 tising” means—

4 (i) a billboard;

5 (ii) a sign or placard in an arena, sta-
6 dium, shopping mall, or video game arcade
7 (whether any of the foregoing is open air
8 or enclosed), but not including any such
9 sign or placard located in an adult-only fa-
10 cility; and

11 (iii) any other advertisement placed
12 outdoors.

13 (B) LIMITATION.—The term “outdoor ad-
14 vertising” shall not include—

15 (i) an advertisement on the outside of
16 a tobacco product manufacturing facility;
17 or

18 (ii) an advertisement that—

19 (I) is inside a retail establish-
20 ment that sells tobacco products
21 (other than solely through a vending
22 machine or vending machines);

23 (II) is placed on the inside sur-
24 face of a window facing outward; and

1 (III) is no larger than 14 square
2 feet.

3 (34) PACKAGE.—The term “package” means a
4 pack, box, carton, pouch, or container of any kind
5 in which a tobacco product or tobacco products are
6 offered for sale, sold, or otherwise distributed to con-
7 sumers. Such term shall not include an outer con-
8 tainer used solely for shipping 1 or more packages
9 of a tobacco product or tobacco products.

10 (35) PERSON.—The term “person” means any
11 individual, partnership, corporation, committee, as-
12 sociation, organization or group of persons, or other
13 legal or business entity.

14 (36) PROOF OF AGE.—The term “proof of age”
15 means a driver’s license or other form of identifica-
16 tion that is issued by a governmental authority and
17 includes a photograph and a date of birth of the in-
18 dividual.

19 (37) RAW TOBACCO.—The term “raw tobacco”
20 means tobacco in a form that is received by a to-
21 bacco product manufacturer as an agricultural com-
22 modity, whether in a form that is—

23 (A) natural, stem or leaf;

24 (B) cured or aged; or

1 (C) as parts or pieces, but not in a recon-
2 stituted form, extracted pulp form, or extract
3 form.

4 (38) REDUCED-EXPOSURE CLAIM.—The term
5 “reduced-exposure claim” means a statement in ad-
6 vertising or labeling intended for 1 or more con-
7 sumers of tobacco products, that a tobacco product
8 provides a reduced exposure of users of that tobacco
9 product to 1 or more toxicants, as compared to an
10 appropriate reference tobacco product or category of
11 tobacco products. A statement or representation that
12 a tobacco product or the tobacco in a tobacco prod-
13 uct contains “no additives” or is “natural”, or that
14 uses a substantially similar term is not a reduced-
15 exposure claim if the advertising or labeling that
16 contains such statement or representation also con-
17 tains the disclosure required by section 108(h).

18 (39) REDUCED-RISK CLAIM.—The term “re-
19 duced-risk claim” means a statement in advertising
20 or labeling intended for 1 or more consumers of to-
21 bacco products, that a tobacco product provides to
22 users of that product a reduced risk of morbidity or
23 mortality resulting from 1 or more chronic diseases
24 or serious adverse health conditions associated with
25 tobacco use, as compared to an appropriate ref-

1 erence tobacco product or category of tobacco prod-
2 ucts, even if it is not stated, represented, or implied
3 that all health risks associated with using that to-
4 bacco product have been reduced or eliminated. A
5 statement or representation that a tobacco product
6 or the tobacco in a tobacco product contains “no ad-
7 ditives” or is “natural”, or that uses a substantially
8 similar term is not a reduced-risk claim if the adver-
9 tising or labeling that contains such statement or
10 representation also contains the disclosure required
11 by section 108(h).

12 (40) RETAILER.—The term “retailer” means
13 any person that—

14 (A) sells tobacco products to individuals
15 for personal consumption; or

16 (B) operates a facility where the sale of to-
17 bacco products to individuals for personal con-
18 sumption is permitted.

19 (41) SAMPLE.—The term “sample” means a to-
20 bacco product distributed to members of the public
21 at no cost for the purpose of promoting the product,
22 but excludes tobacco products distributed—

23 (A) in conjunction with the sale of other
24 tobacco products,

1 (B) for market research, medical or sci-
2 entific study or testing, or teaching,

3 (C) to persons employed in the tobacco in-
4 dustry;

5 (D) to adult consumers in response to con-
6 sumer complaints; or

7 (E) to employees of the manufacturer of
8 the tobacco product.

9 (42) SMALL BUSINESS.—The term “small busi-
10 ness” means a tobacco product manufacturer that—

11 (A) employs 150 or fewer employees; and

12 (B) during the 3-year period prior to the
13 calendar year in which this Act is enacted, had
14 an average annual gross revenue from tobacco
15 products that did not exceed \$40,000,000.

16 (43) SMOKELESS TOBACCO PRODUCT.—The
17 term “smokeless tobacco product” means any form
18 of finely cut, ground, powdered, reconstituted, proc-
19 essed, or shaped tobacco, leaf tobacco, or stem to-
20 bacco, whether or not combined with any other in-
21 gredient, whether or not in extract or extracted
22 form, and whether or not incorporated within any
23 carrier or construct, that is intended to be placed in
24 the oral or nasal cavity, including dry snuff, moist
25 snuff, and chewing tobacco.

1 (44) SMOKING ARTICLE.—The term “smoking
2 article” means any tobacco-containing article that is
3 intended, when used by a consumer, to be burned or
4 otherwise to employ heat to produce a vapor, aer-
5 osol, or smoke that—

6 (A) incorporates components of tobacco or
7 derived from tobacco; and

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

9 (45) STATE.—The term “State” means any
10 State of the United States and, except as otherwise
11 specifically provided, includes any Indian tribe or
12 tribal organization, the District of Columbia, the
13 Commonwealth of Puerto Rico, Guam, the Virgin Is-
14 lands, American Samoa, Wake Island, Midway Is-
15 land, Kingman Reef, Johnston Atoll, the Northern
16 Marianas, and any other trust territory or posses-
17 sion of the United States.

18 (46) TAR.—The term “tar” means nicotine-free
19 dry particulate matter as defined in ISO 4387, enti-
20 tled “Cigarettes—Determination of total and nico-
21 tine-free dry particulate matter using a routine ana-
22 lytical smoking machine”.

23 (47) TOBACCO.—The term “tobacco” means a
24 tobacco plant or any part of a harvested tobacco
25 plant intended for use in the production of a tobacco

1 product, including leaf, lamina, stem, or stalk,
2 whether in green, cured, or aged form, whether in
3 raw, treated, or processed form, and whether or not
4 combined with other materials, including any by-
5 product, extract, extracted pulp material, or any
6 other material (other than purified nicotine) derived
7 from a tobacco plant or any component thereof, and
8 including strip, filler, stem, powder, and granulated,
9 blended, or reconstituted forms of tobacco.

10 (48) TOBACCO PRODUCT.—The term “tobacco
11 product” means—

12 (A) the singular of the term “tobacco
13 products”, as defined in section 5702(c) of the
14 Internal Revenue Code of 1986;

15 (B) any other product that contains to-
16 bacco as a principal ingredient and that, be-
17 cause of its appearance, type, or the tobacco
18 used in the product, or its packaging and label-
19 ing, is likely to be offered to, or purchased by,
20 consumers as a tobacco product as described in
21 subparagraph (A); and

22 (C) any form of tobacco or any construct
23 incorporating tobacco, intended for human con-
24 sumption, whether by—

- 1 (i) placement in the oral or nasal cav-
2 ity;
3 (ii) inhalation of vapor, aerosol, or
4 smoke; or
5 (iii) any other means.

6 (49) TOBACCO PRODUCT CATEGORY.—The term
7 “tobacco product category” means a type of tobacco
8 product characterized by its composition, compo-
9 nents, and intended use, and includes tobacco prod-
10 ucts classified as cigarettes, loose tobacco for roll-
11 your-own tobacco products, little cigars, cigars, pipe
12 tobacco, moist snuff, dry snuff, chewing tobacco, and
13 other forms of tobacco products (which are treated
14 in this Act collectively as a single category).

15 (50) TOBACCO PRODUCT COMMUNICATION.—
16 The term “tobacco product communication” means
17 any means, medium, or manner for providing infor-
18 mation relating to any tobacco product, including
19 face-to-face interaction, mailings by postal service or
20 courier to an individual who is an addressee, and
21 electronic mail to an individual who is an addressee.

22 (51) TOBACCO PRODUCT MANUFACTURER.—
23 The term “tobacco product manufacturer” means an
24 entity that directly—

1 (A) manufactures a tobacco product that is
2 intended to be distributed commercially in the
3 United States, including a tobacco product in-
4 tended to be distributed commercially in the
5 United States through an importer;

6 (B) is the first purchaser for resale in the
7 United States of tobacco products manufac-
8 tured outside the United States for distribution
9 commercially in the United States; or

10 (C) is a successor or assign of any of the
11 foregoing.

12 (52) TOXICANT.—The term “toxicant” means a
13 chemical or physical agent that produces an adverse
14 biological effect.

15 (53) TRANSIT ADVERTISEMENTS.—The term
16 “transit advertisements” means advertising on or
17 within private or public vehicles and all advertise-
18 ments placed at, on, or within any bus stop, taxi
19 stand, transportation waiting area, train station, air-
20 port, or any similar location.

21 (54) TRIBAL ORGANIZATIONAL.—The term
22 “tribal organization” has the meaning given such
23 term by section 4(1) of the Indian Self Determina-
24 tion and Education Assistance Act (25 U.S.C.
25 450b(1)).

1 (55) UNITED STATES.—The term “United
2 States” means the several States, as defined in this
3 Act.

4 (56) VENDING MACHINE.—The term “vending
5 machine” means any mechanical, electric, or elec-
6 tronic self-service device that, upon insertion of
7 money, tokens, or any other form of payment, auto-
8 matically dispenses tobacco products.

9 (57) VIDEO GAME ARCADE.—The term “video
10 game arcade” means an entertainment establish-
11 ment primarily consisting of video games (other than
12 video games intended primarily for use by adults) or
13 pinball machines.

14 (58) YOUTH.—The term “youth” means any in-
15 dividual who is not an adult.

16 **TITLE I—GENERAL PROVISIONS**

17 **SEC. 101. ESTABLISHMENT OF THE TOBACCO REGULATORY** 18 **AGENCY.**

19 (a) ESTABLISHMENT OF AGENCY.—There is estab-
20 lished within the Department of Health and Human Serv-
21 ices the Tobacco Regulatory Agency. The Agency shall not
22 be part of the Food and Drug Administration, and shall
23 not in any way be under the authority of the Commis-
24 sioner of Food and Drugs.

1 (b) AGENCY HEAD; REGULATIONS; COST-BENEFIT
2 ANALYSIS.—

3 (1) IN GENERAL.—The Agency shall be headed
4 by an Administrator, to be appointed by the Presi-
5 dent with the advice and consent of the Senate, who
6 shall have the authority provided under this Act,
7 perform the functions that relate to the subject mat-
8 ter of this Act, and have the authority to promulgate
9 regulations for the efficient enforcement of this Act.

10 (2) REGULATIONS.—In promulgating regula-
11 tions under section 107, section 108, or section
12 502(c), or any regulation that is likely to have an
13 annual effect on the economy of \$50,000,000 or
14 more, or have a material adverse effect on adult
15 users of tobacco products, tobacco product manufac-
16 turers, distributors or retailers, the Administrator
17 shall—

18 (A) determine the technological and eco-
19 nomic ability of parties that would be required
20 to comply with the regulation involved to com-
21 ply with such regulation;

22 (B) consider experience gained under any
23 similar relevant regulations at the Federal or
24 State level; and

1 (C) determine the reasonableness of the re-
2 lationship between the costs of complying with
3 such regulation and the public health benefits
4 to be achieved by such regulation.

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

6 (a) EXCLUSION OF TOBACCO PRODUCTS AND NICO-
7 TINE-CONTAINING PRODUCTS FROM THE FEDERAL
8 FOOD, DRUG, AND COSMETIC ACT.—No tobacco product
9 or nicotine-containing product shall be regulated as a food,
10 drug, or device under subsection (f), (g), or (h) of section
11 201, or chapter IV or V, of the Federal Food, Drug, and
12 Cosmetic Act (21 U.S.C. 321(f), (g), or (h), 341 et seq.,
13 and 351 et seq.), except that any tobacco product commer-
14 cially distributed domestically and any nicotine-containing
15 product commercially distributed domestically shall be
16 subject to chapter V of such Act if the manufacturer or
17 a distributor of such product markets it with an explicit
18 claim that the product is intended for use in the cure,
19 mitigation, treatment, or prevention of disease in man or
20 other animals, within the meaning of section 201(g)(1)(C)
21 or section 201(h)(2) of such Act.

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

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

4 (2) affect any action pending in any Federal,
5 State, or tribal court, or any agreement, consent de-
6 cree, or contract of any kind.

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

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

12 (2) raw tobacco that is grown for a tobacco
13 product manufacturer by a grower, and that is in
14 the possession of that grower or of a person that is
15 not a tobacco product manufacturer and is within
16 the scope of subparagraphs (A) through (F) of para-
17 graph (3); or

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

21 (A) producers of raw tobacco, including to-
22 bacco growers;

23 (B) tobacco warehouses, and other persons
24 that receive raw tobacco from growers;

25 (C) tobacco grower cooperatives;

- 1 (D) persons that cure raw tobacco;
2 (E) persons that process raw tobacco; and
3 (F) persons that store raw tobacco for
4 aging.

5 If a producer of raw tobacco is also a tobacco prod-
6 uct manufacturer, an affiliate of a tobacco product
7 manufacturer, or a person producing raw tobacco for
8 a tobacco product manufacturer, then that producer
9 shall be subject to this Act only to the extent of that
10 producer's capacity as a tobacco product manufac-
11 turer.

12 **SEC. 103. EXISTING FEDERAL LAWS MAINTAINED.**

13 (a) IN GENERAL.—Except as otherwise amended or
14 repealed by this Act, all Federal laws in effect on the effec-
15 tive date of this Act that regulate tobacco, tobacco prod-
16 ucts, or tobacco product manufacturers shall remain in ef-
17 fect. Such laws shall include—

- 18 (1) the Federal Cigarette Labeling and Adver-
19 tising Act (15 U.S.C. 1331 et seq.);
20 (2) the Comprehensive Smokeless Tobacco
21 Health Education Act of 1986 (15 U.S.C. 4401 et
22 seq.);
23 (3) section 1926 of the Public Health Service
24 Act (42 U.S.C. 300x-26); and

1 (4) those laws authorizing the regulation of to-
 2 bacco, tobacco products, or tobacco product manu-
 3 facturers by the Federal Trade Commission, the De-
 4 partment of Agriculture, the Environmental Protec-
 5 tion Agency, the Internal Revenue Service, and the
 6 Alcohol and Tobacco Tax and Trade Bureau of the
 7 Department of the Treasury.

8 (b) REPEALS.—The following provisions shall be re-
 9 pealed—

10 (1) Section 6 of the Federal Cigarette Labeling
 11 and Advertising Act (15 U.S.C. 1335).

12 (2) Section 2(f) of the Comprehensive Smoke-
 13 less Tobacco Health Education Act of 1986 (15
 14 U.S.C. 4401(f)).

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

19 In carrying out the purpose described in 2(13) the
 20 following shall apply:

21 (1) All proceedings for the enforcement, or to
 22 restrain violations, of this Act shall be by and in the
 23 name of the United States. Subpoenas for witnesses
 24 who are required to attend a court of the United
 25 States, in any district, may be enforceable in any

1 other district in any proceeding under this section.
2 No State, or political subdivision thereof, may pro-
3 ceed or intervene in any Federal or State court
4 under this Act or under any regulation promulgated
5 under this Act, or allege any violation thereof, except
6 a violation by the Administrator. Nothing in this Act
7 shall be construed to create a right of action by any
8 private person for any violation of any provision of
9 this Act or of any regulation promulgated under this
10 Act.

11 (2) With respect to any subject matter covered
12 by this Act or by any regulation promulgated under
13 this Act, no conflicting requirement or prohibition
14 shall be imposed under State or local law upon any
15 tobacco product manufacturer or distributor.

16 (3) Paragraph (2) shall not apply to any re-
17 quirement or prohibition imposed under State or
18 local law prior to December 31, 2009.

19 **SEC. 105. ADVISORY COMMITTEES.**

20 (a) **ESTABLISHMENT.**—The Administrator shall es-
21 tablish advisory committees for purposes required by this
22 Act and otherwise as the Administrator determines appro-
23 priate.

24 (b) **COMPOSITION.**—

1 (1) IN GENERAL.—An advisory committee es-
2 tablished under this Act shall be composed of 11
3 members, of whom—

4 (A) 3 members shall be officers or employ-
5 ees of the Federal Government, or a State or
6 local government;

7 (B) 3 members shall be representatives of
8 the interests of scientific and health profes-
9 sionals;

10 (C) 2 members shall be representatives of
11 the interests of the general public; and

12 (D) 3 members shall be representatives of
13 the tobacco products manufacturing industry,
14 of which, 1 such member shall be a representa-
15 tive of small businesses.

16 (2) ADMINISTRATIVE PROVISIONS.—The Ad-
17 ministrators shall designate the chairperson of each
18 advisory committee under this Act from among its
19 members, shall furnish any such advisory committee
20 with clerical and other assistance, and shall establish
21 for all members (other than those who are employees
22 of the Federal Government), appropriate compensa-
23 tion and travel expenses, as authorized by section
24 7503 of title 5, United States Code.

1 **SEC. 106. ILLICIT TRADE.**

2 (a) **NO ACTION TO INCREASE ILLICIT TRADE.**—The
3 Administrator shall not promulgate any regulation or take
4 any other action under this Act that has the effect of—

5 (1) increasing illicit trade involving tobacco or
6 any tobacco product; or

7 (2) making affected tobacco products unaccept-
8 able to a substantial number of the current users of
9 such products, thereby creating a substantial risk
10 that such users will resort to illicit tobacco products,
11 or tobacco products that are otherwise noncompliant
12 or unlawful.

13 (b) **STUDY AND REPORT.**—

14 (1) **STUDY.**—The Administration shall, after
15 consultation with other relevant agencies, conduct a
16 study of trade in tobacco products that involves the
17 passage of such products either from or to any for-
18 eign country across any border of the United States,
19 to—

20 (A) collect data on such trade in tobacco
21 products, including illicit trade involving to-
22 bacco products, and make recommendations on
23 the monitoring of such trade;

24 (B) collect data on any advertising in-
25 tended to be broadcast, transmitted, or distrib-
26 uted from the United States to another country

1 and make recommendations on how to prevent
 2 or eliminate, and what technologies could help
 3 facilitate the elimination of, such advertising;
 4 and

5 (C) collect data on such trade in tobacco
 6 products by a person that is not—

7 (i) a participating manufacturer (as
 8 that term is defined in section II(jj) of the
 9 Master Settlement Agreement of November
 10 23, 1998, between certain of the States
 11 and certain tobacco product manufactur-
 12 ers); or

13 (ii) an affiliate or subsidiary of a par-
 14 ticipating manufacturer.

15 (2) REPORT.—Not later than 18 months after
 16 the effective date of this Act, the Administrator shall
 17 submit to the Secretary, and the appropriate com-
 18 mittees of Congress, a report concerning the study
 19 conducted under paragraph (1).

20 **SEC. 107. ADULTERATED TOBACCO PRODUCTS.**

21 A tobacco product shall be deemed to be adulter-
 22 ated—

23 (1) if such product bears or contains any poi-
 24 sonous or deleterious substance other than—

25 (A) tobacco;

1 (B) a substance naturally present in to-
2 bacco;

3 (C) a pesticide or fungicide chemical res-
4 idue in or on tobacco if such pesticide or fun-
5 gicide chemical is registered by the Environ-
6 mental Protection Agency for use on tobacco in
7 the United States; or

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

10 (i) is approved for use in the country
11 of origin of the tobacco; or

12 (ii) has not been banned, and the reg-
13 istration of which has not been canceled,
14 by the Environmental Protection Agency
15 for use on tobacco in the United States
16 that may render it injurious to health, but
17 in the event that the substance is not an
18 added substance, such tobacco product
19 shall not be considered adulterated under
20 this subsection if the quantity of such sub-
21 stance in such tobacco product does not or-
22 dinarily render it injurious to health;

23 (2) if there is significant scientific agreement
24 that, as a result of the tobacco that such product
25 contains, such product presents a risk to human

1 health that is materially higher than the risk pre-
2 sented by—

3 (A) such product on the effective date of
4 this Act; or

5 (B) if such product was not distributed
6 commercially domestically on that date, by com-
7 parable tobacco products of the same style and
8 within the same category that were commer-
9 cially distributed domestically on that date;

10 (3) if such product has been prepared, packed,
11 or held under unsanitary conditions whereby it may
12 have become contaminated with filth;

13 (4) if the package of such product is composed,
14 in whole or in part, of any poisonous or deleterious
15 substance that may render the contents injurious to
16 health;

17 (5) if the tar yield of such product is in viola-
18 tion of section 502; or

19 (6) if such product is not in compliance with
20 the standard prescribed by section 803.

