1. **Authorizing Legislation**

PUBLIC LAW 111–31—JUNE 22, 2009

FAMILY SMOKING PREVENTION AND

TOBACCO CONTROL AND FEDERAL

RETIREMENT REFORM

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123 STAT. 1776 PUBLIC LAW 111–31—JUNE 22, 2009

Public Law 111–31

111th Congress

An Act

To protect the public health by providing the Food and Drug Administration with

certain authority to regulate tobacco products, to amend title 5, United States

Code, to make certain modifications in the Thrift Savings Plan, the Civil Service

Retirement System, and the Federal Employees’ Retirement System, and for

other purposes.

*Be it enacted by the Senate and House of Representatives of*

*the United States of America in Congress assembled,*

**DIVISION A—FAMILY SMOKING PREVENTION**

**AND TOBACCO CONTROL**

**ACT**

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

(a) SHORT TITLE.—This division may be cited as the ‘‘Family

Smoking Prevention and Tobacco Control Act’’.

(b) TABLE OF CONTENTS.—The table of contents of this division

is as follows:

Sec. 1. Short title; table of contents.

Sec. 2. Findings.

Sec. 3. Purpose.

Sec. 4. Scope and effect.

Sec. 5. Severability.

Sec. 6. Modification of deadlines for Secretarial action.

TITLE I—AUTHORITY OF THE FOOD AND DRUG ADMINISTRATION

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

Sec. 102. Final rule.

Sec. 103. Conforming and other amendments to general provisions.

Sec. 104. Study on raising the minimum age to purchase tobacco products.

Sec. 105. Enforcement action plan for advertising and promotion restrictions.

Sec. 106. Studies of progress and effectiveness.

TITLE II—TOBACCO PRODUCT WARNINGS; CONSTITUENT AND SMOKE

CONSTITUENT DISCLOSURE

Sec. 201. Cigarette label and advertising warnings.

Sec. 202. Authority to revise cigarette warning label statements.

Sec. 203. State regulation of cigarette advertising and promotion.

Sec. 204. Smokeless tobacco labels and advertising warnings.

Sec. 205. Authority to revise smokeless tobacco product warning label statements.

Sec. 206. Tar, nicotine, and other smoke constituent disclosure to the public.

TITLE III—PREVENTION OF ILLICIT TRADE IN TOBACCO PRODUCTS

Sec. 301. Labeling, recordkeeping, records inspection.

Sec. 302. Study and report.

**SEC. 2. FINDINGS.**

The Congress finds the following:

21 USC 387 note.

21 USC 301 note.

Family Smoking

Prevention and

Tobacco Control

Act.

June 22, 2009

[H.R. 1256]

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00002 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

PUBLIC LAW 111–31—JUNE 22, 2009 123 STAT. 1777

(1) The use of tobacco products by the Nation’s children

is a pediatric disease of considerable proportions that results

in new generations of tobacco-dependent children and adults.

(2) A consensus exists within the scientific and medical

communities that tobacco products are inherently dangerous

and cause cancer, heart disease, and other serious adverse

health effects.

(3) Nicotine is an addictive drug.

(4) Virtually all new users of tobacco products are under

the minimum legal age to purchase such products.

(5) Tobacco advertising and marketing contribute significantly

to the use of nicotine-containing tobacco products by

adolescents.

(6) Because past efforts to restrict advertising and marketing

of tobacco products have failed adequately to curb

tobacco use by adolescents, comprehensive restrictions on the

sale, promotion, and distribution of such products are needed.

(7) Federal and State governments have lacked the legal

and regulatory authority and resources they need to address

comprehensively the public health and societal problems caused

by the use of tobacco products.

(8) Federal and State public health officials, the public

health community, and the public at large recognize that the

tobacco industry should be subject to ongoing oversight.

(9) Under article I, section 8 of the Constitution, the Congress

is vested with the responsibility for regulating interstate

commerce and commerce with Indian tribes.

(10) The sale, distribution, marketing, advertising, and use

of tobacco products are activities in and substantially affecting

interstate commerce because they are sold, marketed, advertised,

and distributed in interstate commerce on a nationwide

basis, and have a substantial effect on the Nation’s economy.

(11) The sale, distribution, marketing, advertising, and use

of such products substantially affect interstate commerce

through the health care and other costs attributable to the

use of tobacco products.

(12) It is in the public interest for Congress to enact legislation

that provides the Food and Drug Administration with

the authority to regulate tobacco products and the advertising

and promotion of such products. The benefits to the American

people from enacting such legislation would be significant in

human and economic terms.

(13) Tobacco use is the foremost preventable cause of premature

death in America. It causes over 400,000 deaths in

the United States each year, and approximately 8,600,000

Americans have chronic illnesses related to smoking.

(14) Reducing the use of tobacco by minors by 50 percent

would prevent well over 10,000,000 of today’s children from

becoming regular, daily smokers, saving over 3,000,000 of them

from premature death due to tobacco-induced disease. Such

a reduction in youth smoking would also result in approximately

$75,000,000,000 in savings attributable to reduced

health care costs.

(15) Advertising, marketing, and promotion of tobacco products

have been especially directed to attract young persons

to use tobacco products, and these efforts have resulted in

increased use of such products by youth. Past efforts to oversee

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00003 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

123 STAT. 1778 PUBLIC LAW 111–31—JUNE 22, 2009

these activities have not been successful in adequately preventing

such increased use.

(16) In 2005, the cigarette manufacturers spent more than

$13,000,000,000 to attract new users, retain current users,

increase current consumption, and generate favorable long-term

attitudes toward smoking and tobacco use.

(17) Tobacco product advertising often misleadingly portrays

the use of tobacco as socially acceptable and healthful

to minors.

(18) Tobacco product advertising is regularly seen by persons

under the age of 18, and persons under the age of 18

are regularly exposed to tobacco product promotional efforts.

(19) Through advertisements during and sponsorship of

sporting events, tobacco has become strongly associated with

sports and has become portrayed as an integral part of sports

and the healthy lifestyle associated with rigorous sporting

activity.

(20) Children are exposed to substantial and unavoidable

tobacco advertising that leads to favorable beliefs about tobacco

use, plays a role in leading young people to overestimate the

prevalence of tobacco use, and increases the number of young

people who begin to use tobacco.

(21) The use of tobacco products in motion pictures and

other mass media glamorizes its use for young people and

encourages them to use tobacco products.

(22) Tobacco advertising expands the size of the tobacco

market by increasing consumption of tobacco products including

tobacco use by young people.

(23) Children are more influenced by tobacco marketing

than adults: more than 80 percent of youth smoke three heavily

marketed brands, while only 54 percent of adults, 26 and older,

smoke these same brands.