21 **SEC. 108. MISBRANDED TOBACCO PRODUCTS.**

22 A tobacco product shall be deemed to be mis-
23 branded—

24 (1) if the labeling of such product is false or
25 misleading in any particular;

1 (2) if such product is in package form unless
2 the product bears a label containing—

3 (A) an identification of the type of prod-
4 uct, by the common or usual name of such type
5 of product;

6 (B) an accurate statement of the quantity
7 of the contents in the package in terms of
8 weight, measure, or numerical count, except
9 that reasonable variations shall be permitted,
10 and exemptions as to small packages shall be
11 established by regulations promulgated by the
12 Administrator;

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

16 (D) the information required by section
17 601(c) and (e) or section 602(c) and (e), as ap-
18 plicable;

19 (3) if any word, statement, or other information
20 required by or under authority of this Act to appear
21 on the label, labeling, or advertising of such product
22 is not prominently placed thereon with such con-
23 spicuousness (as compared with other words, state-
24 ments, or designs on the label, labeling, or adver-
25 tising, as applicable) and in such terms as to render

1 it reasonably likely to be read and understood by the
2 ordinary individual under customary conditions of
3 purchase and use;

4 (4) if any word, statement, or other information
5 is required by this Act to appear on the label of such
6 product, unless such word, statement, or other infor-
7 mation also appears on the outside container or
8 wrapper, if any, of the retail package of such to-
9 bacco product, or is easily legible through the out-
10 side container or wrapper;

11 (5) if such product was manufactured, pre-
12 pared, or processed in an establishment not duly
13 registered under section 109, if such product was
14 not included in a list required by section 109, or if
15 a notice or other information with respect to such
16 product was not provided as required by section 109;

17 (6) if the packaging, labeling, or advertising of
18 such product is in violation of this Act or of an ap-
19 plicable regulation promulgated in accordance with
20 this Act;

21 (7) if such product contains tobacco or another
22 ingredient as to which a required disclosure under
23 this Act was not made;

1 (8) if such product is labeled or advertised, or
2 the tobacco contained in such product is advertised,
3 as—

4 (A) containing “no additives” or any sub-
5 stantially similar term, unless the labeling or
6 advertising, as applicable, also contains, clearly
7 and prominently, the following disclosure: “No
8 additives in our tobacco does NOT mean safer”;
9 or

10 (B) being “natural”, or any substantially
11 similar term, unless the labeling or advertising,
12 as applicable, also contains, clearly and promi-
13 nently, the following disclosure: “Natural does
14 NOT mean safer”;

15 (9) if in the labeling or advertising of such
16 product a term descriptive of the tobacco in the to-
17 bacco product is used otherwise than in accordance
18 with a sanction or approval granted by a Federal
19 agency;

20 (10) if with respect to such product a disclosure
21 required by section 603 was not made;

22 (11) if with respect to such product a certifi-
23 cation required by section 803 was not submitted or
24 is materially false or misleading; or

1 (12) if the manufacturer or distributor of such
2 product made with respect to the product a claim
3 prohibited by section 301.

4 **SEC. 109. REGISTRATION AND LISTING.**

5 (a) DEFINITIONS.—In this section:

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

17 (2) NAME.—The term “name” includes, in the
18 case of a partnership, the name of the general part-
19 ner and, in the case of a privately held corporation,
20 the name of the chief executive officer of the cor-
21 poration and the State of incorporation.

22 (b) ANNUAL REGISTRATION.—Not later than Decem-
23 ber 31, 2010, and December 31 of each year thereafter,
24 a person that owns or operates any establishment in any
25 State engaged in the manufacture, preparation, or proc-

1 essing of a tobacco product or products for commercial
2 distribution domestically shall register with the Adminis-
3 trator its name, places of business, and all such establish-
4 ments.

5 (c) NEW PRODUCERS.—A person, upon first engag-
6 ing, for commercial distribution domestically, in the manu-
7 facture, preparation, or processing of a tobacco product
8 or products in any establishment that it owns or operates
9 in any State, shall immediately register with the Adminis-
10 trator its name, places of business, and such establish-
11 ment.

12 (d) REGISTRATION OF FOREIGN ESTABLISH-
13 MENTS.—

14 (1) IN GENERAL.—Not later than December 31,
15 2010, and December 31 of each year thereafter, a
16 person that, within any foreign country, owns or op-
17 erates any establishment engaged in the manufac-
18 ture, preparation, or processing of a tobacco product
19 that is imported or offered for import into the
20 United States shall, through electronic means or
21 otherwise as permitted by the Administrator, reg-
22 ister with the Administrator the name and place of
23 business of each such establishment, the name of the
24 United States agent for the establishment, and the

1 name of each importer of such tobacco product in
2 the United States that is known to such person.

3 (2) OTHER INFORMATION.—A person described
4 in paragraph (1) shall, in addition to the informa-
5 tion required under paragraph (1), provide the infor-
6 mation required by subsection (j), including sales
7 made by mail or through the Internet, or other elec-
8 tronic means.

9 (3) COOPERATIVE AGREEMENTS.—The Admin-
10 istrator may enter into cooperative arrangements
11 with officials of foreign countries to ensure that ade-
12 quate and effective means are available for purposes
13 of determining, from time to time, whether tobacco
14 products manufactured, prepared, or processed by
15 an establishment described in paragraph (1), if im-
16 ported or offered for import into the United States,
17 shall be refused admission on any of the grounds set
18 forth in section 708.

19 (e) ADDITIONAL ESTABLISHMENTS.—A person duly
20 registered in accordance with the preceding subsections of
21 this section shall immediately register with the Adminis-
22 trator any additional establishment that it owns or oper-
23 ates and in which it begins the manufacture, preparation,
24 or processing of a tobacco product or products for com-

1 mercial distribution domestically or for import into the
2 United States.

3 (f) EXCLUSIONS FROM APPLICATION OF THIS SEC-
4 TION.—The preceding subsections of this section shall not
5 apply to—

6 (1) persons that manufacture, prepare, or proc-
7 ess tobacco products solely for use in research,
8 teaching, chemical or biological analysis, or export;
9 or

10 (2) such other classes of persons as the Admin-
11 istrator may by regulation exempt from the applica-
12 tion of this section upon a finding that registration
13 by such classes of persons in accordance with this
14 section is not necessary for the protection of the
15 public health.

16 (g) INSPECTION OF PREMISES.—An establishment
17 registered with the Administrator pursuant to this section
18 shall be subject to inspection pursuant to section 706. An
19 established described in the preceding sentence that is en-
20 gaged in the manufacture, preparation, or processing of
21 a tobacco product or products shall be inspected under
22 section 706 by 1 or more officers or employees duly des-
23 igned by the Administrator at least once in the 2-year
24 period beginning with the date of registration of such es-
25 tablishment pursuant to this section and at least once in

1 every successive 2-year period thereafter, except that the
2 inspection of establishments outside the United States
3 may be conducted by other personnel pursuant to a coop-
4 erative arrangement under subsection (d)(3).

5 (h) FILING OF LISTS OF TOBACCO PRODUCTS MANU-
6 FACTURED, PREPARED, OR PROCESSED BY REGISTRANTS;
7 STATEMENTS; ACCOMPANYING DISCLOSURES.—

8 (1) FILING OF LISTS.—A person that registers
9 with the Administrator under subsection (b), (c),
10 (d), or (e) shall, at the time of such registration, file
11 with the Administrator a list of all brand styles
12 (with each brand style in each list listed by the com-
13 mon or usual name of the tobacco product category
14 to which it belongs and by any proprietary name)
15 that are being manufactured, prepared, or processed
16 by such person for commercial distribution domesti-
17 cally or for import into the United States, and that
18 such person has not included in any list of tobacco
19 products filed by such person with the Administrator
20 under this paragraph or paragraph (2) prior to such
21 time of registration. Such list shall be prepared in
22 such form and manner as the Administrator may
23 prescribe, and shall be accompanied by the label for
24 each such brand style and a representative sampling

1 of any other labeling and advertising for each such
2 brand style.

3 (2) REPORTS OF INFORMATION.—A person that
4 registers with the Administrator under this section
5 (referred in this paragraph as the “registrant”) shall
6 report to the Administrator, not later than August
7 30 the preceding 6-month period from January
8 through June, and not later than February 28 (or
9 29 as applicable) for the preceding 6-month period
10 from July through December, each year the fol-
11 lowing information:

12 (A) A list of each brand style introduced
13 by the registrant for commercial distribution
14 domestically or for import into the United
15 States that has not been included in any list
16 previously filed by such registrant with the Ad-
17 ministrator under this subparagraph or para-
18 graph (1). A list under this subparagraph shall
19 list a brand style by the common or usual name
20 of the tobacco product category to which it be-
21 longs and by any proprietary name, and shall
22 be accompanied by the other information re-
23 quired by paragraph (1).

24 (B) If, subsequent to the date on which
25 the registrant last made a report under this

1 paragraph (or if such registrant has not pre-
2 viously made a report under this paragraph,
3 after the effective date of this Act), such reg-
4 istrant has discontinued the manufacture, prep-
5 aration, or processing for commercial distribu-
6 tion domestically or for import into the United
7 States of a brand style included in a list filed
8 by such registrant under subparagraph (A) or
9 paragraph (1), notice of such discontinuance,
10 the date of such discontinuance, and the iden-
11 tity (by the common or usual name of the to-
12 bacco product category to which it belongs and
13 by any proprietary name) of such tobacco prod-
14 uct.

15 (C) If, subsequent to the date on which the
16 registrant reported pursuant to subparagraph
17 (B) a notice of discontinuance of a tobacco
18 product, the registrant has resumed the manu-
19 facture, preparation, or processing for commer-
20 cial distribution domestically or for import into
21 the United States of that brand style, notice of
22 such resumption, the date of such resumption,
23 the identity of such brand style (by the common
24 or usual name of the tobacco product category
25 to which it belongs and by any proprietary

1 name), and the other information required by
2 paragraph (1), unless the registrant has pre-
3 viously reported such resumption to the Admin-
4 istrator pursuant to this subparagraph.

5 (D) Any material change in any informa-
6 tion previously submitted pursuant to this para-
7 graph or paragraph (1).

8 (i) **ELECTRONIC REGISTRATION.**—A registration
9 under subsection (b), (c), (d), or (e) (including the submis-
10 sion of updated information) shall be submitted to the Ad-
11 ministrator by electronic means, unless the Administrator
12 grants a request for a waiver of such requirement because
13 the use of electronic means is not reasonable for the per-
14 son requesting such waiver.

15 **SEC. 110. EFFECTIVE DATE.**

16 Except as otherwise specifically provided, this Act
17 shall be effective on the date of enactment of this Act.

1 **TITLE II—RESTRICTIONS ON**
2 **YOUTH ACCESS TO TOBACCO**
3 **PRODUCTS AND EXPOSURE**
4 **OF YOUTH TO TOBACCO**
5 **PRODUCT MARKETING AND**
6 **ADVERTISING**

7 **SEC. 201. PROHIBITIONS ON YOUTH TARGETING.**

8 Effective 18 months after the date of enactment of
9 this Act, no person shall engage in any of the following
10 activities or practices in the advertising, promotion, or
11 marketing of any tobacco product:

12 (1) The use, or causing the use, of any cartoon
13 in the advertising, promoting, packaging, or labeling
14 of any tobacco product.

15 (2) The use, or causing the use, of any human
16 image in the advertising, promoting, packaging, or
17 labeling of any tobacco product, except for the fol-
18 lowing:

19 (A) The use, or continued use, in adver-
20 tising, promoting, marketing, packaging, or la-
21 beling of any human image appearing on a to-
22 bacco product package before December 31,
23 2009.

24 (B) The use, or continued use, of a human
25 image in the advertising, promoting, or mar-

1 keting of a tobacco product, if conducted solely
2 in an adult-only facility or facilities.

3 (C) The use, or continued use, of a human
4 image in a tobacco product communication
5 means directed solely to persons that the to-
6 bacco product manufacturer has a good-faith
7 belief are age-verified adults.

8 (3) The advertising of tobacco products in any
9 magazine or newspaper intended for distribution to
10 the general public.

11 (4) The engaging in any brand name sponsor-
12 ship in the United States, other than a brand name
13 sponsorship occurring solely in an adult-only facility
14 or facilities.

15 (5) The engaging in any brand name sponsor-
16 ship of any event in the United States in which any
17 paid participants or contestants are youth.

18 (6) The sponsoring of any athletic event be-
19 tween opposing teams in any football, basketball,
20 baseball, soccer, or hockey league.

21 (7)(A) The securing of a right, by agreement,
22 to name any stadium or arena located within the
23 United States with a brand name; or

1 (B) otherwise causing a stadium or arena lo-
2 cated within the United States to be named with a
3 brand name.

4 (8) The securing of a right by agreement pur-
5 suant to which payment is made or other consider-
6 ation is provided to use a brand name in association
7 with any football, basketball, baseball, soccer, or
8 hockey league, or any team involved in any such
9 league.

10 (9) The use of, or causing the use of, by agree-
11 ment requiring the payment of money or other con-
12 sideration, a brand name with any nationally recog-
13 nized or nationally established trade name or brand
14 designation of any non-tobacco item or service, or
15 any nationally recognized or nationally established
16 sports team, entertainment group or individual ce-
17 lebrity for purposes of advertising, except for an
18 agreement between or among persons that enter into
19 such agreement for the sole purpose of avoiding in-
20 fringement claims.

21 (10) The license, express authorization, or oth-
22 erwise causing of any person to use or advertise
23 within the United States any brand name in a man-
24 ner that—

1 (A) does not pertain to a tobacco product;

2 or

3 (B) causes that person to use the brand
4 name to advertise, promote, package or label,
5 distribute, or sell any product or service that is
6 not a tobacco product.

7 (11) The marketing, distribution, offering, sell-
8 ing, licensing, or authorizing of, or the causing to be
9 marketed, distributed, offered, sold, licensed, or au-
10 thORIZED, any apparel or other merchandise bearing
11 a brand name, except—

12 (A) apparel or other merchandise that is
13 used by individuals representing a tobacco prod-
14 uct manufacturer within an adult-only facility
15 and that is not distributed, by sale or otherwise,
16 to any member of the general public;

17 (B) apparel or merchandise provided to an
18 adult employee of a tobacco product manufac-
19 turer for use by such employee;

20 (C) items or materials used to hold or dis-
21 play tobacco products at retail;

22 (D) items or materials the sole function of
23 which is to advertise tobacco products;

24 (E) written or electronic publications;

1 (F) coupons or other items used by adults
2 solely in connection with the purchase of to-
3 bacco products;

4 (G) that the composition, structure, form,
5 or appearance of any tobacco product, package,
6 label, or labeling shall not be affected by the
7 prohibitions of this paragraph; and

8 (H) that no person shall be required to re-
9 trieve, collect, or otherwise recover any item or
10 material that was marketed, distributed, of-
11 fered, sold, licensed, or caused to be marketed,
12 distributed, offered, sold, or licensed by such
13 person;

14 (12) The distribution, or causing the distribu-
15 tion, of any free sample domestically, except in an
16 adult-only facility or facilities to individuals who are
17 age-verified adults.

18 (13) The making of, or causing to be made, any
19 payment or the payment of, or causing to be paid,
20 any other consideration to any other person to use,
21 display, make reference to, or use as a prop in any
22 performance medium any tobacco product, tobacco
23 product package, advertisement for a tobacco prod-
24 uct, or any other item bearing a brand name. For
25 the purposes of this paragraph, the terms “perform-

1 ance medium” and “performance media” mean any
2 motion picture, television show, theatrical production
3 or other live performance, live or recorded perform-
4 ance of music, commercial film or video, or video
5 game. This paragraph shall not apply to the fol-
6 lowing:

7 (A) Performance media for which the audi-
8 ence or viewers are within 1 or more adult-only
9 facilities, if such performance media are not au-
10 dible or visible to persons outside such adult-
11 only facility or facilities.

12 (B) Performance media not intended to be
13 heard or viewed by the general public.

14 (C) Instructional performance media that
15 concern tobacco products and their use, and
16 that are intended to be heard or viewed only by,
17 or provided only to, age-verified adults.

18 (D) Performance media used in tobacco
19 product communications to age-verified adults.

20 (14) Engaging in outdoor advertising or transit
21 advertisements of tobacco products within the
22 United States, except for the following:

23 (A) Advertising that is within an adult-
24 only facility.

1 (B) The use of outdoor advertising for
2 purposes of identification of an adult-only facil-
3 ity, to the extent that such outdoor advertising
4 is placed at the site, premises, or location of the
5 adult-only facility.

6 (C) The use of outdoor advertising in iden-
7 tifying a brand name sponsorship at an adult-
8 only facility, if such outdoor advertising—

9 (i) is placed at the site, premises, or
10 location of the adult-only facility where
11 such brand name sponsorship will occur no
12 more than 30 days before the start of the
13 initial sponsored event; and

14 (ii) is removed within 10 days after
15 the end of the last sponsored event.

16 (15) The distribution or sale domestically of
17 any package or other container of cigarettes con-
18 taining fewer than 20 cigarettes.

19 (16) The advertising of tobacco products on any
20 broadcast, cable, or satellite transmission to a tele-
21 vision or radio receiver, or other medium of elec-
22 tronic communication subject to the jurisdiction of
23 the Federal Communications Commission, except
24 electronic communications—

1 (A) contained on log-in or home pages con-
2 taining no tobacco product advertising other
3 than brand name identification;

4 (B) in an adult-only facility or facilities;

5 (C) through the Internet or other indi-
6 vidual user-accessible electronic communication
7 means, including websites accessible using the
8 Internet, if the advertiser takes reasonable ac-
9 tion to restrict access to individuals who are
10 adults by—

11 (i) requiring individuals accessing
12 such electronic communications to be age-
13 verified adults; and

14 (ii) making good-faith efforts to verify
15 that such individuals are adults.

16 (17) The distribution or sale of tobacco prod-
17 ucts directly to consumers by mail or courier, unless
18 the person receiving purchase requests for tobacco
19 products takes reasonable action to prevent delivery
20 to individuals who are not adults by—

21 (A) requiring that the addressees of the to-
22 bacco products be age-verified adults;

23 (B) making good faith efforts to verify
24 that such addressees are adults; and

1 (C) addressing the tobacco products deliv-
2 ered by mail, courier or common carrier to a
3 physical address and not a post office box.

4 (18) The providing of any gift of a non-tobacco
5 product, except matches, in connection with the pur-
6 chase of a tobacco product.

7 (19) The engaging in the sponsorship or pro-
8 motion, or causing the sponsorship or promotion, of
9 any consumer sweepstakes, contest, drawing, or
10 similar activity resulting in the award of a prize in
11 connection with advertising.

12 (20) The offering, promoting, conducting, or
13 authorizing, or causing to be offered, promoted, con-
14 ducted, or authorized, any consumer sweepstakes,
15 drawing, contest, or other activity resulting in the
16 awarding of a prize, based on redemption of a proof-
17 of-purchase, coupon, or other item awarded as a re-
18 sult of the purchase or use of a tobacco product.

19 (21) The making of, or causing to be made, any
20 payment or the payment of, or causing to be paid,
21 any other consideration, to any other person with re-
22 gard to the display or placement of any cigarettes,
23 or any advertising for cigarettes, in any retail estab-
24 lishment that is not an adult-only facility.