(24) Tobacco company documents indicate that young

people are an important and often crucial segment of the

tobacco market. Children, who tend to be more price sensitive

than adults, are influenced by advertising and promotion practices

that result in drastically reduced cigarette prices.

(25) Comprehensive advertising restrictions will have a

positive effect on the smoking rates of young people.

(26) Restrictions on advertising are necessary to prevent

unrestricted tobacco advertising from undermining legislation

prohibiting access to young people and providing for education

about tobacco use.

(27) International experience shows that advertising regulations

that are stringent and comprehensive have a greater

impact on overall tobacco use and young people’s use than

weaker or less comprehensive ones.

(28) Text only requirements, although not as stringent

as a ban, will help reduce underage use of tobacco products

while preserving the informational function of advertising.

(29) It is in the public interest for Congress to adopt legislation

to address the public health crisis created by actions of

the tobacco industry.

(30) The final regulations promulgated by the Secretary

of Health and Human Services in the August 28, 1996, issue

of the Federal Register (61 Fed. Reg. 44615–44618) for inclusion

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00004 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

PUBLIC LAW 111–31—JUNE 22, 2009 123 STAT. 1779

as part 897 of title 21, Code of Federal Regulations, are consistent

with the first amendment to the United States Constitution

and with the standards set forth in the amendments made

by this subtitle for the regulation of tobacco products by the

Food and Drug Administration, and the restriction on the sale

and distribution of, including access to and the advertising

and promotion of, tobacco products contained in such regulations

are substantially related to accomplishing the public

health goals of this division.

(31) The regulations described in paragraph (30) will

directly and materially advance the Federal Government’s

substantial interest in reducing the number of children and

adolescents who use cigarettes and smokeless tobacco and in

preventing the life-threatening health consequences associated

with tobacco use. An overwhelming majority of Americans who

use tobacco products begin using such products while they

are minors and become addicted to the nicotine in those products

before reaching the age of 18. Tobacco advertising and

promotion play a crucial role in the decision of these minors

to begin using tobacco products. Less restrictive and less comprehensive

approaches have not and will not be effective in

reducing the problems addressed by such regulations. The

reasonable restrictions on the advertising and promotion of

tobacco products contained in such regulations will lead to

a significant decrease in the number of minors using and

becoming addicted to those products.

(32) The regulations described in paragraph (30) impose

no more extensive restrictions on communication by tobacco

manufacturers and sellers than are necessary to reduce the

number of children and adolescents who use cigarettes and

smokeless tobacco and to prevent the life-threatening health

consequences associated with tobacco use. Such regulations are

narrowly tailored to restrict those advertising and promotional

practices which are most likely to be seen or heard by youth

and most likely to entice them into tobacco use, while affording

tobacco manufacturers and sellers ample opportunity to convey

information about their products to adult consumers.

(33) Tobacco dependence is a chronic disease, one that

typically requires repeated interventions to achieve long-term

or permanent abstinence.

(34) Because the only known safe alternative to smoking

is cessation, interventions should target all smokers to help

them quit completely.

(35) Tobacco products have been used to facilitate and

finance criminal activities both domestically and internationally.

Illicit trade of tobacco products has been linked to organized

crime and terrorist groups.

(36) It is essential that the Food and Drug Administration

review products sold or distributed for use to reduce risks

or exposures associated with tobacco products and that it be

empowered to review any advertising and labeling for such

products. It is also essential that manufacturers, prior to marketing

such products, be required to demonstrate that such

products will meet a series of rigorous criteria, and will benefit

the health of the population as a whole, taking into account

both users of tobacco products and persons who do not currently

use tobacco products.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00005 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

123 STAT. 1780 PUBLIC LAW 111–31—JUNE 22, 2009

(37) Unless tobacco products that purport to reduce the

risks to the public of tobacco use actually reduce such risks,

those products can cause substantial harm to the public health

to the extent that the individuals, who would otherwise not

consume tobacco products or would consume such products

less, use tobacco products purporting to reduce risk. Those

who use products sold or distributed as modified risk products

that do not in fact reduce risk, rather than quitting or reducing

their use of tobacco products, have a substantially increased

likelihood of suffering disability and premature death. The

costs to society of the widespread use of products sold or distributed

as modified risk products that do not in fact reduce risk

or that increase risk include thousands of unnecessary deaths

and injuries and huge costs to our health care system.

(38) As the National Cancer Institute has found, many

smokers mistakenly believe that ‘‘low tar’’ and ‘‘light’’ cigarettes

cause fewer health problems than other cigarettes. As the

National Cancer Institute has also found, mistaken beliefs

about the health consequences of smoking ‘‘low tar’’ and ‘‘light’’

cigarettes can reduce the motivation to quit smoking entirely

and thereby lead to disease and death.

(39) Recent studies have demonstrated that there has been

no reduction in risk on a population-wide basis from ‘‘low

tar’’ and ‘‘light’’ cigarettes, and such products may actually

increase the risk of tobacco use.

(40) The dangers of products sold or distributed as modified

risk tobacco products that do not in fact reduce risk are so

high that there is a compelling governmental interest in

ensuring that statements about modified risk tobacco products

are complete, accurate, and relate to the overall disease risk

of the product.

(41) As the Federal Trade Commission has found, consumers

have misinterpreted advertisements in which one

product is claimed to be less harmful than a comparable

product, even in the presence of disclosures and advisories

intended to provide clarification.

(42) Permitting manufacturers to make unsubstantiated

statements concerning modified risk tobacco products, whether

express or implied, even if accompanied by disclaimers would

be detrimental to the public health.

(43) The only way to effectively protect the public health

from the dangers of unsubstantiated modified risk tobacco products

is to empower the Food and Drug Administration to require

that products that tobacco manufacturers sold or distributed

for risk reduction be reviewed in advance of marketing, and

to require that the evidence relied on to support claims be

fully verified.

(44) The Food and Drug Administration is a regulatory

agency with the scientific expertise to identify harmful substances

in products to which consumers are exposed, to design

standards to limit exposure to those substances, to evaluate

scientific studies supporting claims about the safety of products,

and to evaluate the impact of labels, labeling, and advertising

on consumer behavior in order to reduce the risk of harm

and promote understanding of the impact of the product on

health. In connection with its mandate to promote health and

reduce the risk of harm, the Food and Drug Administration

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00006 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

PUBLIC LAW 111–31—JUNE 22, 2009 123 STAT. 1781

routinely makes decisions about whether and how products

may be marketed in the United States.