1 **SEC. 202. STATE LAW REGARDING SALE OF TOBACCO**
2 **PRODUCTS TO INDIVIDUALS UNDER AGE OF**
3 **18.**

4 Section 1926 of the Public Health Service Act (42
5 U.S.C. 300x-26) is amended by adding at the end the fol-
6 lowing:

7 “(e) ELEMENTS OF STATE DISTRIBUTION LAW.—

8 “(1) IN GENERAL.—Subject to paragraphs (2)
9 and (3), for fiscal year 2010 and each subsequent
10 fiscal year, the Secretary shall reduce, as provided
11 for in subsection (h), the amount of any grant under
12 section 1921 for any State that does not have in ef-
13 fect a law with substantially the following provisions:

14 **“SECTION 1. DISTRIBUTION TO MINORS.**

15 ““(a) No person shall distribute a tobacco product
16 to an individual under 18 years of age or a different min-
17 imum age established under State law. A person who vio-
18 lates this subsection shall be liable for a civil money pen-
19 alty of not less than \$25 nor more than \$125 for each
20 violation of this subsection.

21 ““(b) The employer of an employee who has violated
22 subsection (a) twice while in the employ of such employer
23 shall be liable for a civil money penalty of \$125 for each
24 subsequent violation by such employee.

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

1 “(1) the defendant—

2 “(A) relied upon proof of age that ap-
3 peared on its face to be valid in accordance with
4 the Federal Tobacco Act of 2009;

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

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

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

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

15 “(a) An individual under 18 years of age or a dif-
16 ferent minimum age established under State law shall not
17 purchase or attempt to purchase, receive or attempt to re-
18 ceive, possess or attempt to possess, a tobacco product.
19 An individual who violates this subsection shall be liable
20 for a civil money penalty of not less than \$25 nor more
21 than \$125 for each such violation, and shall be required
22 to perform not less than 4 hours nor more than 10 hours
23 of community service. Upon the second or each subsequent
24 violation of this subsection, such individual shall be re-

1 quired to perform not less than 8 hours nor more than
2 20 hours of community service.

3 “(b) A law enforcement agency, upon determining
4 that an individual under 18 years of age or a different
5 minimum age established under State law allegedly pur-
6 chased, received, possessed, or attempted to purchase, re-
7 ceive, or possess, a tobacco product in violation of sub-
8 section (a) shall notify the individual’s parent or parents,
9 custodian, or guardian as to the nature of the alleged vio-
10 lation if the name and address of a parent or parents,
11 guardian, or custodian is reasonably ascertainable by the
12 law enforcement agency. The notice required by this sub-
13 section shall be made not later than 48 hours after the
14 individual who allegedly violated subsection (a) is cited by
15 such agency for the violation. The notice may be made
16 by any means reasonably calculated to give prompt actual
17 notice, including notice in person, by telephone, or by first-
18 class mail.

19 “(c) Subsection (a) shall not be construed to pro-
20 hibit an individual under 18 years of age or a different
21 minimum age established under State law from possessing
22 a tobacco product during regular working hours and in
23 the course of such individual’s employment if the tobacco
24 product is not possessed for such individual’s consump-
25 tion.

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

2 “It shall be unlawful for any person to distribute
3 cigarettes or a smokeless tobacco product other than in
4 an unopened package that complies in full with section
5 108 of the Federal Tobacco Act of 2009. A person who
6 distributes a cigarette or a smokeless tobacco product in
7 violation of this section shall be liable for a civil money
8 penalty of not less than \$25 nor more than \$125 for each
9 such violation.

10 **“SEC. 4. SIGNAGE.**

11 “It shall be unlawful for any person who sells to-
12 bacco products over-the-counter to fail to post conspicu-
13 ously on the premises where such person sells tobacco
14 products over-the-counter a sign communicating that—

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

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

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

24 A person who fails to post a sign that complies fully with
25 this section shall be liable for a civil money penalty of not
26 less than \$25 nor more than \$125.

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

2 ““(a) Not later than 180 days of the effective date
3 of this Act, a person engaged in the business of selling
4 tobacco products at retail shall implement a program to
5 notify each employee employed by that person who sells
6 tobacco products at retail that—

7 ““(1) the sale or other distribution of tobacco
8 products to any individual under 18 years of age or
9 a different minimum age established under State
10 law, and the purchase, receipt, or possession of to-
11 bacco products in a place open to the public by any
12 individual under 18 years of age or a different min-
13 imum age established under State law, is prohibited;
14 and

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

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

20 ““(b) It shall be a defense to a charge that an em-
21 ployer violated subsection (a) that the employee acknowl-
22 edged receipt, either in writing or by electronic means,
23 prior to the alleged violation, of a statement in substan-
24 tially the following form: “I understand that State law
25 prohibits the distribution of tobacco products to individ-
26 uals under 18 years of age or a different minimum age

1 established under State law and out-of-package distribu-
2 tion of cigarettes and smokeless tobacco products, and
3 permits a defense based on evidence that a prospective
4 purchaser's proof of age was reasonably relied upon and
5 appeared on its face to be valid. I understand that if I
6 sell, give, or voluntarily provide a tobacco product to an
7 individual under 18 years of age or a different minimum
8 age established under State law, I may be found respon-
9 sible for a civil money penalty of not less than \$25 nor
10 more than \$125 for each violation. I promise to comply
11 with this law”.

12 ““(c) If an employer is charged with a violation of
13 subsection (a) and the employer uses as a defense to such
14 charge the defense provided by subsection (b), the em-
15 ployer shall be deemed to be liable for such violation if
16 such employer pays the penalty imposed on the employee
17 involved in such violation or in any way reimburses the
18 employee for such penalty.

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

20 ““(a) It shall be unlawful for any person who sells
21 tobacco products over-the-counter at retail to maintain
22 packages of such products in any location accessible to
23 customers that is not under the control of a cashier or
24 other employee during regular business hours. This sub-
25 section shall not apply to any adult-only facility.

1 “(b) Any person who violates subsection (a) shall be
2 liable for a civil money penalty of not less than \$25 nor
3 more than \$125 for each such violation, except that no
4 person shall be responsible for more than one violation per
5 day at any one retail store.

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

7 “(a) It shall be unlawful to distribute or sell tobacco
8 products directly to consumers by mail or courier, unless
9 the person receiving such purchase requests for tobacco
10 products takes reasonable action to prevent delivery to in-
11 dividuals who are not adults by—

12 “(1) requiring that addressees of the tobacco
13 products be age-verified adults;

14 “(2) making good faith efforts to verify that
15 such addressees have attained the minimum age for
16 purchase of tobacco products established by the re-
17 spective States wherein the addresses of the address-
18 ees are located; and

19 “(3) addressing the tobacco products delivered
20 by mail or courier to a physical addresses and not
21 to post office boxes.

22 “(b) Any person who violates subsection (a) shall be
23 liable for a civil money penalty of not less than \$25 nor
24 more than \$125 for each such violation.

1 **“SEC. 8. RANDOM UNANNOUNCED INSPECTIONS; REPORT-**
2 **ING; AND COMPLIANCE.**

3 “(a) The State Police, or a local law enforcement
4 authority duly designated by the State Police, shall en-
5 force this Act in a manner that can reasonably be expected
6 to reduce the extent to which tobacco products are distrib-
7 uted to individuals under 18 years of age or a different
8 minimum age established under State law and shall con-
9 duct random, unannounced inspections in accordance with
10 the procedures set forth in this Act and in regulations
11 issued under section 1926 of the Public Health Service
12 Act (42 U.S.C. 300x-26).

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

19 “(1) Prior to the use of any individual under
20 18 years of age or a different minimum age estab-
21 lished under State law in a random, unannounced
22 inspection, written consent shall be obtained from a
23 parent, custodian, or guardian of such individual.

24 “(2) An individual under 18 years of age or a
25 different minimum age established under State law
26 shall act solely under the supervision and direction

1 of the State Police or a local law enforcement au-
2 thority duly designated by the State Police during a
3 random, unannounced inspection.

4 ““(3) An individual under 18 years of age or a
5 different minimum age established under State law
6 used in random, unannounced inspections shall not
7 be used in any such inspection at a store in which
8 such individual is a regular customer.

9 ““(4) If an individual under 18 years of age or
10 a different minimum age established under State law
11 participating in random, unannounced inspections is
12 questioned during such an inspection about such in-
13 dividual’s age, such individual shall state his or her
14 actual age and shall present a true and correct proof
15 of age if requested at any time during the inspection
16 to present it.

17 ““(c) Any person who uses any individual under 18
18 years of age or a different minimum age established under
19 State law, other than as permitted by subsection (b), to
20 test compliance with this Act, shall be liable for a civil
21 money penalty of not less than \$25 nor more than \$125
22 for each such violation.

23 ““(d) Civil money penalties collected for violations of
24 this Act and fees collected under section 9 shall be used

1 only to defray the costs of administration and enforcement
2 of this Act.

3 **“SEC. 9. LICENSURE.**

4 “(a) Each person engaged in the over-the-counter
5 distribution at retail of tobacco products shall hold a li-
6 cense issued under this section. A separate license shall
7 be required for each place of business where tobacco prod-
8 ucts are distributed at retail. A license issued under this
9 section is not assignable and is valid only for the person
10 in whose name it is issued and for the place of business
11 designated in the license.

12 “(b) The annual license fee is \$25 for each place
13 of business where tobacco products are distributed at re-
14 tail.

15 “(c) Every application for a license, including re-
16 newal of a license, under this section shall be made upon
17 a form provided by the Tobacco Regulatory Agency, and
18 shall set forth the name under which the applicant trans-
19 acts or intends to transact business, the location of the
20 place of business for which the license is to be issued, the
21 street address to which all notices relevant to the license
22 are to be sent (in this Act referred to as “notice address”),
23 and any other identifying information that the Tobacco
24 Regulatory Agency may require.

1 “(d) The Tobacco Regulatory Agency shall issue or
2 renew a license or deny an application for a license or the
3 renewal of a license within 30 days of receiving a properly
4 completed application and the license fee. The Tobacco
5 Regulatory Agency shall provide notice to an applicant of
6 action on an application denying the issuance of a license
7 or refusing to renew a license.

8 “(e) Every license issued by the Tobacco Regulatory
9 Agency pursuant to this section shall be valid for 1 year
10 from the date of issuance and shall be renewed upon appli-
11 cation except as otherwise provided in this Act.

12 “(f) Upon notification of a change of address for a
13 place of business for which a license has been issued, a
14 license shall be reissued for the new address without the
15 filing of a new application.

16 “(g) The Tobacco Regulatory Agency shall notify
17 every person in the State who is engaged in the distribu-
18 tion at retail of tobacco products of the license require-
19 ments of this section and of the date by which such person
20 should have obtained a license.

21 “(h)(1) Except as provided in paragraph (2), any
22 person who engages in the distribution at retail of tobacco
23 products without a license required by this section shall
24 be liable for a civil money penalty in an amount equal to—

25 “(A) 2 times the applicable license fee; and

1 “(B) \$50 for each day that such distribution
2 continues without a license.

3 “(2) Any person who engages in the distribution at
4 retail of tobacco products after a license issued under this
5 section has been suspended or revoked is liable for a civil
6 money penalty of \$100 per day for each day on which such
7 distribution continues after the date such person received
8 notice of such suspension or revocation.

9 “(i) No person shall engage in the distribution at
10 retail of tobacco products on or after 180 days after the
11 date of enactment this Act unless such person is author-
12 ized to do so by a license issued pursuant to this section
13 or is an employee or agent of a person that has been
14 issued such a license.

15 **“SEC. 10. SUSPENSION, REVOCATION, DENIAL, AND NON-**
16 **RENEWAL OF LICENSES.**

17 “(a) Upon a finding that a licensee has been deter-
18 mined by a court of competent jurisdiction to have violated
19 this Act during the license term, the State shall notify the
20 licensee in writing, served personally or by registered mail
21 at the notice address, that any subsequent violation of this
22 Act at the same place of business may result in an admin-
23 istrative action to suspend the license for a period deter-
24 mined by the Tobacco Regulatory Agency.

1 “(b) Upon finding that a further violation by this
2 Act has occurred involving the same place of business for
3 which the license was issued and the licensee has been
4 served notice once under subsection (a), the Tobacco Reg-
5 ulatory Agency may initiate an administrative action to
6 suspend the license for a period to be determined by the
7 Tobacco Regulatory Agency but not to exceed 6 months.
8 If an administrative action to suspend a license is initi-
9 ated, the Tobacco Regulatory Agency shall immediately
10 notify the licensee in writing at the notice address of the
11 initiation of the action and the reasons therefor and per-
12 mit the licensee an opportunity, at least 30 days after
13 written notice is served personally or by registered mail
14 upon the licensee, to show why suspension of the license
15 would be unwarranted or unjust.

16 “(c) The Tobacco Regulatory Agency may initiate
17 an administrative action to revoke a license that previously
18 has been suspended under subsection (b) if, after the sus-
19 pension and during the 1-year period for which the license
20 was issued, the licensee committed a further violation of
21 this Act, at the same place of business for which the li-
22 cense was issued. If an administrative action to revoke a
23 license is initiated, the Tobacco Regulatory Agency shall
24 immediately notify the licensee in writing at the notice ad-
25 dress of the initiation of the action and the reasons there-

1 fore and permit the licensee an opportunity, at least 30
2 days after written notice is served personally or by reg-
3 istered mail upon the licensee, to show why revocation of
4 the license would be unwarranted or unjust.

5 “(d) A person whose license has been suspended or
6 revoked with respect to a place of business pursuant to
7 this section shall pay a fee of \$50 for the renewal or
8 reissuance of the license at that same place of business,
9 in addition to any applicable annual license fees.

10 “(e) Revocation of a license under subsection (c)
11 with respect to a place of business shall not be grounds
12 to deny an application by any person for a new license
13 with respect to such place of business for more than 12
14 months subsequent to the date of such revocation. Revoca-
15 tion or suspension of a license with respect to a particular
16 place of business shall not be grounds to deny an applica-
17 tion for a new license, to refuse to renew a license, or to
18 revoke or suspend an existing license at any other place
19 of business.

20 “(f) A licensee may seek judicial review of an action
21 of the Tobacco Regulatory Agency suspending, revoking,
22 denying, or refusing to renew a license under this section
23 by filing a complaint in a court of competent jurisdiction.
24 Any such complaint shall be filed within 30 days after the

1 date on which notice of the action is received by the li-
2 censee. The court shall review the evidence de novo.

3 “(g) The State shall not report any action sus-
4 pending, revoking, denying, or refusing to renew a license
5 under this section to the Secretary of Health and Human
6 Services, unless the opportunity for judicial review of the
7 action pursuant to subsection (f), if any, has been ex-
8 hausted or the time for seeking such judicial review has
9 expired.

10 **“SEC. 11. NO PRIVATE RIGHT OF ACTION.**

11 “Nothing in this Act shall be construed to create
12 a right of action by any private person for any violation
13 of any provision of this Act.

14 **“SEC. 12. JURISDICTION AND VENUE.**

15 “Any action alleging a violation of this Act may be
16 brought only in a court of general jurisdiction in the city
17 or county where the violation is alleged to have occurred.

18 **“SEC. 13. REPORT.**

19 “The Tobacco Regulatory Agency shall prepare for
20 submission annually to the Secretary of Health and
21 Human Services the report required by section 1926 of
22 the Public Health Service Act (42 U.S.C. 300x-26).

23 **“SEC. 14. DEFINITIONS.**

24 “For purposes of this Act:

1 “(1) The term “adult-only facility” shall have
2 the meaning given such term in section 3 of the
3 Federal Tobacco Act of 2009.

4 “(2) The term “age-verified adult” shall have
5 the meaning given such term in section 3 of the
6 Federal Tobacco Act of 2009.

7 “(3) The term “package” means a pack, box,
8 or container of any kind or, if not a container, any
9 wrapping (including cellophane), in which a tobacco
10 product or products are offered for sale, sold, or oth-
11 erwise distributed to consumers, and includes car-
12 tons in which packages of tobacco products are con-
13 tained for sale, offer for sale, or otherwise distrib-
14 uted to consumers.

15 “(4) The term “proof of age” shall have the
16 meaning given such term in section 3 of the Federal
17 Tobacco Act of 2009.

18 “(5) The term “sample” shall have the mean-
19 ing given such term in section 3 of the Federal To-
20 bacco Act of 2009.

21 “(6) The term “tobacco product” shall have
22 the meaning given such term in section 3 of the
23 Federal Tobacco Act of 2009.

24 “(7) The term “under the control” means
25 within the reach of the cashier or other employee, or

1 otherwise protected by security, surveillance, or de-
2 tection methods, including electronic scanners, such
3 that the tobacco product cannot be purchased except
4 in a face-to-face transaction.’.

5 “(2) APPLICATION TO CERTAIN STATES.—In
6 the case of a State whose legislature does not con-
7 vene a regular session in fiscal year 2009, and in the
8 case of a State whose legislature does not convene
9 a regular session in fiscal year 2010, the require-
10 ment described in paragraph (1) as a condition of a
11 receipt of a grant under section 1921 shall apply
12 only for fiscal year 2011 and subsequent fiscal
13 years.

14 “(3) LIMITATION.—Paragraph (1) shall not af-
15 fect any State or local law that—

16 “(A) was in effect on the date of enact-
17 ment of the Federal Tobacco Act of 2009; and

18 “(B) covers the same subject matter as the
19 law described in paragraph (1).

20 Any State law that meets the conditions of this
21 paragraph shall also be deemed to meet the require-
22 ment described in paragraph (1) as a condition of a
23 receipt of a grant under section 1921, if such State
24 law is at least as stringent as the law described in
25 paragraph (1).

1 “(f) ENFORCING OF STATE LAW.—

2 “(1) IN GENERAL.—For the first applicable fis-
3 cal year and for each subsequent fiscal year, a fund-
4 ing agreement for a grant under section 1921 is a
5 funding agreement under which the State involved
6 will enforce the law described in subsection (e)(1) in
7 a manner that can reasonably be expected to reduce
8 the extent to which tobacco products are available to
9 individuals under the age of 18 or a different min-
10 imum age established under State law for the pur-
11 chase of tobacco products.

12 “(2) REQUIREMENTS.—For the first applicable
13 fiscal year and for each subsequent fiscal year, a
14 funding agreement for a grant under 1921 is a
15 funding agreement under which the State involved
16 will—

17 “(A) conduct random, unannounced in-
18 spections to ensure compliance with the law de-
19 scribed in subsection (e)(1); and

20 “(B) annually submit to the Secretary a
21 report describing—

22 “(i) the activities carried out by the
23 State to enforce such law during the fiscal
24 year preceding the fiscal year for which the
25 State is seeking the grant;

1 “(ii) the extent of success the State
2 has achieved in reducing the availability of
3 tobacco products to individuals under 18
4 years of age or a different minimum age
5 established under State law, including the
6 results of the inspections conducted under
7 subparagraph (A); and

8 “(iii) the strategies to be utilized by
9 the State for enforcing such law during the
10 fiscal year for which the grant is sought.

11 “(g) FUNDING SOURCES.—The law specified in sub-
12 section (e)(1) may be administered and enforced by a
13 State using—

14 “(1) any amounts made available to the State
15 through a grant under section 1921;

16 “(2) any amounts made available to the State
17 under section 1901;

18 “(3) any fees collected for licenses issued pursu-
19 ant to the law described in subsection (e)(1);

20 “(4) any fines or penalties assessed for viola-
21 tions of the law specified in subsection (e)(1); or

22 “(5) any other funding source that the legisla-
23 ture of the State may prescribe by law.

24 “(h) COMPLIANCE DETERMINATIONS.—Prior to
25 making a grant under section 1921 to a State for the first

1 applicable fiscal year or any subsequent fiscal year, the
2 Secretary shall make a determination of whether the State
3 has maintained compliance with subsections (e) and (f).
4 If, after notice to the State and an opportunity for a hear-
5 ing, the Secretary determines that the State is not in com-
6 pliance with such subsections, the Secretary shall reduce
7 the amount of the allotment under section 1921 for the
8 State for the fiscal year involved by an amount equal to—

9 “(1) in the case of the first applicable fiscal
10 year, 10 percent of the amount determined under
11 section 1933 for the 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 1933 for the State for the
15 fiscal year;

16 “(3) in the case of the second such fiscal year,
17 30 percent of the amount determined under section
18 1933 for the State for the fiscal year; and

19 “(4) in the case of the third such fiscal year or
20 any subsequent fiscal year, 40 percent of the amount
21 determined under section 1933 for the State for the
22 fiscal year.

23 The Secretary may not grant to any State a waiver of
24 the terms and requirements of this subsection or sub-
25 section (e) or (f).

1 “(i) DEFINITION.—For the purposes of subsections
2 (e) through (h), the term ‘first applicable fiscal year’
3 means—

4 “(1) fiscal year 2010, in the case of any State
5 described in subsection (e)(2); and

6 “(2) fiscal year 2009, in the case of any other
7 State.

8 “(j) REFERENCES.—For purposes of subsections (e)
9 through (h), references to section 1921 shall include any
10 successor grant programs to the programs established
11 under section 1921.

12 “(k) INDIANS.—

13 “(1) IN GENERAL.—As required by paragraph
14 (2), and subject to paragraph (5), an Indian tribe
15 shall satisfy the requirements of subsection (e)(1) by
16 enacting a law or ordinance with substantially the
17 same provisions as the law described in subsection
18 (e)(1).

19 “(2) COMPLIANCE.—An Indian tribe shall com-
20 ply with subsection (e)(1) within 180 days after the
21 Administrator finds, in accordance with this para-
22 graph, that—

23 “(A) the Indian tribe has a governing body
24 carrying out substantial governmental powers
25 and duties;

1 “(B) the functions to be exercised by the
2 Indian tribe under this subsection pertain to ac-
3 tivities on trust land within the jurisdiction of
4 the tribe; and

5 “(C) the Indian tribe is reasonably ex-
6 pected to be capable of carrying out the func-
7 tions required under this section.

8 Not later than 2 years of the date of enactment of
9 the Federal Tobacco Act of 2009, with respect to
10 each Indian tribe in the United States, the Adminis-
11 trator shall make the findings contemplated by this
12 paragraph or determine that such findings cannot be
13 made, in accordance with the procedures specified in
14 paragraph (5).

15 “(3) REGULATIONS.—With respect to an Indian
16 tribe that is subject to subsection (e)(1), the Admin-
17 istrator shall promulgate regulations that—

18 “(A) provide whether and to what extent if
19 any, the law described in subsection (e)(1) may
20 be modified as adopted by Indian tribes; and

21 “(B) ensure, to the extent possible, that
22 each Indian tribe’s retailer licensing program
23 under subsection (e)(1) is no less stringent than
24 the program of the State or States in which the
25 Indian tribe is located.

1 “(4) NONCOMPLIANCE.—If with respect to any
2 Indian tribe the Administrator determines that com-
3 pliance with the requirements of subsection (e)(1) is
4 inappropriate or administratively infeasible, the Ad-
5 ministrator shall specify other means for the Indian
6 tribe to achieve the purposes of the law described in
7 subsection (e)(1) with respect to persons who engage
8 in the distribution at retail of tobacco products on
9 tribal lands.

10 “(5) PROCEDURES.—The findings and regula-
11 tions promulgated under paragraphs (2) and (3)
12 shall be promulgated in conformance with section
13 553 of title 5, United States Code, and shall comply
14 with the following provisions:

15 “(A) In making findings as provided in
16 paragraph (2), and in drafting and promul-
17 gating regulations as provided in paragraph (3)
18 (including drafting and promulgating any re-
19 vised regulations), the Administrator shall con-
20 fer with, and allow for active participation by,
21 representatives and members of Indian tribes,
22 and tribal organizations.

23 “(B) In carrying out rulemaking processes
24 under this subsection, the Administrator shall
25 follow the guidance of subchapter III of chapter

1 5 of title 5, United States Code, commonly
2 known as the Negotiated Rulemaking Act of
3 1990.

4 “(C) The tribal participants in the negotia-
5 tion process referred to in subparagraph (B)
6 shall be nominated by and shall represent the
7 groups described in this subsection and shall in-
8 clude tribal representatives from all geographic
9 regions.

10 “(D) The negotiations conducted under
11 this paragraph shall be conducted in a timely
12 manner.

13 “(E) If the Administrator determines that
14 an extension of the deadlines under subsection
15 (k)(1) is appropriate, the Secretary may submit
16 proposed legislation to Congress for the exten-
17 sion of such deadlines.

18 “(6) LIMITATION.—This subsection shall not
19 affect any law or ordinance that—

20 “(A) was in effect on tribal lands on Fed-
21 eral Tobacco Act of 2009; and

22 “(B) covers the same subject matter as the
23 law described in subsection (e)(1).

24 Any law or ordinance that meets the conditions of
25 this paragraph shall also be deemed to meet the re-

1 requirement described in subsection (k)(1), if such law
2 or ordinance is at least as stringent as the law de-
3 scribed in subsection (e)(1).

4 “(7) DEFINITIONS.—In this subsection:

5 “(A) ADMINISTRATOR.—The term ‘Admin-
6 istrator’ means the Administrator of the To-
7 bacco Regulatory Agency.

8 “(B) INDIAN TRIBE.—The term ‘Indian
9 tribe’ has the meaning given such term in sec-
10 tion 4(e) of the Indian Self Determination and
11 Education Assistance Act (25 U.S.C. 450b(e)).

12 “(C) TRIBAL LANDS.—The term ‘tribal
13 lands’ means all lands within the exterior
14 boundaries of any Indian reservation, all lands
15 the title to which is held by the United States
16 in trust for an Indian tribe, or lands the title
17 to which is held by an Indian tribe subject to
18 a restriction by the United States against alien-
19 ation, and all dependent Indian communities.

20 “(D) TRIBAL ORGANIZATION.—The term
21 ‘tribal organization’ has the same meaning
22 given such term in section 4(l) of the Indian
23 Self Determination and Education Assistance
24 Act (25 U.S.C. 450b(l)).”.

1 **SEC. 203. RESTRICTIONS ON DESCRIPTORS USED IN MAR-**
2 **KETING OF CIGARETTES.**

3 (a) IN GENERAL.—Except as provided in subsection
4 (b), no person shall use, with respect to any cigarette
5 brand style commercially distributed domestically, on the
6 portion of the package of such cigarette brand style that
7 customarily is visible to consumers before purchase, or in
8 advertising of such cigarette brand style that is not located
9 in an adult-only facility or is not addressed solely to age-
10 verified adults any of the following as a descriptor of any
11 cigarette brand style:

12 (1) The name of any candy or fruit.

13 (2) The word “candy”, “citrus”, “cream”,
14 “fruit”, “sugar”, “sweet”, “tangy”, or “tart”.

15 (3) Any extension or variation of any of the
16 words “candy”, “citrus”, “cream”, “fruit”, “sugar”,
17 “sweet”, “tangy”, or “tart”, including “creamy”, or
18 “fruity.”

19 (b) LIMITATION.—Subsection (a) shall not apply to
20 the use of the following words or to any extension or vari-
21 ation of any such words: “clove” and “menthol”.

22 (c) SCENTED MATERIALS.—No person shall use, in
23 the advertising or labeling of any cigarette commercially
24 distributed domestically, any scented materials, except in
25 an adult-only facility.

26 (d) DEFINITIONS.—In this section:

1 (1) CANDY.—The term “candy” means a con-
 2 fection made from sugar or sugar substitute, includ-
 3 ing any confection identified generically or by brand,
 4 and shall include the words “cacao”, “chocolate”,
 5 “cinnamon”, “cocoa”, “honey”, “licorice”, “maple”,
 6 “mocha”, and “vanilla”.

7 (2) FRUIT.—The term “fruit” means any fruit
 8 identified by generic name, type, or variety, includ-
 9 ing “apple”, “banana”, “cherry”, and “orange”.
 10 Such term does not include words that identify
 11 seeds, nuts or peppers, or types or varieties thereof
 12 or words that are extensions or variations of such
 13 words.

14 **TITLE III—REDUCED-EXPOSURE**
 15 **AND REDUCED-RISK CLAIMS**
 16 **FOR TOBACCO PRODUCTS,**
 17 **AND RANKING OF TOBACCO**
 18 **PRODUCT CATEGORIES**

19 **SEC. 301. PROHIBITION OF UNAPPROVED REDUCED-EXPO-**
 20 **SURE AND REDUCED-RISK CLAIMS.**

21 (a) PROHIBITION OF UNAPPROVED REDUCED-EXPO-
 22 SURE AND REDUCED-RISK CLAIMS.—No person shall
 23 make, or cause to be made, in any tobacco product label-
 24 ing or advertising, a statement or other representation re-
 25 garding a tobacco product that is likely to be received and

1 understood by a significant number of objective, reason-
2 able consumers as making either a reduced-exposure claim
3 or a reduced-risk claim, unless an application regarding
4 such claim with respect to such tobacco product has been
5 approved in accordance with this title and has not been
6 withdrawn in accordance with this title. Nothing in this
7 Act shall be construed to restrict—

8 (1) the full exchange of scientific information
9 concerning a tobacco product, including the dissemi-
10 nation of scientific findings in scientific and lay
11 media;

12 (2) communications with employees, contrac-
13 tors, or suppliers;

14 (3) communications to a governmental entity,
15 body, official, or employee;

16 (4) communications in, or in connection with,
17 litigation or arbitration; or

18 (5) communications to securities holders.

19 No liability under State law shall be imposed on the basis,
20 wholly or in part, of any statement or representation mak-
21 ing a reduced-exposure claim or a reduced-risk claim in
22 a scientific or lay medium of communication (other than
23 advertising in such medium) or otherwise within the scope
24 of paragraphs (1) through (5).

1 (b) TOBACCO PRODUCTS WITH NO REDUCED-EXPO-
2 SURE OR REDUCED-RISK CLAIM UNAFFECTED.—Nothing
3 in this section shall be construed to prevent any person
4 from introducing into interstate commerce any tobacco
5 product the labeling and advertising of which do not make
6 any statement or other representation prohibited by sub-
7 section (a).

8 (c) NICOTINE-REPLACEMENT THERAPIES.—A prod-
9 uct that is intended to be used as part of a nicotine re-
10 placement therapy in the treatment of tobacco depend-
11 ence, or as part of a tobacco product cessation program,
12 shall not be considered to be either—

13 (1) a tobacco product for which a reduced-expo-
14 sure claim might be made; or

15 (2) a tobacco product for which a reduced-risk
16 claim might be made.

17 **SEC. 302. APPLICATIONS FOR APPROVAL OF REDUCED-EX-**
18 **POSURE AND REDUCED-RISK CLAIMS.**

19 A person may submit to the Administrator an appli-
20 cation for approval of a reduced-exposure claim or a re-
21 duced-risk claim for a tobacco product as compared to 1
22 or more other reference products either within the tobacco
23 product category that includes the subject tobacco product
24 or in a tobacco product category that does not include the

1 subject tobacco product. Such an application shall contain
2 the following:

3 (1) A complete description, including the for-
4 mulation, construction, and a full list of the compo-
5 nents, of the tobacco product for which the proposed
6 reduced-exposure claim or reduced-risk claim might
7 be made.

8 (2) The proposed reduced-exposure or reduced-
9 risk claim or claims for that tobacco product.

10 (3) Full reports of investigations of the subject
11 tobacco product, as compared to 1 or more other to-
12 bacco products, with respect to—

13 (A) the chemical compositions of the to-
14 bacco products (or of the smoke of the tobacco
15 product if the subject tobacco product is in-
16 tended for smoking);

17 (B) the toxicological and any other biologi-
18 cal effects of the tobacco products (or of the
19 smoke of the tobacco product if the subject to-
20 bacco product is intended for smoking) in lab-
21 oratory test systems, animals, and humans; and

22 (C) human behavior in the use of the to-
23 bacco products; and

24 (4) Such samples of the tobacco product as the
25 Administrator may request.

1 **SEC. 303. STANDARDS FOR APPROVAL OF APPLICATIONS**
2 **FOR REDUCED-EXPOSURE OR REDUCED-RISK**
3 **CLAIMS.**

4 (a) STANDARDS FOR APPROVAL OF REDUCED-EXPO-
5 SURE CLAIMS.—The Administrator shall approve an appli-
6 cation submitted under section 302 for a reduced-exposure
7 claim, as originally submitted or as modified, if the Ad-
8 ministrator finds each of the following:

9 (1) That the subject tobacco product (or the
10 smoke from the subject tobacco product, if the sub-
11 ject tobacco product is intended for smoking, when
12 evaluated under not more than 2 machine-smoking
13 regimens), yields a reduced amount of 1 or more
14 toxicants when compared to an appropriate reference
15 tobacco product or products.

16 (2) That the subject tobacco product, when
17 evaluated under conditions of actual use by tobacco-
18 product users, presents a reduced exposure to 1 or
19 more toxicants when compared to an appropriate
20 reference tobacco product or products, as dem-
21 onstrated by—

22 (A) data on smoking behavior or other be-
23 havior in the use of the tobacco product, as ap-
24 plicable, by users of the tobacco product;

25 (B) data showing a statistically significant
26 reduction of at least 1 toxicant biomarker, or

1 other scientifically validated indicator of toxi-
2 cant exposure; and

3 (C) data showing either—

4 (i) no statistically significant increase
5 in exposure to any toxicant or in any bio-
6 marker of toxicant exposure; or

7 (ii) that any statistically significant
8 increase in exposure to any toxicant or in
9 any toxicant biomarker of exposure does
10 not pose a significant risk of increasing
11 morbidity or mortality of users of the to-
12 bacco product.

13 (3) That there is a sufficiently persuasive sci-
14 entific rationale to justify a reasonable expectation,
15 among qualified experts, that the reduction in expo-
16 sure to 1 or more toxicants would result in a mean-
17 ingful reduction of morbidity or mortality, as sup-
18 ported by—

19 (A) biologically meaningful quantitative
20 risk assessment data;

21 (B) biologically meaningful pre-clinical
22 toxicology data; or

23 (C) biologically meaningful data from
24 short-term studies in users of tobacco products.

1 (4) That there is a sufficiently persuasive sci-
2 entific rationale to justify a reasonable expectation,
3 among qualified experts, that use of the subject to-
4 bacco product by tobacco-product users would not
5 result in a statistically significant increase in biologi-
6 cal activity when compared to an appropriate ref-
7 erence tobacco product or products, as supported
8 by—

9 (A) biologically meaningful quantitative
10 risk assessment data;

11 (B) biologically meaningful pre-clinical
12 toxicology data; or

13 (C) biologically meaningful data from
14 short-term studies in users of tobacco products.

15 (b) STANDARDS FOR APPROVAL OF REDUCED-RISK

16 CLAIMS.—The Administrator shall approve an application
17 submitted under section 302 for a reduced-risk claim, as
18 originally submitted or as modified, if the Administrator
19 makes each of the findings required by paragraphs (1)
20 through (4) of subsection (a) and finds that an epidemio-
21 logic study or other human studies lead to significant sci-
22 entific agreement that—

23 (1)(A) the totality of available scientific evi-
24 dence warrants the conclusion that the subject to-
25 bacco product, when compared to an appropriate ref-

1 erence tobacco product or products, provides a
2 meaningful reduction of 1 or more chronic diseases
3 or serious adverse health conditions associated with
4 tobacco use; or

5 (B) the totality of the available scientific evi-
6 dence shows—

7 (i) that actual use of the subject tobacco
8 product by users of tobacco products, as com-
9 pared to actual use of an appropriate reference
10 tobacco product or products by users of tobacco
11 products, results in an altered intake of an ap-
12 propriately identified and measured substance;
13 and

14 (ii) that the change in intake from the use
15 of the subject tobacco product results in a
16 meaningful reduction in a valid measure of
17 chronic disease or serious adverse health condi-
18 tion associated with tobacco use; and

19 (2) the validity of the anticipated reduction in
20 1 or more tobacco-related diseases or adverse health
21 conditions is not likely to be reversed by new and
22 evolving science.

1 **SEC. 304. GENERAL PROVISIONS.**

2 (a) CONFIDENTIALITY OF APPLICATIONS.—The Ad-
3 ministrator shall treat the content of all applications sub-
4 mitted under section 302 as confidential.

5 (b) REFERRAL TO ADVISORY COMMITTEE.—The Ad-
6 ministrator may refer an application submitted under sec-
7 tion 302 to an Advisory Committee having expertise in
8 1 or more of the fields of biological science, medicine, sta-
9 tistics, or other discipline relevant to the review of the ap-
10 plication.

11 (c) ACTION ON AN APPLICATION.—

12 (1) IN GENERAL.—Not later than 180 days
13 after the receipt of an application under section 302,
14 or such additional period as may be agreed upon by
15 the Administrator and the applicant, after consulta-
16 tion with appropriate technical experts of the Food
17 and Drug Administration, the Federal Trade Com-
18 mission, and the Centers for Disease Control and
19 Prevention, the Administrator shall—

20 (A) approve the application as initially
21 submitted or as modified; or

22 (B) refuse to approve the application as
23 initially submitted or as modified, provide a de-
24 tailed written statement of the reasons for such
25 refusal, and give the applicant notice of an op-
26 portunity for a hearing on the record before the

1 Administrator on the question whether such ap-
2 plication is approvable.

3 (2) HEARING ON DISAPPROVAL.—If an appli-
4 cant accepts the opportunity for a hearing under
5 paragraph (1)(B) by written request submitted not
6 later than 30 days after notice of such opportunity
7 is received by the applicant, such hearing shall com-
8 mence not later than 90 days after the expiration of
9 such 30-day period unless the Administrator and the
10 applicant otherwise agree. Any such hearing shall
11 thereafter be conducted on an expedited basis, and
12 the Administrator's order thereon shall be issued not
13 later than 90 days after the date fixed by the Ad-
14 ministrator for the filing of final briefs or for the
15 final hearing.

16 (d) POST-MARKET SURVEILLANCE AND STUDIES.—
17 The Administrator shall require that an applicant under
18 this title whose application has been approved conduct
19 post-market surveillance and studies of the tobacco prod-
20 uct that is the subject of the approved application, unless
21 the Administrator finds that the information likely to re-
22 sult from such surveillance or studies is not likely to be
23 useful for the protection of the public health.

24 (e) WITHDRAWAL OF APPROVAL.—The Adminis-
25 trator, after due notice and an opportunity for a hearing

1 on the record before the Administrator, shall withdraw the
2 approval of an application under this title if the Adminis-
3 trator determines that—

4 (1) new evidence not contained in such applica-
5 tion or not available to the Administrator until after
6 such application was approved, or evidence from
7 tests by new methods, or tests by methods not
8 deemed reasonably applicable when such application
9 was approved, evaluated together with the evidence
10 available to the Administrator when the application
11 was approved, demonstrates that there is a lack of
12 adequate support for the findings necessary for the
13 approval of the application;

14 (2) the applicant knowingly or recklessly failed
15 to include material information in the application, or
16 the application included any untrue statement of
17 material fact by the applicant; or

18 (3) the applicant failed to conduct, or to submit
19 reports on, post-market surveillance or studies as re-
20 quired under this section.

21 (f) JUDICIAL REVIEW.—

22 (1) IN GENERAL.—An applicant may appeal an
23 order of the Administrator refusing or withdrawing
24 approval of an application under this title in accord-
25 ance with this subsection.

1 (2) FILING.—An appeal under this subsection
2 shall be make by filing in the United States court
3 of appeals for the circuit wherein the applicant re-
4 sides or wherein the principal place of business of
5 such applicant is located, or in the United States
6 Court of Appeals for the District of Columbia Cir-
7 cuit, not later than 60 days after the date on which
8 such order was entered, a written petition seeking
9 that the order of the Administrator be set aside. A
10 copy of such petition shall be transmitted forthwith
11 by the clerk of the court to the Administrator, or
12 any officer designated by the Administrator for that
13 purpose, and thereupon the Administrator shall cer-
14 tify and file in the court the record upon which the
15 order complained of was entered, as provided in sec-
16 tion 2112 of title 28, United States Code.

17 (3) JURISDICTION.—Upon the filing of a peti-
18 tion under paragraph (2), the court involved shall
19 have exclusive jurisdiction to affirm or set aside the
20 order that is the subject of the petition, except that
21 until the filing of the record the Administrator may
22 modify or set aside the order that is being appealed.

23 (4) ADMINISTRATIVE PROVISIONS.—No objec-
24 tion to the order of the Administrator shall be con-
25 sidered by the court under this subsection unless

1 such objection shall have been urged before the Ad-
2 ministrator or unless there were reasonable grounds
3 for failure so to do. The findings of the Adminis-
4 trator as to the facts, if supported by substantial
5 evidence, shall be conclusive. If any person shall
6 apply to the court for leave to adduce additional evi-
7 dence, and shall show to the satisfaction of the court
8 that such additional evidence is material and that
9 there were reasonable grounds for failure to adduce
10 such evidence in the proceeding before the Adminis-
11 trator, the court may order such additional evidence
12 to be taken before the Administrator and to be ad-
13 duced upon the hearing in such manner and upon
14 such terms and conditions as to the court may seem
15 proper. The Administrator may modify his or her
16 findings as to the facts by reason of the additional
17 evidence so taken, and the Administrator shall file
18 with the court such modified findings which, if sup-
19 ported by substantial evidence, shall be conclusive,
20 and the Administrator's recommendation, if any, for
21 the setting aside of the original order.