(45) The Federal Trade Commission was created to protect

consumers from unfair or deceptive acts or practices, and to

regulate unfair methods of competition. Its focus is on those

marketplace practices that deceive or mislead consumers, and

those that give some competitors an unfair advantage. Its mission

is to regulate activities in the marketplace. Neither the

Federal Trade Commission nor any other Federal agency except

the Food and Drug Administration possesses the scientific

expertise needed to implement effectively all provisions of the

Family Smoking Prevention and Tobacco Control Act.

(46) If manufacturers state or imply in communications

directed to consumers through the media or through a label,

labeling, or advertising, that a tobacco product is approved

or inspected by the Food and Drug Administration or complies

with Food and Drug Administration standards, consumers are

likely to be confused and misled. Depending upon the particular

language used and its context, such a statement could result

in consumers being misled into believing that the product is

endorsed by the Food and Drug Administration for use or

in consumers being misled about the harmfulness of the product

because of such regulation, inspection, approval, or compliance.

(47) In August 2006 a United States district court judge

found that the major United States cigarette companies continue

to target and market to youth. USA v. Philip Morris,

USA, Inc., et al. (Civil Action No. 99–2496 (GK), August 17,

2006).

(48) In August 2006 a United States district court judge

found that the major United States cigarette companies

dramatically increased their advertising and promotional

spending in ways that encourage youth to start smoking subsequent

to the signing of the Master Settlement Agreement in

1998. USA v. Philip Morris, USA, Inc., et al. (Civil Action

No. 99–2496 (GK), August 17, 2006).

(49) In August 2006 a United States district court judge

found that the major United States cigarette companies have

designed their cigarettes to precisely control nicotine delivery

levels and provide doses of nicotine sufficient to create and

sustain addiction while also concealing much of their nicotinerelated

research. USA v. Philip Morris, USA, Inc., et al. (Civil

Action No. 99–2496 (GK), August 17, 2006).

**SEC. 3. PURPOSE.**

The purposes of this division are—

(1) to provide authority to the Food and Drug Administration

to regulate tobacco products under the Federal Food, Drug,

and Cosmetic Act (21 U.S.C. 301 et seq.), by recognizing it

as the primary Federal regulatory authority with respect to

the manufacture, marketing, and distribution of tobacco products

as provided for in this division;

(2) to ensure that the Food and Drug Administration has

the authority to address issues of particular concern to public

health officials, especially the use of tobacco by young people

and dependence on tobacco;

21 USC 387 note.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00007 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

123 STAT. 1782 PUBLIC LAW 111–31—JUNE 22, 2009

(3) to authorize the Food and Drug Administration to set

national standards controlling the manufacture of tobacco products

and the identity, public disclosure, and amount of ingredients

used in such products;

(4) to provide new and flexible enforcement authority to

ensure that there is effective oversight of the tobacco industry’s

efforts to develop, introduce, and promote less harmful tobacco

products;

(5) to vest the Food and Drug Administration with the

authority to regulate the levels of tar, nicotine, and other

harmful components of tobacco products;

(6) in order to ensure that consumers are better informed,

to require tobacco product manufacturers to disclose research

which has not previously been made available, as well as

research generated in the future, relating to the health and

dependency effects or safety of tobacco products;

(7) to continue to permit the sale of tobacco products to

adults in conjunction with measures to ensure that they are

not sold or accessible to underage purchasers;

(8) to impose appropriate regulatory controls on the tobacco

industry;

(9) to promote cessation to reduce disease risk and the

social costs associated with tobacco-related diseases; and

(10) to strengthen legislation against illicit trade in tobacco

products.

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

(a) INTENDED EFFECT.—Nothing in this division (or an amendment

made by this division) shall be construed to—

(1) establish a precedent with regard to any other industry,

situation, circumstance, or legal action; or

(2) affect any action pending in Federal, State, or tribal

court, or any agreement, consent decree, or contract of any

kind.

(b) AGRICULTURAL ACTIVITIES.—The provisions of this division

(or an amendment made by this division) which authorize the

Secretary to take certain actions with regard to tobacco and tobacco

products shall not be construed to affect any authority of the Secretary

of Agriculture under existing law regarding the growing,

cultivation, or curing of raw tobacco.

(c) REVENUE ACTIVITIES.—The provisions of this division (or

an amendment made by this division) which authorize the Secretary

to take certain actions with regard to tobacco products shall not

be construed to affect any authority of the Secretary of the Treasury

under chapter 52 of the Internal Revenue Code of 1986.

**SEC. 5. SEVERABILITY.**

If any provision of this division, of the amendments made

by this division, or of the regulations promulgated under this division

(or under such amendments), or the application of any such

provision to any person or circumstance is held to be invalid,

the remainder of this division, such amendments and such regulations,

and the application of such provisions to any other person

or circumstance shall not be affected and shall continue to be

enforced to the fullest extent possible.

21 USC 387 note.

21 USC 387 note.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00008 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

PUBLIC LAW 111–31—JUNE 22, 2009 123 STAT. 1783

**SEC. 6. MODIFICATION OF DEADLINES FOR SECRETARIAL ACTION.**

(a) DELAYED COMMENCEMENT OF DATES FOR SECRETARIAL

ACTION.—

(1) IN GENERAL.—Except as provided in subsection (c), with

respect to any time periods specified in this division (or in

an amendment made by this division) that begin on the date

of enactment of this Act, within which the Secretary of Health

and Human Services is required to carry out and complete

specified activities, the calculation of such time periods shall

commence on the date described in subsection (b).

(2) LIMITATION.—Subsection (a) shall only apply with

respect to obligations of the Secretary of Health and Human

Services that must be completed within a specified time period

and shall not apply to the obligations of any other person

or to any other provision of this division (including the amendments

made by this division) that do not create such obligations

of the Secretary and are not contingent on actions by the

Secretary.

(b) DATE DESCRIBED.—The date described in this subsection

is the first day of the first fiscal quarter following the initial

2 consecutive fiscal quarters of fiscal year 2010 for which the

Secretary of Health and Human Services has collected fees under

section 919 of the Federal Food, Drug, and Cosmetic Act (as added

by section 101).

(c) EXCEPTION.—Subsection (a) shall not apply to any time

period (or date) contained—

(1) in section 102, except that the reference to ‘‘180 days’’

in subsection (a)(1) of such section shall be deemed to be

‘‘270 days’’; and

(2) in sections 201 through 204 (or the amendments made

by any such sections).

(d) ADJUSTMENT.—The Secretary of Health and Human Services

may extend or reduce the duration of one or more time periods

to which subsection (a) applies if the Secretary determines appropriate,

except that no such period shall be extended for more than

90 days.

**TITLE I—AUTHORITY OF THE FOOD**

**AND DRUG ADMINISTRATION**

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

(a) DEFINITION OF TOBACCO PRODUCTS.—Section 201 of the

Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended

by adding at the end the following:

‘‘(rr)(1) The term ‘tobacco product’ means any product made

or derived from tobacco that is intended for human consumption,

including any component, part, or accessory of a tobacco product

(except for raw materials other than tobacco used in manufacturing

a component, part, or accessory of a tobacco product).

‘‘(2) The term ‘tobacco product’ does not mean an article that

is a drug under subsection (g)(1), a device under subsection (h),

or a combination product described in section 503(g).

‘‘(3) The products described in paragraph (2) shall be subject

to chapter V of this Act.

Applicability.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00009 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

123 STAT. 1784 PUBLIC LAW 111–31—JUNE 22, 2009

‘‘(4) A tobacco product shall not be marketed in combination

with any other article or product regulated under this Act (including

a drug, biologic, food, cosmetic, medical device, or a dietary supplement).’’.

(b) FDA AUTHORITY OVER TOBACCO PRODUCTS.—The Federal

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

(1) by redesignating chapter IX as chapter X;

(2) by redesignating sections 901 through 910 as sections

1001 through 1010; and

(3) by inserting after chapter VIII the following:

**‘‘CHAPTER IX—TOBACCO PRODUCTS**

**‘‘SEC. 900. DEFINITIONS.**

‘‘In this chapter:

‘‘(1) ADDITIVE.—The term ‘additive’ means any substance

the intended use of which results or may reasonably be expected

to result, directly or indirectly, in its becoming a component

or otherwise affecting the characteristic of any tobacco product

(including any substances intended for use as a flavoring or

coloring or in producing, manufacturing, packing, processing,

preparing, treating, packaging, transporting, or holding), except

that such term does not include tobacco or a pesticide chemical

residue in or on raw tobacco or a pesticide chemical.

‘‘(2) BRAND.—The term ‘brand’ means a variety of tobacco

product distinguished by the tobacco used, tar content, nicotine

content, flavoring used, size, filtration, packaging, logo, registered

trademark, brand name, identifiable pattern of colors,

or any combination of such attributes.

‘‘(3) CIGARETTE.—The term ‘cigarette’—

‘‘(A) means a product that—

‘‘(i) is a tobacco product; and

‘‘(ii) meets the definition of the term ‘cigarette’

in section 3(1) of the Federal Cigarette Labeling and

Advertising Act; and

‘‘(B) includes tobacco, in any form, that is functional

in the product, which, because of its appearance, the type

of tobacco used in the filler, or its packaging and labeling,

is likely to be offered to, or purchased by, consumers as

a cigarette or as roll-your-own tobacco.

‘‘(4) CIGARETTE TOBACCO.—The term ‘cigarette tobacco’

means any product that consists of loose tobacco that is

intended for use by consumers in a cigarette. Unless otherwise

stated, the requirements applicable to cigarettes under this

chapter shall also apply to cigarette tobacco.

‘‘(5) COMMERCE.—The term ‘commerce’ has the meaning

given that term by section 3(2) of the Federal Cigarette Labeling

and Advertising Act.

‘‘(6) COUNTERFEIT TOBACCO PRODUCT.—The term ‘counterfeit

tobacco product’ means a tobacco product (or the container

or labeling of such a product) that, without authorization, bears

the trademark, trade name, or other identifying mark, imprint,

or device, or any likeness thereof, of a tobacco product listed

in a registration under section 905(i)(1).

‘‘(7) DISTRIBUTOR.—The term ‘distributor’ as regards a

tobacco product means any person who furthers the distribution

of a tobacco product, whether domestic or imported, at any

21 USC 387.

21 USC 391

*et seq*.

21 USC 391,

301 note,

392 and note,

393–399a.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00010 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

PUBLIC LAW 111–31—JUNE 22, 2009 123 STAT. 1785

point from the original place of manufacture to the person

who sells or distributes the product to individuals for personal

consumption. Common carriers are not considered distributors

for purposes of this chapter.

‘‘(8) ILLICIT TRADE.—The term ‘illicit trade’ means any practice

or conduct prohibited by law which relates to production,

shipment, receipt, possession, distribution, sale, or purchase

of tobacco products including any practice or conduct intended

to facilitate such activity.

‘‘(9) INDIAN COUNTRY.—The term ‘Indian country’ has the

meaning given such term in section 1151 of title 18, United

States Code.

‘‘(10) INDIAN TRIBE.—The term ‘Indian tribe’ has the

meaning given such term in section 4(e) of the Indian Self-

Determination and Education Assistance Act.

‘‘(11) LITTLE CIGAR.—The term ‘little cigar’ means a product

that—

‘‘(A) is a tobacco product; and

‘‘(B) meets the definition of the term ‘little cigar’ in

section 3(7) of the Federal Cigarette Labeling and Advertising

Act.

‘‘(12) NICOTINE.—The term ‘nicotine’ means the chemical

substance named 3-(1-Methyl-2-pyrrolidinyl) pyridine or

C[10]H[14]N[2], including any salt or complex of nicotine.

‘‘(13) PACKAGE.—The term ‘package’ means a pack, box,

carton, or container of any kind or, if no other container,

any wrapping (including cellophane), in which a tobacco product

is offered for sale, sold, or otherwise distributed to consumers.

‘‘(14) RETAILER.—The term ‘retailer’ means any person,

government, or entity who sells tobacco products to individuals

for personal consumption, or who operates a facility where

self-service displays of tobacco products are permitted.

‘‘(15) ROLL-YOUR-OWN TOBACCO.—The term ‘roll-your-own

tobacco’ means any tobacco product which, because of its

appearance, type, packaging, or labeling, is suitable for use

and likely to be offered to, or purchased by, consumers as

tobacco for making cigarettes.

‘‘(16) SMALL TOBACCO PRODUCT MANUFACTURER.—The term

‘small tobacco product manufacturer’ means a tobacco product

manufacturer that employs fewer than 350 employees. For purposes

of determining the number of employees of a manufacturer

under the preceding sentence, the employees of a manufacturer

are deemed to include the employees of each entity

that controls, is controlled by, or is under common control

with such manufacturer.

‘‘(17) SMOKE CONSTITUENT.—The term ‘smoke constituent’

means any chemical or chemical compound in mainstream or

sidestream tobacco smoke that either transfers from any component

of the cigarette to the smoke or that is formed by the

combustion or heating of tobacco, additives, or other component

of the tobacco product.