22 (5) JUDGMENT.—The judgment of the court af-
23 firming or setting aside any order of the Adminis-
24 trator under this subsection shall be final, subject to
25 review by the Supreme Court of the United States

1 upon certiorari or certification as provided for in
2 section 1254 of title 28, United States Code.

3 (6) LIMITATION.—The commencement of pro-
4 ceedings under this subsection shall not, unless spe-
5 cifically ordered by the court to the contrary, oper-
6 ate as a stay of the Administrator’s order.

7 (g) REGULATIONS.—Not later than 24 months after
8 the effective date of this Act, the Administrator shall pro-
9 mulgate regulations governing, among other things—

10 (1) the content of an application under section
11 302;

12 (2) the procedures for amending or
13 supplementing such an application;

14 (3) the procedures for the Administrator to ap-
15 prove, approve with modifications, or refuse to ap-
16 prove applications submitted under section 302;

17 (4) the design of, conduct of, recordkeeping on,
18 and reporting on post-market surveillance and stud-
19 ies under this section; and

20 (5) post-approval reporting by holders of ap-
21 proved applications.

22 (h) LIMITATION.—Nothing in this Act shall be con-
23 strued to require a tobacco product manufacturer to inves-
24 tigate, evaluate, develop, or pursue the marketing of any
25 tobacco product for which a reduced-exposure claim or a

1 reduced-risk claim might be made. Except as otherwise
2 provided in this section, nothing in this Act shall be con-
3 strued to require a tobacco product manufacturer to sup-
4 ply any information, data, or technology to the Adminis-
5 trator regarding the development or properties of any to-
6 bacco product for which a reduced-exposure claim or re-
7 duced-risk claim might be made.

8 **SEC. 305. ESTABLISHMENT OF RANKINGS.**

9 (a) STANDARDS AND PROCEDURES FOR
10 RANKINGS.—Not later than 24 months after the effective
11 date of this Act, the Administrator shall, by regulation
12 and after consultation with an Advisory Committee estab-
13 lished for such purpose, establish the standards and proce-
14 dures for promulgating rankings, comprehensible to con-
15 sumers of tobacco products, of the following categories of
16 tobacco products and 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 nicotine-containing prod-
20 ucts 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.

8 (10) Other nicotine-containing 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 categories specified in paragraphs (1) through (10).

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) shall, in assessing the risks of serious or
22 chronic tobacco-related diseases and adverse health
23 conditions presented by a particular category, con-
24 sider the range of tobacco products or nicotine-con-
25 taining products within the category, and give ap-

1 appropriate weight to the market shares of the respec-
2 tive 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 such 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, 2011.
13 Thereafter, on an annual basis, the Administrator shall,
14 by order, promulgate to the general public updated
15 rankings that—

16 (1) are in accordance with such regulations;

17 and

18 (2) reflect the scientific evidence available at
19 the time of promulgation.

20 The Administrator shall open and maintain an ongoing
21 public docket for receipt of data and other information
22 submitted by any person with respect to such annual pro-
23 mulgation of rankings.

1 **SEC. 306. COMPULSORY LICENSING.**

2 (a) GRANT OF LICENSE.—A person that owns intel-
3 lectual property rights to any technology that is the basis
4 for the approval of a reduced-risk claim for a brand style
5 of cigarettes under section 304(c) shall, to the fullest ex-
6 tent of such rights, license to any licensee any and all such
7 rights to the technology that are needed to make, use, and
8 sell in the United States cigarettes incorporating such
9 technology, if the licensee—

10 (1) is incorporated within the United States;

11 (2) requests such a license; and

12 (3) agrees to commercially reasonable terms, in-
13 cluding payment of a commercially reasonable fee,
14 which fee shall take into account the costs of devel-
15 opment and testing, as well as the value, of any as-
16 sociated intellectual property rights or protection.

17 (b) BINDING ARBITRATION.—The parties shall sub-
18 mit to binding arbitration any dispute regarding the terms
19 of a license provided under subsection (a).

20 (c) LIMITATION ON LICENSE.—This section shall not
21 apply to any technology that is not, in whole or in part,
22 necessary to the approval of a reduced-risk claim for a
23 brand style of cigarettes under section 304(c).

24 **SEC. 307. MOIST SNUFF WARNINGS.**

25 Not later than 24 months after the effective date of
26 this Act, the Administrator, after consultation with an Ad-

1 visory Committee, shall review the warning labels required
2 to appear on packages of moist snuff products under sec-
3 tion 3 of the Comprehensive Smokeless Tobacco Health
4 Education Act of 1986 (15 U.S.C. 4402) in light of cur-
5 rent population-based science, and shall make a rec-
6 ommendation to the Secretary and Congress as to whether
7 the contents of the warning labels are accurate and are
8 supported by current scientific data and whether the labels
9 convey to users of tobacco products information that is
10 truthful and not misleading, and that assists users of to-
11 bacco products in comparing the health risks presented
12 by moist snuff products with the health risks presented
13 by cigarettes and other types of tobacco products.

14 **TITLE IV—DISCLOSURES TO THE**
15 **AGENCY REGARDING TO-**
16 **BACCO PRODUCTS**

17 **SEC. 401. CONFIDENTIAL DISCLOSURES TO THE AGENCY.**

18 (a) ANNUAL REPORTS BY MANUFACTURERS.—Not
19 later than September 1, 2009, and each September 1
20 thereafter, each tobacco product manufacturer shall sub-
21 mit to the Administrator, as to each brand style it manu-
22 factures for commercial distribution domestically, a list of
23 the ingredients added to tobacco in the manufacture of
24 that brand style, without regard to the quantity used, and
25 including, separately, each spice, each natural or artificial

1 flavoring, and each preservative used in the brand style.
2 In each such list, each ingredient shall be listed by its
3 chemical name and chemical abstract service registry
4 number, if available, or, if not available, by its common
5 or usual name. The ingredients shall be listed in descend-
6 ing order of predominance by weight, measure, or numer-
7 ical count.

8 (b) EVALUATION BY THE ADMINISTRATOR.—

9 (1) IN GENERAL.—At such times as the Admin-
10 istrator considers appropriate, the Administrator
11 shall request that technical experts of the Food and
12 Drug Administration and the Centers for Disease
13 Control and Prevention review and comment on the
14 information provided under subsection (a), with re-
15 spect to—

16 (A) a summary of—

17 (i) current scientific data pertaining
18 to the health effects of the ingredients
19 added to tobacco in the manufacture of to-
20 bacco products; and

21 (ii) any proposed additional research
22 activities on such health effects; and

23 (B) information pertaining to any such in-
24 gredient that in the judgment of technical ex-
25 perts of the Food and Drug Administration or

1 the Centers for Disease Control and Prevention
2 meaningfully increases the health risk or risks
3 presented to users of tobacco products con-
4 taining such ingredient.

5 (2) CONFIDENTIAL INFORMATION.—Except for
6 information required to be disclosed in accordance
7 with any of sections 601 through 603, all informa-
8 tion submitted under subsection (a) and provided to
9 technical experts of the Food and Drug Administra-
10 tion or to the Centers for Disease Control and Pre-
11 vention shall be treated as trade secret or confiden-
12 tial commercial information subject to section 552
13 (b)(4) of title 5, United States Code, and section
14 1905 of title 18, United States Code, and shall not
15 be revealed, to any person other than those author-
16 ized by the Administrator in carrying out their offi-
17 cial duties under this section.

18 (c) REPORTS BY THE ADMINISTRATOR.—

19 (1) IN GENERAL.—At such times as the Admin-
20 istrator considers appropriate, the Administrator
21 shall transmit to the Congress a report, based on the
22 information provided under subsection (a), con-
23 taining—

24 (A) a summary of research activities and
25 proposed research activities on the health ef-

1 facts of ingredients added to tobacco in the
2 manufacture of tobacco products and the find-
3 ings of such research;

4 (B) information pertaining to any such in-
5 gredient that in the judgment of the Adminis-
6 trator meaningfully increases the health risk or
7 risks presented to users of tobacco products
8 containing such ingredient, and

9 (C) any other information, other than
10 trade secrets and confidential commercial infor-
11 mation, the inclusion of which the Adminis-
12 trator determines to be in the public interest.

13 (2) CONFIDENTIAL INFORMATION.—

14 (A) IN GENERAL.—Except for information
15 required to be disclosed in accordance with sec-
16 tions 601 through 603, all information provided
17 to the Administrator under paragraph (1) shall
18 be treated as trade secret or confidential com-
19 mercial information subject to section 552
20 (b)(4) of title 5, United States Code, and sec-
21 tion 1905 of title 18, United States Code, and
22 shall not be revealed, to any person other than
23 those authorized by the Administrator in car-
24 rying out their official duties under this section.

1 (B) LIMITATION.—Subparagraph (A) shall
2 not be construed to authorize the withholding of
3 a list provided under subsection (a) from any
4 duly authorized subcommittee or committee of
5 the Congress. If a subcommittee or committee
6 of the Congress requests the Administrator to
7 provide it such a list, the Administrator shall
8 make the list available to the subcommittee or
9 committee and shall, at the same time, notify in
10 writing the tobacco product manufacturer that
11 provided the list of such request.

12 (C) PROCEDURES.—The Administrator
13 shall establish written procedures to assure the
14 confidentiality of information provided under
15 paragraph (1). Such procedures shall include
16 the designation of a duly authorized agent to
17 serve as custodian of such information. The
18 agent shall—

19 (i) take physical possession of the in-
20 formation and, when such information is
21 not in use by a person authorized to have
22 access to it, shall store such information in
23 a locked cabinet or file; and

1 (ii) maintain a complete record of all
2 persons that inspect or use the informa-
3 tion.

4 Such procedures shall require that any person
5 permitted access to the information shall be in-
6 structed in writing not to disclose the informa-
7 tion to anyone who is not entitled to have ac-
8 cess to the information.

9 (d) INCLUSION OF NICOTINE YIELD RATINGS OF
10 CIGARETTES.—Not later than September 1, 2009, and
11 each September 1 thereafter, each tobacco product manu-
12 facturer of cigarettes shall include in its annual report
13 submitted in accordance with subsection (a), for each
14 brand style of cigarettes it manufactures for commercial
15 distribution domestically, nicotine yield ratings determined
16 in accordance with the standards established under section
17 402.

18 (e) INCLUSION OF NICOTINE INFORMATION RELAT-
19 ING TO SMOKELESS TOBACCO PRODUCTS.—Not later
20 than September 1, 2009, and each September 1 there-
21 after, each tobacco product manufacturer of a smokeless
22 tobacco product shall include in its annual report sub-
23 mitted in accordance with subsection (a), for each brand
24 style of smokeless tobacco product it manufactures for
25 commercial distribution domestically, nicotine information

1 determined in accordance with the standards established
2 under section 403.

3 **SEC. 402. NICOTINE REPORTING REQUIREMENTS FOR**
4 **CIGARETTES.**

5 (a) IN GENERAL.—The testing of cigarettes for pur-
6 poses of this title shall comply with this section.

7 (b) SELECTION OF CIGARETTES FOR TESTING.—
8 Cigarettes of each brand style tested shall be randomly
9 selected from cigarette packages obtained from the manu-
10 facturing facility of the tobacco product manufacturer.

11 (c) BRAND STYLES IDENTICAL IN COMPOSITION.—
12 For purposes of this section, if a brand style of cigarettes
13 is identical to 1 or more other brand styles of cigarettes,
14 except for brand name designation and other aspects not
15 affecting the physical or chemical composition or perform-
16 ance of the cigarettes, then, for purposes of this section,
17 those brand styles shall be treated as if they were a single
18 brand style, and the cigarette manufacturer shall be re-
19 quired to test only 1 of those brand styles in lieu of testing
20 all such brand styles. The cigarette manufacturer shall
21 specify in its annual report to the Administrator under
22 section 401(c) the brand styles covered by the results with
23 respect to the brand style tested.

24 (d) MACHINE-SMOKING REGIMENS.—

1 (1) REGULATIONS.—Not later than December
2 31, 2010, the Administrator shall, by regulation, es-
3 tablish not more than 2 machine-smoking regimens
4 for determining the yield of nicotine from each
5 brand style of cigarettes manufactured for commer-
6 cial distribution domestically.

7 (2) CONDITIONING.—Cigarettes to be tested
8 under this subsection shall be conditioned in accord-
9 ance with ISO 3402:1999, entitled “Tobacco and to-
10 bacco products—Atmosphere for conditioning and
11 testing.”

12 (3) TESTING TRIALS.—In establishing either 1
13 or 2 smoking regimens, the Administrator shall
14 mandate and coordinate interlaboratory, collabo-
15 rative testing trials to verify the suitability and rug-
16 gedness of the smoking regimen or regimens.

17 (4) MEANINGFUL CHANGE IN NICOTINE
18 YIELD.—On the basis of the interlaboratory testing
19 trials, the Administrator shall determine, as to each
20 regimen, the magnitude of change in a measured
21 value that constitutes a meaningful change in the
22 nicotine yield of a cigarette.

23 (5) NICOTINE YIELD VALUES.—The regulations
24 promulgated under this subsection shall require that
25 cigarette manufacturers report all nicotine yield val-

1 ues to a number of decimal places consistent with
2 the established value for a meaningful change in the
3 nicotine yield of a cigarette and in light of any limi-
4 tations associated with the smoking regimen.

5 (6) REQUIREMENT OF REGIMEN.—One of the 2
6 smoking regimens for establishing the yield of nico-
7 tine from each brand style of cigarettes shall be the
8 ISO smoking regimen. When testing a brand style
9 with the ISO smoking regimen, 20 channels of 5
10 cigarettes per channel shall be smoked using a linear
11 smoking machine.

12 (7) ALTERNATIVE REGIMEN.—The other regi-
13 men, if established by the Administrator, shall be
14 the ISO testing regimen modified as follows:

15 (A) Puff volume shall be adjusted to 45
16 milliliters.

17 (B) Puff interval shall be adjusted to 30
18 seconds.

19 (C) Puff duration shall remain 2 seconds.

20 (D) 50 percent of the ventilation holes
21 shall be blocked by the design of the cigarette
22 holding device, placement of adhesive tape over
23 50 percent of the circumference of the cigarette
24 filter to block ventilation holes present, or by
25 another method approved by the Administrator.

1 (E) 20 channels of 3 cigarettes per channel
2 shall be smoked using a linear smoking ma-
3 chine.

4 (e) ASPECTS OF CIGARETTES TO BE DETER-
5 MINED.—For each brand style of cigarettes that is tested
6 under this section, nicotine content and other aspects shall
7 be determined as follows:

8 (1) Total nicotine content of the cigarette, re-
9 ported in milligrams of nicotine, shall be determined
10 using the protocol for measuring nicotine content in
11 tobacco as described in—

12 (A) the rules published on May 2, 1997, at
13 pages 24115 and 24116 of volume 62 of the
14 Federal Register (Protocol for Analysis of Nico-
15 tine, Total Moisture, and pH in Smokeless To-
16 bacco Products); or

17 (B) the colorimetric technique identified as
18 CORESTA Recommended Method No. 35 (De-
19 termination of total alkaloids (as nicotine) in
20 tobacco by continuous flow analysis).

21 In measuring nicotine content, the cigarette manu-
22 facturer shall use the following sampling method:
23 Two cigarettes shall be randomly selected from each
24 pack and conditioned, the tobacco rod split open,
25 and the cigarette tobacco mixed thoroughly before

1 weighing. The minimum sample size shall be 100
2 grams of tobacco. If the weight of the tobacco is less
3 than 100 grams, sufficient additional cigarettes shall
4 be randomly selected from each pack to achieve the
5 minimum sample size.

6 (2) Percent filter tip ventilation, defined as the
7 amount of air dilution in the whole smoke provided
8 by the perforations in the cigarette filter, described
9 in percent, shall be determined in accordance with
10 the current version of ISO 6565:2002, entitled “To-
11 bacco and tobacco products—Draw resistance of
12 cigarettes and pressure drop of filter rods—Stand-
13 ard conditions and measurement”. Two cigarettes
14 shall be randomly selected from each sampled pack,
15 conditioned, and tested for percent filter ventilation.
16 The average percent filter ventilation shall be com-
17 puted for a sample of 60 cigarettes obtained in the
18 manner described in subsection (b).

19 (3) For 3 brand styles of cigarettes selected by
20 the Administrator from each brand family that has
21 a national market share of 3.0 percent or greater,
22 as reported in the most recent (published not later
23 than December 31 of the year preceding the report-
24 ing deadline) Maxwell Report, “Cigarette Brand
25 Sales and Market Share” published by Davenport

1 and Company, Richmond, Virginia, or a comparable
2 report designated by the Administrator, pH of ciga-
3 rette smoke shall be determined on a puff-by-puff
4 basis, in accordance with the method described in
5 Harris, J.L., and Hayes, L.E., “A method for meas-
6 uring the pH of whole smoke”, Tobacco Science,
7 1977: 60: 81–83, or the method described in
8 Sensabaugh, A.J., Jr., and Cundiff, R.H., “A New
9 Technique for Determining the pH of Whole To-
10 bacco Smoke”, Tobacco Science, 1967: 11:25–30,
11 and Brunnemann, K.D. and Hoffmann, D., “The
12 pH of Tobacco Smoke”, Food, Cosmet. Toxicol.,
13 1974:112:115.

14 (f) CLASSIFICATION OF NICOTINE YIELD RAT-
15 INGS.—Nicotine yield ratings reported in the annual re-
16 port in accordance with section 401(a) shall be classified
17 by the cigarette manufacturer on the basis of the larger
18 of the 2 nicotine yield testing results produced under sub-
19 section (d) and in accordance with the following standards:

20 (1) “High Nicotine”: cigarettes yielding more
21 than 1.2 milligrams per cigarette.

22 (2) “Moderate Nicotine”: cigarettes yielding
23 more than 0.2 and less than or equal to 1.2 milli-
24 grams per cigarette.

1 (3) “Low Nicotine”: cigarettes yielding more
2 than or equal to 0.01 and less than or equal to 0.2
3 milligrams per cigarette.

4 (4) “Nicotine Free”: cigarettes yielding less
5 than 0.01 milligrams per cigarette.

6 (g) ACCREDITED LABORATORY.—Each test con-
7 ducted in accordance with this section shall be performed
8 in a laboratory that has been accredited according to the
9 ISO 17025 standard, entitled “General Requirements for
10 the Competence of Calibration and Testing Laboratories”.

11 (h) MANNER OF REPORTING.—The Administrator
12 shall, by regulation, specify the manner in which the re-
13 sults of tests conducted under this section shall be re-
14 ported to the Administrator.

15 **SEC. 403. NICOTINE REPORTING REQUIREMENTS FOR**
16 **SMOKELESS TOBACCO PRODUCTS.**

17 (a) TESTING OF SMOKELESS TOBACCO PRODUCTS.—
18 Unless the Administrator approves equivalent or superior
19 testing standards, information developed under this sec-
20 tion and to be included in the annual report by a manufac-
21 turer of smokeless tobacco products under section 401(d)
22 shall conform to testing standards published on March 23,
23 1999, at pages 14085 through 14096 of volume 64 of the
24 Federal Register (Annual Submission of the Quantity of
25 Nicotine Contained in Smokeless Tobacco Products Manu-

1 factured, Imported, or Packaged in the United States),
2 and, as to each brand style, except as provided in sub-
3 section (b), shall include the following:

4 (1) The pH of the tobacco.

5 (2) The moisture content as a percentage of the
6 dry weight of the tobacco.

7 (3) The nicotine in milligrams per gram of to-
8 bacco.

9 (4) The nicotine as a percentage of the dry
10 weight of the tobacco.

11 (5) The percentage of un-ionized (free) nicotine.

12 (6) The total un-ionized (free) nicotine in milli-
13 grams per gram of tobacco.

14 (7) A classification of each brand style of
15 smokeless tobacco products for nicotine delivery, in
16 accordance with the following standards:

17 (A) “High Nicotine”: smokeless tobacco
18 product yielding more than 2.0 milligrams of
19 total free nicotine per gram.

20 (B) “Moderate Nicotine”: smokeless to-
21 bacco product yielding more than 0.5 and less
22 than or equal to 2.0 milligrams of total free nie-
23 otine per gram.

24 (C) “Low Nicotine”: smokeless tobacco
25 product yielding more than or equal to .01 and

1 less than or equal to 0.5 milligrams of total free
2 nicotine per gram.

3 (D) “Nicotine Free”: smokeless tobacco
4 product yielding less than 0.01 milligrams of
5 total free nicotine per gram.

6 (b) BRAND STYLES IDENTICAL IN COMPOSITION.—
7 For purposes of this section, if a brand style of smokeless
8 tobacco is identical to 1 or more other brand styles of
9 smokeless tobacco, except for brand name designation and
10 other aspects not affecting the physical or chemical com-
11 position or performance of the smokeless tobacco, then,
12 for purposes of this section, those brand styles shall be
13 treated as if they were a single brand style, and the smoke-
14 less tobacco product manufacturer shall be required to test
15 only 1 of those brand styles in lieu of testing all of those
16 brand styles. The smokeless tobacco product manufacturer
17 shall specify in its annual report to the Administrator
18 under section 401(d) the brand styles covered by the re-
19 sults with respect to the brand style tested.

20 (c) ACCREDITED LABORATORY.—Each test con-
21 ducted in accordance with this section shall be performed
22 in a laboratory that has been accredited according to the
23 ISO 17025 standard, entitled “General Requirements for
24 the Competence of Calibration and Testing Laboratories”.

1 **TITLE V—TAR AND NICOTINE**
2 **YIELDS**

3 **SEC. 501. DETERMINATION OF TAR AND NICOTINE YIELDS**
4 **OF CIGARETTES.**

5 (a) MACHINE-SMOKING REGIMEN.—The testing regi-
6 men or regimens and the reporting method established by
7 the Administrator under section 402(c) with respect to the
8 determination and reporting of nicotine yields shall also
9 be used for the determination and disclosure of tar yields
10 under section 504.

11 (b) CONTINUED SUPERVISION BY FEDERAL TRADE
12 COMMISSION.—Prior to the expiration of a reasonable pe-
13 riod determined by the Administrator for conducting test-
14 ing pursuant to the regulations promulgated by the Ad-
15 ministrator under section 402(c), but in no event later
16 than December 31, 2009, manufacturers of cigarettes
17 shall continue to disclose the tar and nicotine yields of
18 their cigarettes under the supervision of the Federal Trade
19 Commission.

20 (c) END OF FEDERAL TRADE COMMISSION AUTHOR-
21 ITY.—After the period specified under subsection (b), the
22 Federal Trade Commission shall have no authority over
23 the testing or reporting of the tar and nicotine yields of
24 cigarettes.

1 (d) ACCREDITED LABORATORY.—Each test con-
2 ducted in accordance with this section shall be performed
3 in a laboratory that has been accredited according to the
4 ISO 17025 standard, entitled “General Requirements for
5 the Competence of Calibration and Testing Laboratories”.

6 **SEC. 502. CIGARETTE TAR LIMITS.**

7 (a) NO INCREASE IN TAR YIELDS.—No tobacco prod-
8 uct manufacturer shall distribute for sale domestically a
9 brand style of cigarettes that generates a tar yield greater
10 than the tar yield of that brand style of cigarettes on Fed-
11 eral Tobacco Act of 2009, as determined by the ISO smok-
12 ing regimen and its associated tolerances. The tar toler-
13 ances for cigarettes with ISO tar yields in the range of
14 1 to 20 milligrams per cigarette, based on variations aris-
15 ing from sampling procedure, test method, and sampled
16 product, itself, are the greater of plus or minus—

17 (1) 15 percent; or

18 (2) 1 milligram per cigarette.

19 (b) LIMIT ON NEW CIGARETTES.—Beginning on the
20 effective date of this Act, no tobacco product manufac-
21 turer shall manufacture for commercial distribution do-
22 mesticallly a brand style of cigarettes that—

23 (1) was not in commercial distribution domesti-
24 cally on the effective date of this Act; and

1 (2) generates a tar yield of greater than 20 mil-
2 ligrams per cigarette as determined by the ISO
3 smoking regimen and its associated tolerances.

4 (c) LIMIT ON ALL CIGARETTES.—Beginning on Jan-
5 uary 1, 2010, no tobacco product manufacturer shall man-
6 ufacture for commercial distribution domestically a brand
7 style of cigarettes that generates a tar yield greater than
8 20 milligrams per cigarette as determined by the ISO
9 smoking regimen and its associated tolerances.

10 (d) REVIEW BY ADMINISTRATOR.—Beginning on the
11 effective date of this Act, the Administrator shall evaluate
12 the available scientific evidence addressing the potential
13 relationship between historical tar yield values and the
14 risk of harm to smokers. If upon a review of such evidence,
15 and after consultation with technical experts of the Food
16 and Drug Administration and the Centers for Disease
17 Control and Prevention and notice and an opportunity for
18 public comment, the Administrator determines that a re-
19 duction in tar yield may reasonably be expected to provide
20 a meaningful reduction of the risk or risks of harm to
21 smokers, the Administrator shall issue an order that—

22 (1) provides that no cigarette manufacturer
23 shall manufacture for commercial distribution do-
24 mestically a cigarette that generates a tar yield that

1 exceeds 14 milligrams as determined by the ISO
2 smoking regimen and its associated tolerances; and

3 (2) provides a reasonable time for manufactur-
4 ers to come into compliance with such prohibition.

5 **SEC. 503. PROHIBITION OF SMOKING ARTICLE YIELD**
6 **TERMS.**

7 Beginning 24 months after the effective date of this
8 Act, no tobacco product manufacturer shall use in pack-
9 aging, labeling, or advertising of cigarettes any of the fol-
10 lowing terms: “low tar”, “medium”, “light”, “mild”,
11 “ultra light,” and “ultra low tar”.

12 **SEC. 504. DISCLOSURE OF TAR AND NICOTINE YIELDS OF**
13 **CIGARETTES.**

14 A tobacco product manufacturer shall include promi-
15 nently in all advertising for each brand style of cigarettes
16 it manufactures for commercial distribution domestically
17 the ISO tar and nicotine yields for that brand style, and
18 shall post on an Internet-accessible website, or other loca-
19 tion electronically accessible to the public, the ISO tar and
20 nicotine yields for every brand style of cigarettes it manu-
21 factures for commercial distribution domestically.

22 **SEC. 505. EVALUATION OF TOBACCO SMOKE TOXICANTS.**

23 Not later than 24 months after the effective date of
24 this Act, the Administrator shall, after consultation with
25 the Centers for Disease Control and Prevention and the

1 Food and Drug Administration, publish a plan to identify
2 and review constituents known to comprise tobacco smoke
3 with regard to the toxicant potential of each such con-
4 stituent. Such plan shall consider and prioritize the rel-
5 ative risk of serious or chronic tobacco-related diseases
6 and adverse health conditions that the various smoke con-
7 stituents might present, taking into account—

8 (1) all relevant chemical, toxicological, human
9 exposure and epidemiologic studies, and other rel-
10 evant competent and reliable scientific evidence;

11 (2) the likelihood that the magnitude of a spe-
12 cific reduction in a smoke constituent may reason-
13 ably be expected to reduce the risk of harm to users
14 of the tobacco product;

15 (3) verification that the magnitude of the spe-
16 cific reduction in a smoke constituent can be
17 achieved by existing agronomic practices, product
18 technology, or manufacturing capability; and

19 (4) that the magnitude of the specific reduction
20 in a smoke constituent does not significantly reduce
21 consumer acceptance of the tobacco product.

1 **TITLE VI—PUBLIC DISCLOSURES**
2 **BY TOBACCO PRODUCT MAN-**
3 **UFACTURERS**

4 **SEC. 601. DISCLOSURES ON PACKAGES OF SMOKING ARTI-**
5 **CLES.**

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

8 (1) the principal face of a package of a smoking
9 article 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, except that
12 a package shall not be characterized as having more
13 than 2 principal faces;

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

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

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

22 (5) the entire back face of the package shall be
23 allocated for required package disclosures in accord-
24 ance with this section; and

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

4 (b) FRONT FACE AND PANELS AVAILABLE TO MANU-
5 FACTURER.—The front face and the side, top, and bottom
6 panels of a package of a smoking article shall be available
7 solely to a manufacturer (including a repackager) for iden-
8 tification of a tobacco product, in accordance with this
9 Act, and for other matter as determined by the manufac-
10 turer, and shall not be available for any disclosure that
11 the Administrator requires a manufacturer to make.

12 (c) REQUIRED INFORMATION ON BACK FACE.—Not
13 later than 24 months after the effective date of this Act,
14 the back face of a package of a smoking article shall be
15 available solely for disclosures required by or under this
16 Act, the Federal Cigarette Labeling and Advertising Act
17 (15 U.S.C. 1331 et seq.), and any other Federal law. Such
18 disclosures shall include—

19 (1) the printed name and address of the manu-
20 facturer, packer, or distributor, and any other iden-
21 tification associated with the manufacturer, packer,
22 or distributor or with the tobacco product that the
23 Administrator may require;

1 (2) 1 statutorily mandated warning label as re-
2 quired by section 4 of the Federal Cigarette Label-
3 ing and Advertising Act (15 U.S.C. 1333);

4 (3) a list of ingredients as required by sub-
5 section (e); and

6 (4) the appropriate tax registration number.

7 (d) AMENDMENT OF FEDERAL CIGARETTE LABEL-
8 ING AND ADVERTISING ACT.—Section 4(b)(1) of the Fed-
9 eral Cigarette Labeling and Advertising Act (15 U.S.C.
10 1333(b)(1)) is amended to read as follows:

11 “(b)(1) Each label statement required under para-
12 graph (1) of subsection (a) shall be located on the back
13 face of a package of cigarettes in accordance with section
14 601 of the Federal Tobacco Act of 2009. The phrase ‘Sur-
15 geon General’s Warning’ shall appear in capital letters,
16 and the size of all other letters in the label shall be the
17 same size as the size of such letters on the date of intro-
18 duction of the Federal Tobacco Act of 2009. All letters
19 in the label shall appear in conspicuous and legible type
20 in contrast by typography, layout, or color with all other
21 printed matter on the package.”.

22 (e) PACKAGE DISCLOSURE OF INGREDIENTS.—Not
23 later than 24 months after the effective date of this Act,
24 the package of a smoking article shall bear a list of the
25 common or usual names of the ingredients present in the

1 smoking article in an amount greater than 0.1 percent of
2 the total dry weight of the tobacco product (including all
3 ingredients), that shall comply with the following:

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

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

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

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

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

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

21 **SEC. 602. DISCLOSURES ON PACKAGES OF CHEWING TO-**
22 **BACCO AND DRY SNUFF.**

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

1 (1) the principal face of a package of chewing
2 tobacco or dry snuff is the face that has the largest
3 surface area or, for faces with identical surface
4 areas, any of the faces that have the largest surface
5 area, except that a package shall not be character-
6 ized as having more than 2 principal faces;

7 (2) the front or top face shall be the principal
8 face of the package;

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

12 (4) the back or bottom face of the package shall
13 be the principal face of a package that is opposite
14 the front or top face of the package;

15 (5) beginning 24 months after the effective date
16 of this Act, the entire back or bottom face of the
17 package shall be allocated for required package dis-
18 closures in accordance with this section; and

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

22 (b) FRONT OR TOP FACE AND PANELS AVAILABLE
23 TO MANUFACTURER.—The front or top face and the side,
24 top, and bottom panels of a package of chewing tobacco
25 or dry snuff shall be available solely to a manufacturer

1 (including a repackager) for identification of a tobacco
2 product, in accordance with this Act, and for other matter
3 as determined by the manufacturer, and shall not be avail-
4 able for any disclosure that the Administrator requires a
5 manufacturer to make.

6 (c) REQUIRED INFORMATION ON BACK OR BOTTOM
7 FACE.—The back or bottom face of a package of chewing
8 tobacco or dry snuff shall be available solely for disclosures
9 required by or under this Act, the Comprehensive Smoke-
10 less Tobacco Health Education Act of 1986 (15 U.S.C.
11 4401 et seq.), and any other Federal law. Such disclosures
12 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) 1 warning label, as required by section 3 of
19 the Comprehensive Smokeless Tobacco Health Edu-
20 cation Act of 1986 (15 U.S.C. 4402);

21 (3) a list of ingredients as required by sub-
22 section (e); and

23 (4) the appropriate tax registration number.

24 (d) AMENDMENT OF COMPREHENSIVE SMOKELESS
25 TOBACCO HEALTH EDUCATION ACT OF 1986.—Section

1 3(b)(1) of the Comprehensive Smokeless Tobacco Health
2 Education Act of 1986 (15 U.S.C. 4402(b)(1)) is amended
3 to read as follows:

4 “(1) in the case of the smokeless tobacco prod-
5 uct package—

6 “(A) in a conspicuous and prominent place
7 on the back face or bottom of the package; and

8 “(B) in a conspicuous format and in con-
9 spicuous and legible type in contrast with all
10 other printed material on the package; and”.

11 (e) PACKAGE DISCLOSURE OF INGREDIENTS.—Be-
12 ginning 24 months after the effective date of this Act, a
13 package of chewing tobacco or dry snuff shall bear a list
14 of the common or usual names of the ingredients present
15 in the chewing tobacco or dry snuff in an amount greater
16 than 0.1 percent of the total dry weight of the tobacco
17 (including all ingredients) that shall comply with the fol-
18 lowing:

19 (1) Such listing of ingredients shall appears
20 under, or be conspicuously accompanied by, the
21 heading “Tobacco and principal tobacco ingredi-
22 ents”.

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

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

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

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

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

12 **SEC. 603. PUBLIC DISCLOSURE OF INGREDIENTS.**

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

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

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

1 (b) INGREDIENTS TO BE DISCLOSED AS TO EACH
2 BRAND STYLE.—

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

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

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

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

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

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

23 (E) The disclosure of any ingredient in ac-
24 cordance with this section may, at the option of

1 the tobacco product manufacturer, designate
2 the functionality or purpose of that ingredient.

3 (c) AGGREGATE DISCLOSURE OF INGREDIENTS.—

4 (1) IN GENERAL.—The public disclosure re-
5 quired of a tobacco product manufacturer under
6 subsection (a)(2) shall consist of a single list of all
7 ingredients used in any brand style that a tobacco
8 product manufacturer manufactures for commercial
9 distribution domestically, without regard to the
10 quantity used, and including, separately, each spice,
11 each natural or artificial flavoring, and each preserv-
12 ative.

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

19 (d) NO REQUIRED DISCLOSURE OF QUANTITIES.—

20 The Administrator shall not require any public disclosure
21 of quantitative information about any ingredient in a to-
22 bacco product.

23 (e) DISCLOSURE ON WEBSITE.—The public disclo-
24 sures required by subsection (a) may be made by posting
25 on an Internet-accessible website, or other location elec-

1 tronically accessible to the public, which is identified on
2 all packages of a tobacco product manufacturer's tobacco
3 products.

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

8 **SEC. 604. CIGARETTE LABEL AND ADVERTISING WARNINGS.**

9 Section 4(a)(1) of the Federal Cigarette Labeling and
10 Advertising Act (15 U.S.C. 1333(a)(1)) is amended to
11 read as follows:

12 “(1) Beginning 18 months after the date of enact-
13 ment of the Federal Tobacco Act of 2009, it shall be un-
14 lawful for any person to manufacture, package, sell, offer
15 to sell, distribute, or import for sale or distribution within
16 the United States any cigarettes the package of which fails
17 to bear, in accordance with the requirements of this sec-
18 tion, 1 of the following labels:

19 “‘SURGEON GENERAL’S WARNING: Ciga-
20 rettes are addictive’.

21 “‘SURGEON GENERAL’S WARNING: To-
22 bacco smoke can harm your children’.

23 “‘SURGEON GENERAL’S WARNING: Ciga-
24 rettes cause fatal lung disease’.

1 “‘SURGEON GENERAL’S WARNING: Ciga-
2 rettes cause cancer’.

3 “‘SURGEON GENERAL’S WARNING: Ciga-
4 rettes cause strokes and heart disease’.

5 “‘SURGEON GENERAL’S WARNING:
6 Smoking during pregnancy can harm your baby’.

7 “‘SURGEON GENERAL’S WARNING:
8 Smoking can kill you’.

9 “‘SURGEON GENERAL’S WARNING: To-
10 bacco smoke causes fatal lung disease in non-smok-
11 ers’.

12 “‘SURGEON GENERAL’S WARNING: Quit-
13 ting smoking now greatly reduces serious risks to
14 your health’.”.

15 **TITLE VII—ENFORCEMENT** 16 **PROVISIONS**

17 **SEC. 701. PROHIBITED ACTS.**

18 The following acts and the causing thereof are hereby
19 prohibited:

20 (1) The introduction or delivery for introduction
21 into interstate commerce of any tobacco product that
22 is adulterated or misbranded.

23 (2) The adulteration or misbranding of any to-
24 bacco product in interstate commerce.

1 (3) The receipt in interstate commerce of any
2 tobacco product that is known to be adulterated or
3 misbranded, and the delivery or proffered delivery
4 thereof for pay or otherwise.

5 (4) The failure to establish or maintain any
6 record, or make any report or other submission, or
7 to provide any notice required by or under this Act,
8 or the refusal to permit access to, verification of, or
9 copying of any record as required by this Act.

10 (5) The refusal to permit entry or inspection as
11 authorized by this Act.

12 (6) The making to the Administrator of a state-
13 ment, report, certification, or other submission re-
14 quired by this Act, with knowledge that such state-
15 ment, report, certification, or other submission is
16 false in a material aspect.

17 (7) The manufacturing, shipping, receiving,
18 storing, selling, distributing, possession, or use of
19 any tobacco product with knowledge that it is an il-
20 licit tobacco product.

21 (8) The forging, simulating without proper per-
22 mission, falsely representing, or without proper au-
23 thority using any brand name.

24 (9) The using by any person to his or her own
25 advantage, or revealing, other than to the Adminis-

1 trator or officers or employees of the Agency, or to
2 the courts when relevant in any judicial proceeding
3 under this Act, any information acquired under au-
4 thority of this Act concerning any item which as a
5 trade secret is entitled to protection, except that this
6 paragraph shall not authorize the withholding of in-
7 formation from the House of Representatives or the
8 Senate or from, to the extent of matter within its ju-
9 risdiction, any committee or subcommittee of such
10 committee or any joint committee of Congress or
11 any subcommittee of such joint committee.

12 (10) The alteration, mutilation, destruction, ob-
13 literation, or removal of the whole or any part of the
14 labeling of, or the doing of any other act with re-
15 spect to, a tobacco product, if such act is done while
16 such tobacco product is held for sale (whether or not
17 the first sale) after shipment in interstate commerce,
18 and results in such tobacco product being adulter-
19 ated or misbranded.

20 (11) The importation of any tobacco product
21 that is adulterated, misbranded, or otherwise not in
22 compliance with this Act.

23 (12) The commission of any act prohibited by
24 section 201.

1 **SEC. 702. INJUNCTION PROCEEDINGS.**

2 (a) JURISDICTION.—The district courts of the United
3 States shall have jurisdiction, for cause shown, to restrain
4 violations of this Act, except for violations of section
5 701(11).

6 (b) TYPE OF TRIAL.—In case of an alleged violation
7 of an injunction or restraining order issued under this sec-
8 tion, which also constitutes a violation of this Act, trial
9 shall be by the court, or upon demand of the defendant,
10 by a jury.

11 **SEC. 703. PENALTIES.**

12 (a) VIOLATIONS OF SECTION 701.—Any person who
13 willfully violates a provision of section 701 shall be impris-
14 oned for not more than 1 year, or fined not more than
15 \$25,000, or both.

16 (b) CIVIL PENALTIES FOR VIOLATION OF SECTION
17 803.—

18 (1) IN GENERAL.—Any person who knowingly
19 distributes or sells, other than through retail sale or
20 retail offer for sale, any cigarette brand style in vio-
21 lation of section 803(a)—

22 (A) for a first offense shall be liable for a
23 civil penalty not to exceed \$10,000 for each dis-
24 tribution or sale; or

1 (B) for a second offense shall be liable for
2 a civil penalty not to exceed \$25,000 for each
3 distribution or sale;
4 except that the penalty imposed under this para-
5 graph against any person with respect to violations
6 during any 30-day period shall not exceed \$100,000.