‘‘(18) SMOKELESS TOBACCO.—The term ‘smokeless tobacco’

means any tobacco product that consists of cut, ground, powdered,

or leaf tobacco and that is intended to be placed in

the oral or nasal cavity.

‘‘(19) STATE; TERRITORY.—The terms ‘State’ and ‘Territory’

shall have the meanings given to such terms in section 201.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00011 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

123 STAT. 1786 PUBLIC LAW 111–31—JUNE 22, 2009

‘‘(20) TOBACCO PRODUCT MANUFACTURER.—The term

‘tobacco product manufacturer’ means any person, including

any repacker or relabeler, who—

‘‘(A) manufactures, fabricates, assembles, processes, or

labels a tobacco product; or

‘‘(B) imports a finished tobacco product for sale or

distribution in the United States.

‘‘(21) TOBACCO WAREHOUSE.—

‘‘(A) Subject to subparagraphs (B) and (C), the term

‘tobacco warehouse’ includes any person—

‘‘(i) who—

‘‘(I) removes foreign material from tobacco leaf

through nothing other than a mechanical process;

‘‘(II) humidifies tobacco leaf with nothing other

than potable water in the form of steam or mist;

or

‘‘(III) de-stems, dries, and packs tobacco leaf

for storage and shipment;

‘‘(ii) who performs no other actions with respect

to tobacco leaf; and

‘‘(iii) who provides to any manufacturer to whom

the person sells tobacco all information related to the

person’s actions described in clause (i) that is necessary

for compliance with this Act.

‘‘(B) The term ‘tobacco warehouse’ excludes any person

who—

‘‘(i) reconstitutes tobacco leaf;

‘‘(ii) is a manufacturer, distributor, or retailer of

a tobacco product; or

‘‘(iii) applies any chemical, additive, or substance

to the tobacco leaf other than potable water in the

form of steam or mist.

‘‘(C) The definition of the term ‘tobacco warehouse’

in subparagraph (A) shall not apply to the extent to which

the Secretary determines, through rulemaking, that regulation

under this chapter of the actions described in such

subparagraph is appropriate for the protection of the public

health.

‘‘(22) UNITED STATES.—The term ‘United States’ means the

50 States of the United States of America and the District

of Columbia, the Commonwealth of Puerto Rico, Guam, the

Virgin Islands, American Samoa, Wake Island, Midway Islands,

Kingman Reef, Johnston Atoll, the Northern Mariana Islands,

and any other trust territory or possession of the United States.

**‘‘SEC. 901. FDA AUTHORITY OVER TOBACCO PRODUCTS.**

‘‘(a) IN GENERAL.—Tobacco products, including modified risk

tobacco products for which an order has been issued in accordance

with section 911, shall be regulated by the Secretary under this

chapter and shall not be subject to the provisions of chapter V.

‘‘(b) APPLICABILITY.—This chapter shall apply to all cigarettes,

cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and

to any other tobacco products that the Secretary by regulation

deems to be subject to this chapter.

‘‘(c) SCOPE.—

‘‘(1) IN GENERAL.—Nothing in this chapter, or any policy

issued or regulation promulgated thereunder, or in sections

Regulations.

21 USC 387a.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00012 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

PUBLIC LAW 111–31—JUNE 22, 2009 123 STAT. 1787

101(a), 102, or 103 of title I, title II, or title III of the Family

Smoking Prevention and Tobacco Control Act, shall be construed

to affect, expand, or limit the Secretary’s authority over

(including the authority to determine whether products may

be regulated), or the regulation of, products under this Act

that are not tobacco products under chapter V or any other

chapter.

‘‘(2) LIMITATION OF AUTHORITY.—

‘‘(A) IN GENERAL.—The provisions of this chapter shall

not apply to tobacco leaf that is not in the possession

of a manufacturer of tobacco products, or to the producers

of tobacco leaf, including tobacco growers, tobacco warehouses,

and tobacco grower cooperatives, nor shall any

employee of the Food and Drug Administration have any

authority to enter onto a farm owned by a producer of

tobacco leaf without the written consent of such producer.

‘‘(B) EXCEPTION.—Notwithstanding subparagraph (A),

if a producer of tobacco leaf is also a tobacco product

manufacturer or controlled by a tobacco product manufacturer,

the producer shall be subject to this chapter in

the producer’s capacity as a manufacturer. The exception

in this subparagraph shall not apply to a producer of

tobacco leaf who grows tobacco under a contract with a

tobacco product manufacturer and who is not otherwise

engaged in the manufacturing process.

‘‘(C) RULE OF CONSTRUCTION.—Nothing in this chapter

shall be construed to grant the Secretary authority to

promulgate regulations on any matter that involves the

production of tobacco leaf or a producer thereof, other than

activities by a manufacturer affecting production.

‘‘(d) RULEMAKING PROCEDURES.—Each rulemaking under this

chapter shall be in accordance with chapter 5 of title 5, United

States Code. This subsection shall not be construed to affect the

rulemaking provisions of section 102(a) of the Family Smoking

Prevention and Tobacco Control Act.

‘‘(e) CENTER FOR TOBACCO PRODUCTS.—Not later than 90 days

after the date of enactment of the Family Smoking Prevention

and Tobacco Control Act, the Secretary shall establish within the

Food and Drug Administration the Center for Tobacco Products,

which shall report to the Commissioner of Food and Drugs in

the same manner as the other agency centers within the Food

and Drug Administration. The Center shall be responsible for the

implementation of this chapter and related matters assigned by

the Commissioner.

‘‘(f) OFFICE TO ASSIST SMALL TOBACCO PRODUCT MANUFACTURERS.—

The Secretary shall establish within the Food and Drug

Administration an identifiable office to provide technical and other

nonfinancial assistance to small tobacco product manufacturers to

assist them in complying with the requirements of this Act.

‘‘(g) CONSULTATION PRIOR TO RULEMAKING.—Prior to promulgating

rules under this chapter, the Secretary shall endeavor to

consult with other Federal agencies as appropriate.

**‘‘SEC. 902. ADULTERATED TOBACCO PRODUCTS.**

‘‘A tobacco product shall be deemed to be adulterated if—

‘‘(1) it consists in whole or in part of any filthy, putrid,

or decomposed substance, or is otherwise contaminated by any

21 USC 387b.

Establishment.

Deadline.

Establishment.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00013 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

123 STAT. 1788 PUBLIC LAW 111–31—JUNE 22, 2009

added poisonous or added deleterious substance that may

render the product injurious to health;

‘‘(2) it has been prepared, packed, or held under insanitary

conditions whereby it may have been contaminated with filth,

or whereby it may have been rendered injurious to health;

‘‘(3) its package is composed, in whole or in part, of any

poisonous or deleterious substance which may render the contents

injurious to health;

‘‘(4) the manufacturer or importer of the tobacco product

fails to pay a user fee assessed to such manufacturer or

importer pursuant to section 919 by the date specified in section

919 or by the 30th day after final agency action on a resolution

of any dispute as to the amount of such fee;

‘‘(5) it is, or purports to be or is represented as, a tobacco

product which is subject to a tobacco product standard established

under section 907 unless such tobacco product is in

all respects in conformity with such standard;

‘‘(6)(A) it is required by section 910(a) to have premarket

review and does not have an order in effect under section

910(c)(1)(A)(i); or

‘‘(B) it is in violation of an order under section 910(c)(1)(A);

‘‘(7) the methods used in, or the facilities or controls used

for, its manufacture, packing, or storage are not in conformity

with applicable requirements under section 906(e)(1) or an

applicable condition prescribed by an order under section

906(e)(2); or

‘‘(8) it is in violation of section 911.

**‘‘SEC. 903. MISBRANDED TOBACCO PRODUCTS.**

‘‘(a) IN GENERAL.—A tobacco product shall be deemed to be

misbranded—

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

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

‘‘(A) the name and place of business of the tobacco

product manufacturer, packer, or distributor;

‘‘(B) an accurate statement of the quantity of the contents

in terms of weight, measure, or numerical count;

‘‘(C) an accurate statement of the percentage of the

tobacco used in the product that is domestically grown

tobacco and the percentage that is foreign grown tobacco;

and

‘‘(D) the statement required under section 920(a),

except that under subparagraph (B) reasonable variations shall

be permitted, and exemptions as to small packages shall be

established, by regulations prescribed by the Secretary;

‘‘(3) if any word, statement, or other information required

by or under authority of this chapter to appear on the label

or labeling is not prominently placed thereon with such

conspicuousness (as compared with other words, statements,

or designs in the labeling) and in such terms as to render

it likely to be read and understood by the ordinary individual

under customary conditions of purchase and use;

‘‘(4) if it has an established name, unless its label bears,

to the exclusion of any other nonproprietary name, its established

name prominently printed in type as required by the

Secretary by regulation;

Regulations.

Labeling.

21 USC 387c.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00014 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

PUBLIC LAW 111–31—JUNE 22, 2009 123 STAT. 1789

‘‘(5) if the Secretary has issued regulations requiring that

its labeling bear adequate directions for use, or adequate

warnings against use by children, that are necessary for the

protection of users unless its labeling conforms in all respects

to such regulations;

‘‘(6) if it was manufactured, prepared, propagated, compounded,

or processed in an establishment not duly registered

under section 905(b), 905(c), 905(d), or 905(h), if it was not

included in a list required by section 905(i), if a notice or

other information respecting it was not provided as required

by such section or section 905(j), or if it does not bear such

symbols from the uniform system for identification of tobacco

products prescribed under section 905(e) as the Secretary by

regulation requires;

‘‘(7) if, in the case of any tobacco product distributed or

offered for sale in any State—

‘‘(A) its advertising is false or misleading in any particular;

or

‘‘(B) it is sold or distributed in violation of regulations

prescribed under section 906(d);

‘‘(8) unless, in the case of any tobacco product distributed

or offered for sale in any State, the manufacturer, packer,

or distributor thereof includes in all advertisements and other

descriptive printed matter issued or caused to be issued by

the manufacturer, packer, or distributor with respect to that

tobacco product—

‘‘(A) a true statement of the tobacco product’s established

name as described in paragraph (4), printed prominently;

and

‘‘(B) a brief statement of—

‘‘(i) the uses of the tobacco product and relevant

warnings, precautions, side effects, and contraindications;

and

‘‘(ii) in the case of specific tobacco products made

subject to a finding by the Secretary after notice and

opportunity for comment that such action is appropriate

to protect the public health, a full description

of the components of such tobacco product or the formula

showing quantitatively each ingredient of such

tobacco product to the extent required in regulations

which shall be issued by the Secretary after an opportunity

for a hearing;

‘‘(9) if it is a tobacco product subject to a tobacco product

standard established under section 907, unless it bears such

labeling as may be prescribed in such tobacco product standard;

or

‘‘(10) if there was a failure or refusal—

‘‘(A) to comply with any requirement prescribed under

section 904 or 908; or

‘‘(B) to furnish any material or information required

under section 909.

‘‘(b) PRIOR APPROVAL OF LABEL STATEMENTS.—The Secretary

may, by regulation, require prior approval of statements made

on the label of a tobacco product to ensure that such statements

do not violate the misbranding provisions of subsection (a) and

that such statements comply with other provisions of the Family

Regulations.

Hearings.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00015 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

123 STAT. 1790 PUBLIC LAW 111–31—JUNE 22, 2009

Smoking Prevention and Tobacco Control Act (including the amendments

made by such Act). No regulation issued under this subsection

may require prior approval by the Secretary of the content

of any advertisement, except for modified risk tobacco products

as provided in section 911. No advertisement of a tobacco product

published after the date of enactment of the Family Smoking

Prevention and Tobacco Control Act shall, with respect to the language

of label statements as prescribed under section 4 of the

Federal Cigarette Labeling and Advertising Act and section 3 of

the Comprehensive Smokeless Tobacco Health Education Act of

1986 or the regulations issued under such sections, be subject

to the provisions of sections 12 through 15 of the Federal Trade

Commission Act.

**‘‘SEC. 904. SUBMISSION OF HEALTH INFORMATION TO THE SECRETARY.**

‘‘(a) REQUIREMENT.—Each tobacco product manufacturer or

importer, or agents thereof, shall submit to the Secretary the following

information:

‘‘(1) Not later than 6 months after the date of enactment

of the Family Smoking Prevention and Tobacco Control Act,

a listing of all ingredients, including tobacco, substances, compounds,

and additives that are, as of such date, added by

the manufacturer to the tobacco, paper, filter, or other part

of each tobacco product by brand and by quantity in each

brand and subbrand.

‘‘(2) A description of the content, delivery, and form of

nicotine in each tobacco product measured in milligrams of

nicotine in accordance with regulations promulgated by the

Secretary in accordance with section 4(e) of the Federal Cigarette

Labeling and Advertising Act.