7 (2) RETAILERS.—Any retailer who knowingly
8 distributes, sells, or offers for sale any cigarette
9 brand style in violation of section 803(a) shall—

10 (A) for a first offense for each sale or offer
11 for sale of cigarettes, if the total number of
12 packages of cigarettes sold or offered for sale—

13 (i) does not exceed 50 packages of
14 cigarettes, be liable for a civil penalty not
15 to exceed \$500 for each sale or offer for
16 sale; and

17 (ii) exceeds 50 packages of cigarettes,
18 be liable for a civil penalty not to exceed
19 \$1,000 for each sale or offer for sale;

20 (B) for each subsequent offense for each
21 sale or offer for sale of cigarettes, if the total
22 number of cigarettes sold or offered for sale—

23 (i) does not exceed 50 packages of
24 cigarettes, be liable for a civil penalty not

1 to exceed \$2,000 for each sale or offer for
2 sale; and

3 (ii) exceeds 50 packages of cigarettes,
4 be liable for a civil penalty not to exceed
5 \$5,000 for each sale or offer for sale;

6 except that the penalty imposed under this
7 paragraph against any person during any 30-
8 day period shall not exceed \$25,000.

9 **SEC. 704. SEIZURE.**

10 (a) ARTICLES SUBJECT TO SEIZURE.—

11 (1) IN GENERAL.—Any tobacco product that is
12 adulterated or misbranded when introduced into or
13 while in interstate commerce or while held for sale
14 (whether or not the first sale) after shipment in
15 interstate commerce, or which may not, under the
16 provisions of this Act, be introduced into interstate
17 commerce, shall be liable to be proceeded against
18 while in interstate commerce, or at any time there-
19 after, on libel of information and condemned in any
20 district court of the United States within the juris-
21 diction of which the tobacco product is found.

22 (2) LIMITATION.—No libel for condemnation
23 shall be instituted under this Act for any alleged
24 misbranding if there is pending in any court a libel
25 for condemnation proceeding under this Act based

1 upon the same alleged misbranding, and not more
2 than 1 such proceeding shall be instituted if no such
3 proceeding is so pending, except that such limita-
4 tions shall not apply—

5 (A) when such misbranding has been the
6 basis of a prior judgment in favor of the United
7 States, in a criminal, injunction, or libel for
8 condemnation proceeding under this Act; or

9 (B) when the Administrator has probable
10 cause to believe from facts found, without hear-
11 ing, by the Administrator or any officer or em-
12 ployee of the Agency that the misbranded to-
13 bacco product is dangerous to health beyond
14 the inherent danger to health posed by tobacco,
15 or that the labeling of the misbranded tobacco
16 product is fraudulent, or would be in a material
17 respect misleading to the injury or damage of
18 the purchaser or consumer.

19 In any case in which the number of libel for con-
20 demnation proceedings is limited as provided for in
21 this paragraph, the proceeding pending or instituted
22 shall, on application of the claimant, seasonably
23 made, be removed for trial to any district agreed
24 upon by stipulation between the parties, or, in case
25 of failure to so stipulate within a reasonable time,

1 the claimant may apply to the court of the district
2 in which the seizure has been made, and such court
3 (after giving the United States attorney for such dis-
4 trict reasonable notice and opportunity to be heard)
5 shall by order, unless good cause to the contrary is
6 shown, specify a district of reasonable proximity to
7 the claimant's principal place of business, to which
8 the case shall be removed for trial.

9 (3) LIST.—The following shall be liable to be
10 proceeded against at any time on libel of information
11 and condemned in any district court of the United
12 States within the jurisdiction of which they are
13 found:

14 (A) Any tobacco product that is an illicit
15 tobacco product.

16 (B) Any container of an illicit tobacco
17 product.

18 (C) Any equipment or thing used in mak-
19 ing an illicit tobacco product.

20 (D) Any adulterated or misbranded to-
21 bacco product.

22 (4) LIMITATION.—

23 (A) IN GENERAL.—Except as provided in
24 subparagraph (B), no libel for condemnation

1 may be instituted under this subsection against
2 any tobacco product that—

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) EXCEPTION.—A libel for condemna-
11 tion may be instituted under this subsection
12 against a tobacco product described in subpara-
13 graph (A) if the tobacco product’s advertising
14 which resulted in the tobacco product being
15 misbranded was disseminated in the establish-
16 ment in which the tobacco product is being held
17 for sale to the ultimate 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.—

1 (1) IN GENERAL.—The tobacco product, equip-
2 ment, or other thing proceeded against under this
3 section shall be liable to seizure by process pursuant
4 to the libel, and the procedure in cases under this
5 section shall conform, to the maximum extent prac-
6 ticable, to the procedure in admiralty, except that on
7 demand of either party any issue of fact joined in
8 any such case shall be tried by jury.

9 (2) CONSOLIDATION.—

10 (A) IN GENERAL.—When libel for con-
11 demnation proceedings under this section, in-
12 volving the same claimant and the same issues
13 of adulteration or misbranding, are pending in
14 2 or more jurisdictions, such pending pro-
15 ceedings, upon application of the claimant sea-
16 sonably made to the court of one such jurisdic-
17 tion, shall be consolidated for trial by order of
18 such court, and tried in—

19 (i) any district selected by the claim-
20 ant where one of such proceedings is pend-
21 ing; or

22 (ii) a district agreed upon by stipula-
23 tion between the parties.

24 (B) APPLICATION FOR CONSOLIDATION.—

25 If no order for consolidation is made under sub-

1 paragraph (A) within a reasonable time, the
2 claimant may apply to the court of one such ju-
3 risdiction and such court (after giving the
4 United States attorney for such district reason-
5 able notice and opportunity to be heard) shall
6 by order, unless good cause to the contrary is
7 shown, specify a district of reasonable proximity
8 to the claimant's principal place of business, in
9 which all such pending proceedings shall be
10 consolidated for trial and tried. Such order of
11 consolidation shall not apply so as to require
12 the removal of any case the date for trial of
13 which has been fixed. The court granting such
14 order shall give prompt notification thereof to
15 the other courts having jurisdiction of the cases
16 covered thereby.

17 (c) SAMPLES AND ANALYSES.—The court at any time
18 after seizure under this section up to a reasonable time
19 before trial shall by order allow any party to a condemna-
20 tion proceeding, or the party's attorney or agent, to obtain
21 a representative sample of the article seized and a true
22 copy of the analysis, if any, on which the proceeding is
23 based and the identifying marks or numbers, if any, of
24 the packages from which the samples analyzed were ob-
25 tained.

1 (d) DISPOSITION OF CONDEMNED TOBACCO PROD-
2 UCTS.—

3 (1) DESTRUCTION OR SALE.—

4 (A) IN GENERAL.—Any tobacco product
5 condemned under this section shall, after entry
6 of the decree, be disposed of by destruction or
7 sale as the court may, in accordance with the
8 provisions of this section, direct, and the pro-
9 ceeds thereof, if sold (less the legal costs and
10 charges), shall be paid into the Treasury of the
11 United States. Such tobacco product shall not
12 be sold under such decree contrary to the provi-
13 sions of this Act or the laws of the jurisdiction
14 in which sold.

15 (B) SUPERVISION.—After entry of the de-
16 cree under subparagraph (A) and upon the pay-
17 ment of the costs of the proceedings and the
18 execution of a good and sufficient bond condi-
19 tioned on such article not being sold or disposed
20 of contrary to the provisions of this Act or the
21 laws of any State in which sold, the court may
22 by order direct that such tobacco product be de-
23 livered to the owner thereof to be destroyed or
24 brought into compliance with the provisions of
25 this Act, under the supervision of an officer or

1 employee duly designated by the Administrator.
2 The expenses of such supervision shall be paid
3 by the person obtaining release of the tobacco
4 product under bond.

5 (C) IMPORTED PRODUCTS.—If the tobacco
6 product involved in a condemnation under this
7 paragraph was imported into the United States
8 and the person seeking its release establishes—

9 (i) that the adulteration, misbranding,
10 or violation did not occur after the tobacco
11 product was imported; and

12 (ii) that the person seeking the release
13 of the tobacco product had no cause for be-
14 lieving that it was adulterated, mis-
15 branded, or in violation before it was re-
16 leased from customs custody;

17 the court may permit the tobacco product to be
18 delivered to the owner for exportation under
19 section 709 in lieu of destruction upon a show-
20 ing by the owner that there is a reasonable cer-
21 tainty that the tobacco product will not be re-
22 imported into the United States.

23 (2) APPLICATION TO EQUIPMENT.—The provi-
24 sions of paragraph (1) shall, to the extent deemed
25 appropriate by the court, apply to any equipment or

1 other thing that is not otherwise within the scope of
2 such paragraph and which is referred to in para-
3 graph (3) of subsection (a).

4 (3) REMISSION OR MITIGATION.—Whenever in
5 any proceeding under this section, involving para-
6 graph (3) of subsection (a), the condemnation of any
7 equipment or thing (other than a tobacco product)
8 is decreed, the court shall allow the claim of any
9 claimant, to the extent of such claimant’s interest,
10 for remission or mitigation of such forfeiture if such
11 claimant proves to the satisfaction of the court—

12 (A) that such claimant has not caused the
13 equipment or thing to be within 1 of the cat-
14 egories referred to in such paragraph (3) and
15 has no interest in any tobacco product referred
16 to in such paragraph;

17 (B) that such claimant has an interest in
18 such equipment or other thing as owner or lien-
19 or or otherwise, acquired by such claimant in
20 good faith; and

21 (C) that such claimant at no time had any
22 knowledge or reason to believe that such equip-
23 ment or other thing was being or would be used
24 in, or to facilitate, the violation of laws of the

1 United States relating to any illicit tobacco
2 product.

3 (e) COSTS AND FEES.—When a decree of condemna-
4 tion is entered against the tobacco product or other article
5 under this section, court costs and fees, and storage and
6 other proper expenses shall be awarded against the person,
7 if any, intervening as claimant of the tobacco product or
8 other article.

9 (f) REMOVAL FOR TRIAL.—In the case of removal for
10 trial of any case as provided for by subsection (a) or (b)—

11 (1) the clerk of the court from which removal
12 is made shall promptly transmit to the court in
13 which the case is to be tried all records in the case
14 necessary in order that such court may exercise ju-
15 risdiction; and

16 (2) the court to which such case was removed
17 shall have the powers and be subject to the duties,
18 for purposes of such case, which the court from
19 which removal was made would have had, or to
20 which such court would have been subject, if such
21 case had not been removed.

22 (g) ADMINISTRATIVE DETENTION OF TOBACCO
23 PRODUCTS.—

24 (1) DETENTION AUTHORITY.—

1 (A) IN GENERAL.—An officer or qualified
2 employee of the Agency may order the deten-
3 tion, in accordance with this subsection, of any
4 tobacco product that is found during an inspec-
5 tion, examination, or investigation under this
6 Act conducted by such officer or qualified em-
7 ployee, if the officer or qualified employee has
8 credible evidence or information indicating that
9 such article presents a threat of serious adverse
10 health consequences beyond those normally in-
11 herent in the use of tobacco products.

12 (B) ADMINISTRATOR'S APPROVAL.—A to-
13 bacco product or component thereof may be or-
14 dered detained under subparagraph (A) only if
15 the Administrator or an official designated by
16 the Administrator approves the order. An offi-
17 cial may not be so designated unless the official
18 is an officer with supervisory responsibility for
19 the inspection, examination, or investigation
20 that led to the order.

21 (2) PERIOD OF DETENTION.—A tobacco prod-
22 uct may be detained under paragraph (1) for a rea-
23 sonable period, not to exceed 20 days, unless a
24 greater period, not to exceed 30 days, is necessary,

1 to institute an action under subsection (a) or section
2 702.

3 (3) SECURITY OF DETAINED TOBACCO PROD-
4 UCT.—An order under paragraph (1) may require
5 that the tobacco product to be detained be labeled
6 or marked as detained, and shall require that the to-
7 bacco product be maintained in or removed to a se-
8 cure facility, as appropriate. A tobacco product sub-
9 ject to such an order shall not be transferred by any
10 person from the place at which the tobacco product
11 is ordered detained, or from the place to which the
12 tobacco product is so removed, as the case may be,
13 until released by the Administrator or until the expi-
14 ration of the detention period applicable under such
15 order, whichever occurs first. This paragraph shall
16 not be construed as authorizing the delivery of the
17 tobacco product pursuant to the execution of a bond
18 while the tobacco product is subject to the order,
19 and section 709 shall not be construed to authorize
20 the delivery of the tobacco product pursuant to the
21 execution of a bond while the article is subject to the
22 order.

23 (4) APPEAL OF DETENTION ORDER.—

24 (A) IN GENERAL.—With respect to a to-
25 bacco product ordered detained under para-

1 graph (1), any person that would be entitled to
2 be a claimant of such tobacco product if the to-
3 bacco product were seized under subsection (a)
4 may appeal the detention order to the Adminis-
5 trator. Within 5 days after such an appeal is
6 filed, the Administrator, after providing oppor-
7 tunity for an informal hearing, shall confirm or
8 terminate the order involved, and such con-
9 firmation by the Administrator shall be consid-
10 ered a final agency action for purposes of sec-
11 tion 702 of title 5, United States Code. If dur-
12 ing such 5-day period the Administrator fails to
13 provide such an opportunity, or to confirm or
14 terminate such order, the order is deemed to be
15 terminated.

16 (B) EFFECT OF INSTITUTING COURT AC-
17 TION.—The process under subparagraph (A)
18 for the appeal of an order under paragraph (1)
19 shall terminate if the Administrator institutes
20 an action under subsection (a) or section 702
21 regarding the tobacco product involved.

22 **SEC. 705. REPORT OF MINOR VIOLATIONS.**

23 Nothing in this Act shall be construed as requiring
24 the Administrator to report for prosecution, or for the in-
25 stitution of libel or injunction proceedings, minor viola-

1 tions of this Act whenever the Administrator believes that
2 the public interest will be adequately served by a suitable
3 written notice or warning.

4 **SEC. 706. INSPECTION.**

5 (a) **AUTHORITY TO INSPECT.**—

6 (1) **IN GENERAL.**—The Administrator shall
7 have the power to inspect the premises of a tobacco
8 product manufacturer for purposes of determining
9 compliance with this Act, or the regulations promul-
10 gated under this Act.

11 (2) **ENTRY OF PREMISES.**—Officers of the
12 Agency designated by the Administrator, upon pre-
13 senting appropriate credentials and a written notice
14 to the person in charge of the premises involved, are
15 authorized to enter, at reasonable times, without a
16 search warrant, any factory, warehouse, or other es-
17 tablishment in which tobacco products are manufac-
18 tured, processed, packaged, or held for domestic dis-
19 tribution.

20 (3) **REASONABLE LIMITS AND MANNER.**—An
21 inspection under this subsection shall be conducted
22 within reasonable limits and in a reasonable manner,
23 and shall be limited to examining only those things,
24 including records, relevant to determining whether

1 violations of this Act, or regulations under this Act,
2 have occurred.

3 (4) LIMITATION.—No inspection under this sec-
4 tion shall extend to financial data, sales data other
5 than shipment data, pricing data, personnel data
6 (other than data as to qualifications of technical and
7 professional personnel performing functions subject
8 to this Act), or research data. A separate notice
9 shall be given for each such inspection, but a notice
10 shall not be required for each entry made during the
11 period covered by the inspection. Each such inspec-
12 tion shall be commenced and completed with reason-
13 able promptness.

14 (b) REPORT OF OBSERVATIONS.—Prior to leaving
15 the premises, the officer of the Agency who has supervised
16 or conducted the inspection shall give to the person in
17 charge of the premises a report in writing setting forth
18 any conditions or practices that appear to manifest a vio-
19 lation of this Act, or the regulations under this Act.

20 (c) SAMPLES.—If an officer has obtained any sample
21 in the course of an inspection under this section, prior to
22 leaving the premises such officer shall give to the person
23 in charge of the premises a receipt describing the samples
24 obtained. As to each such sample obtained, the officer
25 shall furnish promptly to the person in charge of the prem-

1 ises a copy of the sample and of any analysis made upon
2 the sample.

3 **SEC. 707. EFFECT OF COMPLIANCE.**

4 Compliance with the provisions of this Act, and the
5 regulations promulgated under this Act, shall constitute
6 a complete defense to any civil action, including relating
7 to any product 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. 708. IMPORTS.**

12 (a) IMPORTS; LIST OF REGISTERED FOREIGN ES-
13 TABLISHMENTS; SAMPLES FROM UNREGISTERED FOR-
14 EIGN ESTABLISHMENTS; EXAMINATION AND REFUSAL OF
15 ADMISSION.—

16 (1) IN GENERAL.—The Secretary of Homeland
17 Security shall deliver to the Administrator, upon re-
18 quest by the Administrator, samples of tobacco prod-
19 ucts that are being imported or offered for import
20 into the United States, giving notice thereof to the
21 owner or consignee, who may appear before the Ad-
22 ministrator and have the right to introduce testi-
23 mony.

24 (2) LIST OF ESTABLISHMENTS AND SAM-
25 PLES.—The Administrator shall furnish to the Sec-

1 retary of Homeland Security a list of establishments
2 registered pursuant to subsection (d) of section 109,
3 and shall request that, if any tobacco products man-
4 ufactured, prepared, or processed in an establish-
5 ment not so registered are imported or offered for
6 import into the United States, samples of such to-
7 bacco products be delivered to the Administrator,
8 with notice of such delivery to the owner or con-
9 signee, who may appear before the Administrator
10 and have the right to introduce testimony.

11 (3) EXAMINATIONS AND REFUSAL.—If it ap-
12 pears from the examination of samples delivered
13 under this subsection or otherwise that—

14 (A) such tobacco product is forbidden or
15 restricted in sale in the country in which it was
16 produced or from which it was exported; or

17 (B) such tobacco product is adulterated,
18 misbranded, or otherwise in violation of this
19 Act;

20 then such tobacco product shall be refused admis-
21 sion, except as provided in subsection (b).

22 (4) DESTRUCTION.—The Secretary of Home-
23 land Security shall cause the destruction of any such
24 tobacco product refused admission under this sub-
25 section unless such tobacco product is exported,

1 under regulations prescribed by the Secretary of
2 Homeland Security, within 90 days of the date of
3 notice of such refusal or within such additional time
4 as may be permitted pursuant to such regulations.

5 (b) DISPOSITION OF REFUSED TOBACCO PROD-
6 UCTS.—

7 (1) IN GENERAL.—Pending a decision as to the
8 admission of a tobacco product being imported or of-
9 fered for import, the Secretary of Homeland Secu-
10 rity may authorize the delivery of such tobacco prod-
11 uct to the owner or consignee upon the execution by
12 such owner or consignee of a good and sufficient
13 bond providing for the payment of such liquidated
14 damages in the event of default as may be required
15 pursuant to regulations of the Secretary of Home-
16 land Security.

17 (2) ACTIONS FOR COMPLIANCE.—If it appears
18 to the Administrator that a tobacco product that is
19 refused admission under subsection (a)(3) may, by
20 relabeling or other action, be brought into compli-
21 ance with this Act or rendered other than a tobacco
22 product, a final determination as to admission of
23 such tobacco product may be deferred and, upon fil-
24 ing of timely written application by the owner or
25 consignee and the execution by such owner or con-

1 signee of a bond as provided in paragraph (1), the
2 Administrator may, in accordance with regulations,
3 authorize the applicant to perform such relabeling or
4 other action specified in such authorization (includ-
5 ing destruction or export of rejected tobacco prod-
6 ucts or portions thereof, as may be specified in the
7 Administrator's authorization). All such relabeling
8 or other action pursuant to such authorization shall
9 in accordance with regulations be under the super-
10 vision of an officer or employee of the Agency des-
11 ignated by the Administrator, or an officer or em-
12 ployee of the Department of Homeland Security des-
13 ignated by the Secretary of Homeland Security.

14 (c) CHARGES CONCERNING REFUSED TOBACCO
15 PRODUCTS.—All expenses (including travel, per diem or
16 subsistence, and salaries of officers or employees of the
17 United States) in connection with the destruction provided
18 for in subsection (a) and the supervision of the relabeling
19 or other action authorized under the provisions of sub-
20 section (b), the amount of such expenses to be determined
21 in accordance with regulations, and all expenses in connec-
22 tion with the storage, cartage, or labor with respect to any
23 tobacco product refused admission under subsection (a),
24 shall be paid by the owner or consignee and, in default

1 of such payment, shall constitute a lien against any future
2 importations made by such owner or consignee.