‘‘(3) Beginning 3 years after the date of enactment of the

Family Smoking Prevention and Tobacco Control Act, a listing

of all constituents, including smoke constituents as applicable,

identified by the Secretary as harmful or potentially harmful

to health in each tobacco product, and as applicable in the

smoke of each tobacco product, by brand and by quantity in

each brand and subbrand. Effective beginning 3 years after

such date of enactment, the manufacturer, importer, or agent

shall comply with regulations promulgated under section 915

in reporting information under this paragraph, where

applicable.

‘‘(4) Beginning 6 months after the date of enactment of

the Family Smoking Prevention and Tobacco Control Act, all

documents developed after such date of enactment that relate

to health, toxicological, behavioral, or physiologic effects of current

or future tobacco products, their constituents (including

smoke constituents), ingredients, components, and additives.

‘‘(b) DATA SUBMISSION.—At the request of the Secretary, each

tobacco product manufacturer or importer of tobacco products, or

agents thereof, shall submit the following:

‘‘(1) Any or all documents (including underlying scientific

information) relating to research activities, and research

findings, conducted, supported, or possessed by the manufacturer

(or agents thereof) on the health, toxicological, behavioral,

or physiologic effects of tobacco products and their constituents

Effective date.

Effective date.

Deadline.

21 USC 387d.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00016 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

PUBLIC LAW 111–31—JUNE 22, 2009 123 STAT. 1791

(including smoke constituents), ingredients, components, and

additives.

‘‘(2) Any or all documents (including underlying scientific

information) relating to research activities, and research

findings, conducted, supported, or possessed by the manufacturer

(or agents thereof) that relate to the issue of whether

a reduction in risk to health from tobacco products can occur

upon the employment of technology available or known to the

manufacturer.

‘‘(3) Any or all documents (including underlying scientific

or financial information) relating to marketing research

involving the use of tobacco products or marketing practices

and the effectiveness of such practices used by tobacco manufacturers

and distributors.

An importer of a tobacco product not manufactured in the United

States shall supply the information required of a tobacco product

manufacturer under this subsection.

‘‘(c) TIME FOR SUBMISSION.—

‘‘(1) IN GENERAL.—At least 90 days prior to the delivery

for introduction into interstate commerce of a tobacco product

not on the market on the date of enactment of the Family

Smoking Prevention and Tobacco Control Act, the manufacturer

of such product shall provide the information required under

subsection (a).

‘‘(2) DISCLOSURE OF ADDITIVE.—If at any time a tobacco

product manufacturer adds to its tobacco products a new

tobacco additive or increases the quantity of an existing tobacco

additive, the manufacturer shall, except as provided in paragraph

(3), at least 90 days prior to such action so advise

the Secretary in writing.

‘‘(3) DISCLOSURE OF OTHER ACTIONS.—If at any time a

tobacco product manufacturer eliminates or decreases an

existing additive, or adds or increases an additive that has

by regulation been designated by the Secretary as an additive

that is not a human or animal carcinogen, or otherwise harmful

to health under intended conditions of use, the manufacturer

shall within 60 days of such action so advise the Secretary

in writing.

‘‘(d) DATA LIST.—

‘‘(1) IN GENERAL.—Not later than 3 years after the date

of enactment of the Family Smoking Prevention and Tobacco

Control Act, and annually thereafter, the Secretary shall publish

in a format that is understandable and not misleading

to a lay person, and place on public display (in a manner

determined by the Secretary) the list established under subsection

(e).

‘‘(2) CONSUMER RESEARCH.—The Secretary shall conduct

periodic consumer research to ensure that the list published

under paragraph (1) is not misleading to lay persons. Not

later than 5 years after the date of enactment of the Family

Smoking Prevention and Tobacco Control Act, the Secretary

shall submit to the appropriate committees of Congress a report

on the results of such research, together with recommendations

on whether such publication should be continued or modified.

‘‘(e) DATA COLLECTION.—Not later than 24 months after the

date of enactment of the Family Smoking Prevention and Tobacco

Control Act, the Secretary shall establish, and periodically revise

Deadline.

Deadline.

Reports.

Recommendations.

Deadlines.

Publication.

Public

information.

VerDate Nov 24 2008 12:38 Jul 02, 2009 Jkt 079139 PO 00000 Frm 00017 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 GPO1 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

123 STAT. 1792 PUBLIC LAW 111–31—JUNE 22, 2009

as appropriate, a list of harmful and potentially harmful constituents,

including smoke constituents, to health in each tobacco product

by brand and by quantity in each brand and subbrand. The Secretary

shall publish a public notice requesting the submission by

interested persons of scientific and other information concerning

the harmful and potentially harmful constituents in tobacco products

and tobacco smoke.

**‘‘SEC. 905. ANNUAL REGISTRATION.**

‘‘(a) DEFINITIONS.—In this section:

‘‘(1) MANUFACTURE, PREPARATION, COMPOUNDING, OR PROCESSING.—

The term ‘manufacture, preparation, compounding, or

processing’ shall include repackaging or otherwise changing

the container, wrapper, or labeling of any tobacco product package

in furtherance of the distribution of the tobacco product

from the original place of manufacture to the person who makes

final delivery or sale to the ultimate consumer or user.

‘‘(2) NAME.—The term ‘name’ shall include in the case

of a partnership the name of each partner and, in the case

of a corporation, the name of each corporate officer and director,

and the State of incorporation.

‘‘(b) REGISTRATION BY OWNERS AND OPERATORS.—On or before

December 31 of each year, every person who owns or operates

any establishment in any State engaged in the manufacture,

preparation, compounding, or processing of a tobacco product or

tobacco products shall register with the Secretary the name, places

of business, and all such establishments of that person. If enactment

of the Family Smoking Prevention and Tobacco Control Act occurs

in the second half of the calendar year, the Secretary shall designate

a date no later than 6 months into the subsequent calendar year

by which registration pursuant to this subsection shall occur.

‘‘(c) REGISTRATION BY NEW OWNERS AND OPERATORS.—Every

person upon first engaging in the manufacture, preparation,

compounding, or processing of a tobacco product or tobacco products

in any establishment owned or operated in any State by that

person shall immediately register with the Secretary that person’s

name, place of business, and such establishment.

‘‘(d) REGISTRATION OF ADDED ESTABLISHMENTS.—Every person

required to register under subsection (b) or (c) shall immediately

register with the Secretary any additional establishment which

that person owns or operates in any State and in which that

person begins the manufacture, preparation, compounding, or processing

of a tobacco product or tobacco products.

‘‘(e) UNIFORM PRODUCT IDENTIFICATION SYSTEM.—The Secretary

may by regulation prescribe a uniform system for the identification

of tobacco products and may require that persons who

are required to list such tobacco products under subsection (i)

shall list such tobacco products in accordance with such system.