3 **SEC. 709. TOBACCO PRODUCTS FOR EXPORT.**

4 (a) EXEMPTION FOR TOBACCO PRODUCTS EX-
5 PORTED.—Except as provided in subsection (b), a tobacco
6 product intended for export shall be exempt from this Act
7 if—

8 (1) it is not in conflict with the laws of the
9 country to which it is intended for export, as dem-
10 onstrated by—

11 (A) a document issued by the government
12 of that country; or

13 (B) a document provided by a person
14 knowledgeable with respect to the relevant laws
15 of that country and qualified by training and
16 experience to make determinations as to wheth-
17 er the tobacco product is or is not in conflict
18 with such laws;

19 (2) it is labeled on the outside of the shipping
20 package that it is intended for export; and

21 (3) the particular units of tobacco product in-
22 tended for export have not been sold or offered for
23 sale in domestic commerce.

24 (b) PRODUCTS FOR UNITED STATES ARMED FORCES
25 OVERSEAS.—A tobacco product intended for export shall

1 not be exempt from this Act if it is intended for sale or
2 distribution to members or units of the Armed Forces of
3 the United States located outside of the United States.

4 (c) LIMITATION.—This Act shall not apply to a per-
5 son that manufactures or distributes tobacco products
6 solely for export under subsection (a), except to the extent
7 such tobacco products are subject to subsection (b).

8 **TITLE VIII—MISCELLANEOUS** 9 **PROVISIONS**

10 **SEC. 801. USE OF PAYMENTS UNDER THE MASTER SETTLE-** 11 **MENT AGREEMENT AND INDIVIDUAL STATE** 12 **SETTLEMENT AGREEMENTS.**

13 (a) REDUCTION OF GRANT AMOUNTS.—

14 (1) IN GENERAL.—For fiscal year 2010 and
15 each subsequent fiscal year, the Secretary shall re-
16 duce, as provided for in subsection (b), the amount
17 of any grant to a State under section 1921 of the
18 Public Health Service Act (42 U.S.C. 300x–21) if
19 the Secretary determines that the State is expending
20 funds received by such State pursuant to the Master
21 Settlement Agreement, the Florida Settlement
22 Agreement, the Minnesota Settlement Agreement,
23 the Mississippi Memorandum of Understanding, or
24 the Texas Settlement Agreement, as applicable, on
25 tobacco control programs in amounts that are less

1 than the amounts recommended for that State by
2 the Centers for Disease Control and Prevention.

3 (2) CERTAIN STATES.—In the case of a State
4 whose legislature does not convene a regular session
5 in fiscal year 2009, the requirement described in
6 paragraph (1) shall apply only for fiscal year 2010
7 and subsequent fiscal years.

8 (b) DETERMINATION OF STATE SPENDING.—

9 (1) IN GENERAL.—Prior to making a grant to
10 a State under section 1921 of the Public Health
11 Service Act (42 U.S.C. 300x–21) for the first appli-
12 cable fiscal year or any subsequent fiscal year, the
13 Secretary shall make a determination of whether,
14 during the immediately preceding fiscal year, the
15 State has expended on tobacco control programs,
16 from the funds received by such State pursuant to
17 the Master Settlement Agreement, the Florida Set-
18 tlement Agreement, the Minnesota Settlement
19 Agreement, the Mississippi Memorandum of Under-
20 standing, or the Texas Settlement Agreement, as ap-
21 plicable, at least the amount recommended for that
22 State by the Centers for Disease Control and Pre-
23 vention.

24 (2) REDUCTION IN ALLOTMENT.—If, after no-
25 tice to the State and an opportunity for a hearing,

1 the Secretary determines under paragraph (1) that
2 the State has expended less than the recommended
3 amount, the Secretary shall reduce the amount of
4 the allotment to the State under section 1921 of the
5 Public Health Service Act (42 U.S.C. 300x-21) for
6 the fiscal year involved by an amount equal to—

7 (A) in the case of the first applicable fiscal
8 year, 10 percent of the amount determined
9 under section 1933 of such Act (42 U.S.C.
10 300x-33) for the State for the fiscal year;

11 (B) in the case of the first fiscal year fol-
12 lowing such applicable fiscal year, 20 percent of
13 the amount determined under such section
14 1933, for the State for the fiscal year;

15 (C) in the case of the second such fiscal
16 year, 30 percent of the amount determined
17 under such section 1933, for the State for the
18 fiscal year; and

19 (D) in the case of the third such fiscal
20 year or any subsequent fiscal year, 40 percent
21 of the amount determined under such section
22 1933, for the State for the fiscal year.

23 The Secretary shall not grant to any State a waiver of
24 the terms and requirements of this subsection or sub-
25 section (a).

1 (c) DEFINITIONS.—For the purposes of this section:

2 (1) FIRST APPLICABLE FISCAL YEAR.—The
3 term “first applicable fiscal year” means—

4 (A) fiscal year 2011, in the case of any
5 State described in subsection (a)(2); and

6 (B) fiscal year 2010, in the case of any
7 other State.

8 (2) FLORIDA SETTLEMENT AGREEMENT.—The
9 term “Florida Settlement Agreement” means the
10 Settlement Agreement, together with the exhibits
11 thereto, entered into on August 25, 1997, between
12 the State of Florida and signatory tobacco product
13 manufacturers, as specified therein.

14 (3) MASTER SETTLEMENT AGREEMENT.—The
15 term “Master Settlement Agreement” means the
16 Master Settlement Agreement, together with the ex-
17 hibits thereto, entered into on November 23, 1998,
18 between the signatory States and signatory tobacco
19 product manufacturers, as specified therein.

20 (4) MINNESOTA SETTLEMENT AGREEMENT.—
21 The term “Minnesota Settlement Agreement” means
22 the Settlement Agreement, together with the exhibits
23 thereto, entered into on May 8, 1998, between the
24 State of Minnesota and signatory tobacco product
25 manufacturers, as specified therein.

1 (5) MISSISSIPPI MEMORANDUM OF UNDER-
2 STANDING.—The term “Mississippi Memorandum of
3 Understanding” means the Memorandum of Under-
4 standing, together with the exhibits thereto and Set-
5 tlement Agreement contemplated therein, entered
6 into on July 2, 1997, between the State of Mis-
7 sissippi and signatory tobacco product manufactur-
8 ers, as specified therein.

9 (6) SECRETARY.—The term “Secretary” means
10 the Secretary of Health and Human Services.

11 (7) TEXAS SETTLEMENT AGREEMENT.—The
12 term “Texas Settlement Agreement” means the Set-
13 tlement Agreement, together with the exhibits there-
14 to, entered into on January 16, 1998, between the
15 State of Texas and signatory tobacco product manu-
16 facturers, as specified therein.

17 **SEC. 802. USER FEES.**

18 (a) ASSESSMENT OF USER FEES.—The Adminis-
19 trator shall assess an annual user fee for each fiscal year,
20 beginning with fiscal year 2010, determined in accordance
21 with this section, upon each tobacco product manufacturer
22 (including each importer) that is subject to this Act.

23 (b) USE OF USER FEES.—The Administrator shall
24 make user fees collected pursuant to this section available
25 to pay, in each fiscal year, for the costs of the activities

1 of the Agency related to the regulation of tobacco products
2 under this Act.

3 (c) AMOUNTS OF USER FEES.—

4 (1) LIMITATION.—Except as provided in para-
5 graph (2), the total amount of the user fees assessed
6 for each fiscal year pursuant to this section shall be
7 sufficient, and shall not exceed the amount nec-
8 essary, to pay for the costs of the activities described
9 in subsection (b) for the fiscal year involved.

10 (2) AMOUNTS.—The total amount of the assess-
11 ments under this section—

12 (A) for fiscal year 2010 shall not exceed
13 \$100,000,000; and

14 (B) for each subsequent fiscal year, shall
15 not exceed the limitation on the assessment im-
16 posed during the preceding fiscal year, as ad-
17 justed by the Administrator (after notice, pub-
18 lished in the Federal Register) to reflect the
19 greater of—

20 (i) the total percentage change that
21 occurred in the Consumer Price Index for
22 all urban consumers (all items; United
23 States city average) for the 12-month pe-
24 riod ending on June 30 preceding the fis-

1 cal year for which the fee amounts are
2 being established; or

3 (ii) the total percentage change for
4 the previous fiscal year in basic pay under
5 the General Schedule in accordance with
6 section 5332 of title 5, United States
7 Code, as adjusted by any locality-based
8 comparability payment pursuant to section
9 5304 of such title for Federal employees
10 stationed in the District of Columbia.

11 (3) NOTIFICATION.—The Administrator shall
12 notify each tobacco product manufacturer subject to
13 this section of the amount of the annual assessment
14 imposed on such tobacco product manufacturer
15 under subsection (d). Such notifications shall occur
16 not later than the July 31 prior to the beginning of
17 the fiscal year for which such assessment is being
18 made, and payments of all assessments shall be
19 made not later than 60 days after the date of each
20 such notification. Such notification shall contain a
21 complete list of the assessments imposed on tobacco
22 product manufacturers for that fiscal year.

23 (d) LIABILITY OF TOBACCO PRODUCT MANUFACTUR-
24 ERS FOR USER FEES.—

1 (1) DETERMINATION.—The user fee to be paid
2 by each tobacco product manufacturer for a fiscal
3 year shall be determined by multiplying—

4 (A) such tobacco product manufacturer’s
5 market share of tobacco products, as deter-
6 mined under regulations issued pursuant to
7 subsection (e); by

8 (B) the total user fee assessment for such
9 fiscal year, as determined under subsection (e).

10 (2) LIMITATION.—Except as provided in para-
11 graph (3), no tobacco product manufacturer shall be
12 required to pay a percentage of a total annual user
13 fee for all tobacco product manufacturers that ex-
14 ceeds the market share of such manufacturer.

15 (3) FAILURE TO PAY.—If—

16 (A) a tobacco product manufacturer fails
17 to pay the user fee in full by the due date;

18 (B) the Administrator, after diligent in-
19 quiry, concludes that such manufacturer is un-
20 likely to make such payment in full by the time
21 such payment will be needed by the Adminis-
22 trator; and

23 (C) the Administrator and the Department
24 of Justice make diligent efforts to obtain pay-

1 ment in full from such tobacco product manu-
2 facturer;
3 the Administrator may re-allocate the unpaid
4 amount owed by that tobacco product manufacturer
5 to the other tobacco product manufacturers on the
6 basis of their respective market shares. If the Ad-
7 ministrator makes such re-allocation, the Adminis-
8 trator shall set a reasonable time, not less than 60
9 days from the date of notice of the amount due, for
10 payment of that amount by such manufacturers. If
11 and to the extent that the Administrator ultimately
12 receives from that tobacco product manufacturer or
13 any successor to such tobacco product manufacturer
14 any payment of the previously unpaid user fee
15 amount, the Administrator shall credit such payment
16 to the tobacco product manufacturers that made
17 payments of any such re-allocated amount, in pro-
18 portion to their respective payments of such amount.
19 (e) REGULATIONS.—Not later than 12 months after
20 the date of enactment of this Act, the Administrator shall,
21 by regulation, establish a system for determining the mar-
22 ket shares of tobacco products for each tobacco product
23 manufacturer subject to this section. In promulgating reg-
24 ulations under this subsection, the Administrator shall—

1 (1) take into account the differences between
2 categories and subcategories of tobacco products in
3 terms of sales, manner of unit packaging, and any
4 other factors relevant to the calculation of market
5 share for a tobacco product manufacturer;

6 (2) take into account that different tobacco
7 product manufacturers rely to varying degrees on
8 the sales of different categories and subcategories of
9 tobacco products; and

10 (3) provide that the market share of tobacco
11 products for each tobacco product manufacturer
12 shall be recalculated on an annual basis.

13 **SEC. 803. FIRE SAFETY STANDARDS FOR CIGARETTES.**

14 (a) PROHIBITION.—Beginning on January 1, 2012,
15 no person shall distribute, sell, or offer for sale domesti-
16 cally any brand style of cigarettes unless—

17 (1) cigarettes of that brand style randomly
18 sampled from a manufacturing facility of the to-
19 bacco product manufacturer have been tested in ac-
20 cordance with subsection (b);

21 (2) not more than 25 percent of the cigarettes
22 of that brand style tested in a complete test in ac-
23 cordance with subsection (b) exhibit full-length
24 burns; and

1 (3) a written certification has been filed by the
2 tobacco product manufacturer with the Adminis-
3 trator in accordance with subsection (c), and that
4 written certification is current in accordance with
5 subsection (d), except that—

6 (A) nothing in this section shall be con-
7 strued to prohibit a distributor or retailer that
8 is in possession of any cigarette brand style in-
9 ventory prior to January 1, 2012, from distrib-
10 uting or selling the cigarettes of that inventory
11 after January 1, 2012, but prior to July 1,
12 2012; and

13 (B) nothing in this section shall be con-
14 strued to prohibit any person from distributing
15 or selling, or offering to distribute or sell, ciga-
16 rettes of a brand style that has not been tested
17 and certified as meeting the performance stand-
18 ard set forth in paragraph (2) if the cigarettes
19 are manufactured and packaged for distribution
20 or sale outside the United States and are not
21 intended for sale or distribution to members or
22 units of the Armed Forces of the United States
23 located outside of the United States; and

24 (4) the cigarette packages, cartons, and cases
25 containing that brand style are marked—

1 (A) to indicate that cigarettes of that
2 brand style have been certified in accordance
3 with this section; and

4 (B) in a manner designated by order by
5 the Administrator.

6 (b) TESTING OF CIGARETTES.—Testing of each
7 brand style of cigarettes shall be conducted—

8 (1) in accordance with the American Society of
9 Testing and Materials standard E2187–4, entitled
10 “Standard Test Method for Measuring the Ignition
11 Strength of Cigarettes”;

12 (2) for each cigarette on 10 layers of filter
13 paper;

14 (3) so that a replicate test of 40 cigarettes for
15 each brand style of cigarettes comprises a complete
16 test trial for that brand style; and

17 (4) in a laboratory that has been accredited in
18 accordance with ISO/IEC 17205 of the International
19 Organization for Standardization and that has an
20 implemented quality control and quality assurance
21 program that includes a procedure capable of deter-
22 mining the repeatability of the testing results to a
23 repeatability value that is not greater than 0.19.

24 (c) CERTIFICATIONS BY MANUFACTURERS.—Each
25 tobacco product manufacturer shall submit, with respect

1 to each brand style of cigarettes that such manufacturer
2 manufactures for commercial distribution domestically, a
3 written certification—

4 (1) that contains—

5 (A) the brand name and brand style name;

6 (B) the cigarette length in millimeters;

7 (C) the cigarette circumference in millime-
8 ters;

9 (D) the classification of the cigarette as
10 menthol or non-menthol;

11 (E) the classification of the cigarette as fil-
12 ter or non-filter;

13 (F) a description of the type of package
14 used for the brand style;

15 (G) the name, address, and telephone num-
16 ber of the laboratory that conducted the testing,
17 if different from those of the tobacco product
18 manufacturer; and

19 (H) the date that the testing occurred;

20 (2) attesting that the brand style listed in the
21 certification has been tested in accordance with all
22 requirements of subsection (b); and

23 (3) attesting that the brand style meets the per-
24 formance standard set forth in subsection (a)(2).

1 (d) DURATION OF EFFECTIVENESS OF CERTIFI-
2 CATION.—A certification for each brand style of cigarettes
3 under subsection (c) shall be deemed current for the 3-
4 year period beginning on the date of on which the certifi-
5 cation is received by the Administrator. Such date shall
6 be stated in a written acknowledgment of receipt sent by
7 the Administrator to the submitter. Cigarettes of each
8 brand style shall be tested in accordance with subsection
9 (a)(1), and a new certification shall be submitted in ac-
10 cordance with subsection (c), prior to the end of each such
11 3-year certification period.

12 (e) CHANGES IN CIGARETTES.—If a tobacco product
13 manufacturer makes a change to the cigarettes of a brand
14 style that is likely to alter the ability of the cigarettes of
15 that brand style to meet the performance standard set
16 forth in subsection (a)(2), the tobacco product manufac-
17 turer shall conduct subsequent tests with respect to that
18 brand style in accordance with the requirements of sub-
19 section (b) and submit to the Administrator a new certifi-
20 cation in accordance with subsection (c) prior to intro-
21 ducing or delivering for introduction, or causing the intro-
22 duction or delivery for introduction, into interstate com-
23 merce of any cigarettes of such changed brand style for
24 commercial distribution domestically or to members or
25 units of the armed forces of the United States located out-

1 side of the United States. If a tobacco product manufac-
2 turer makes a change to the cigarettes of a brand style
3 that is not likely to alter the ability of the cigarettes of
4 that brand style to meet the performance standard set
5 forth in subsection (a)(2), such re-testing shall not be re-
6 quired.

7 (f) RECORDS.—Each tobacco product manufacturer
8 shall keep a record of all testing conducted in support of
9 a certification under this section for a period of not less
10 than 3-years from the date on which the certification is
11 received by the Administrator, and shall send to the Ad-
12 ministrator, upon request by the Administrator during
13 that period, any and all records of such testing and the
14 results obtained.

15 (g) PREEMPTION.—With respect to fire safety or ig-
16 nition-propensity, the Administrator and any State or po-
17 litical subdivision thereof shall not—

18 (1) require testing of cigarettes that would be
19 in addition to, or different from, the testing pre-
20 scribed in subsections (a)(1) and (b);

21 (2) require a performance standard that is in
22 addition to, or different from, the performance
23 standard set forth in subsection (a)(2); or

24 (3) require any other or additional package
25 marking.

1 No requirement or prohibition based on fire safety or igni-
2 tion propensity shall be imposed under State or local law
3 with respect to any cigarette.

4 **SEC. 804. INSPECTION BY THE ALCOHOL AND TOBACCO**
5 **TAX TRADE BUREAU OF RECORDS OF CER-**
6 **TAIN CIGARETTE AND SMOKELESS TOBACCO**
7 **SELLERS.**

8 (a) IN GENERAL.—Any officer of the Alcohol and To-
9 bacco Tax Trade Bureau may, during normal business
10 hours, enter the premises of any person described in sub-
11 section (b) for the purposes of inspecting—

12 (1) any records or information required to be
13 maintained by such person under the provisions of
14 law referred to in subsection (d); or

15 (2) any cigarettes or smokeless tobacco kept or
16 stored by such person at such premises.

17 (b) COVERED PERSONS.—Subsection (a) shall apply
18 to any person who engages in a delivery sale, and who
19 ships, sells, distributes, or receives any quantity in excess
20 of 10,000 cigarettes, or any quantity in excess of 500 sin-
21 gle-unit consumer-sized cans or packages of smokeless to-
22 bacco, within a single month.

23 (c) RELIEF.—

24 (1) IN GENERAL.—The district courts of the
25 United States shall have the authority in a civil ac-

1 tion under this subsection to compel inspections au-
2 thorized by subsection (a).

3 (2) VIOLATIONS.—Whoever violates subsection
4 (a) or an order issued pursuant to paragraph (1)
5 shall be subject to a civil penalty in an amount that
6 shall not exceed \$10,000 for each such violation.

7 (d) COVERED PROVISIONS OF LAW.—The provisions
8 of law referred to in this subsection are—

9 (1) the Act of October 19, 1949 (15 U.S.C.
10 375; commonly referred to as the “Jenkins Act”);

11 (2) chapter 114 of title 18, United States Code;
12 and

13 (3) this title.

14 (e) DELIVERY SALE DEFINED.—In this section, the
15 term “delivery sale” has the meaning given that term in
16 2343(e) of title 18, United States Code.

17 **SEC. 805. TOBACCO GROWER PROTECTION.**

18 No provision of this Act shall be construed to permit
19 the Secretary of Health and Human Services, or any other
20 Federal official, to require changes to traditional farming
21 practices, including standard cultivation practices, curing
22 processes, seed composition, tobacco type, fertilization,
23 soil, record keeping, or any other requirement affecting
24 farming practices.

1 SEC. 806. SEVERABILITY.

2 If any provision of this Act, the amendments made
3 by this Act, or the application of any provision of this Act
4 or amendments to any person or circumstance is held to
5 be invalid, the remainder of this Act, the amendments
6 made by this Act, and the application of the provisions
7 of this Act or amendments to any other person or cir-
8 cumstance shall not be affected, and shall continue to be
9 enforced to the fullest extent possible.

○