‘‘(f) PUBLIC ACCESS TO REGISTRATION INFORMATION.—The Secretary

shall make available for inspection, to any person so

requesting, any registration filed under this section.

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

Every establishment registered with the Secretary under this section

shall be subject to inspection under section 704 or subsection

(h), and every such establishment engaged in the manufacture,

compounding, or processing of a tobacco product or tobacco products

shall be so inspected by 1 or more officers or employees duly

Deadline.

21 USC 387e.

Publication.

Notice.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00018 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

PUBLIC LAW 111–31—JUNE 22, 2009 123 STAT. 1793

designated by the Secretary at least once in the 2-year period

beginning with the date of registration of such establishment under

this section and at least once in every successive 2-year period

thereafter.

‘‘(h) REGISTRATION BY FOREIGN ESTABLISHMENTS.—Any

establishment within any foreign country engaged in the manufacture,

preparation, compounding, or processing of a tobacco product

or tobacco products, shall register under this section under regulations

promulgated by the Secretary. Such regulations shall require

such establishment to provide the information required by subsection

(i) and shall include provisions for registration of any such

establishment upon condition that adequate and effective means

are available, by arrangement with the government of such foreign

country or otherwise, to enable the Secretary to determine from

time to time whether tobacco products manufactured, prepared,

compounded, or processed in such establishment, if imported or

offered for import into the United States, shall be refused admission

on any of the grounds set forth in section 801(a).

‘‘(i) REGISTRATION INFORMATION.—

‘‘(1) PRODUCT LIST.—Every person who registers with the

Secretary under subsection (b), (c), (d), or (h) shall, at the

time of registration under any such subsection, file with the

Secretary a list of all tobacco products which are being manufactured,

prepared, compounded, or processed by that person for

commercial distribution and which have not been included in

any list of tobacco products filed by that person with the Secretary

under this paragraph or paragraph (2) before such time

of registration. Such list shall be prepared in such form and

manner as the Secretary may prescribe and shall be accompanied

by—

‘‘(A) in the case of a tobacco product contained in

the applicable list with respect to which a tobacco product

standard has been established under section 907 or which

is subject to section 910, a reference to the authority for

the marketing of such tobacco product and a copy of all

labeling for such tobacco product;

‘‘(B) in the case of any other tobacco product contained

in an applicable list, a copy of all consumer information

and other labeling for such tobacco product, a representative

sampling of advertisements for such tobacco product,

and, upon request made by the Secretary for good cause,

a copy of all advertisements for a particular tobacco

product; and

‘‘(C) if the registrant filing a list has determined that

a tobacco product contained in such list is not subject

to a tobacco product standard established under section

907, a brief statement of the basis upon which the registrant

made such determination if the Secretary requests

such a statement with respect to that particular tobacco

product.

‘‘(2) CONSULTATION WITH RESPECT TO FORMS.—The Secretary

shall consult with the Secretary of the Treasury in

developing the forms to be used for registration under this

section to minimize the burden on those persons required to

register with both the Secretary and the Tax and Trade Bureau

of the Department of the Treasury.

Regulations.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00019 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

123 STAT. 1794 PUBLIC LAW 111–31—JUNE 22, 2009

‘‘(3) BIANNUAL REPORT OF ANY CHANGE IN PRODUCT LIST.—

Each person who registers with the Secretary under this section

shall report to the Secretary once during the month of June

of each year and once during the month of December of each

year the following:

‘‘(A) A list of each tobacco product introduced by the

registrant for commercial distribution which has not been

included in any list previously filed by that person with

the Secretary under this subparagraph or paragraph (1).

A list under this subparagraph shall list a tobacco product

by its established name and shall be accompanied by the

other information required by paragraph (1).

‘‘(B) If since the date the registrant last made a report

under this paragraph that person has discontinued the

manufacture, preparation, compounding, or processing for

commercial distribution of a tobacco product included in

a list filed under subparagraph (A) or paragraph (1), notice

of such discontinuance, the date of such discontinuance,

and the identity of its established name.

‘‘(C) If since the date the registrant reported under

subparagraph (B) a notice of discontinuance that person

has resumed the manufacture, preparation, compounding,

or processing for commercial distribution of the tobacco

product with respect to which such notice of discontinuance

was reported, notice of such resumption, the date of such

resumption, the identity of such tobacco product by established

name, and other information required by paragraph

(1), unless the registrant has previously reported such

resumption to the Secretary under this subparagraph.

‘‘(D) Any material change in any information previously

submitted under this paragraph or paragraph (1).

‘‘(j) REPORT PRECEDING INTRODUCTION OF CERTAIN SUBSTANTIALLY

EQUIVALENT PRODUCTS INTO INTERSTATE COMMERCE.—

‘‘(1) IN GENERAL.—Each person who is required to register

under this section and who proposes to begin the introduction

or delivery for introduction into interstate commerce for

commercial distribution of a tobacco product intended for

human use that was not commercially marketed (other than

for test marketing) in the United States as of February 15,

2007, shall, at least 90 days prior to making such introduction

or delivery, report to the Secretary (in such form and manner

as the Secretary shall prescribe)—

‘‘(A) the basis for such person’s determination that—

‘‘(i) the tobacco product is substantially equivalent,

within the meaning of section 910, to a tobacco product

commercially marketed (other than for test marketing)

in the United States as of February 15, 2007, or to

a tobacco product that the Secretary has previously

determined, pursuant to subsection (a)(3) of section

910, is substantially equivalent and that is in compliance

with the requirements of this Act; or

‘‘(ii) the tobacco product is modified within the

meaning of paragraph (3), the modifications are to

a product that is commercially marketed and in compliance

with the requirements of this Act, and all of

the modifications are covered by exemptions granted

by the Secretary pursuant to paragraph (3); and

Notice.

Notice.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00020 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

PUBLIC LAW 111–31—JUNE 22, 2009 123 STAT. 1795

‘‘(B) action taken by such person to comply with the

requirements under section 907 that are applicable to the

tobacco product.

‘‘(2) APPLICATION TO CERTAIN POST-FEBRUARY 15, 2007, PRODUCTS.—

A report under this subsection for a tobacco product

that was first introduced or delivered for introduction into

interstate commerce for commercial distribution in the United

States after February 15, 2007, and prior to the date that

is 21 months after the date of enactment of the Family Smoking

Prevention and Tobacco Control Act shall be submitted to the

Secretary not later than 21 months after such date of enactment.

‘‘(3) EXEMPTIONS.—

‘‘(A) IN GENERAL.—The Secretary may exempt from

the requirements of this subsection relating to the demonstration

that a tobacco product is substantially equivalent

within the meaning of section 910, tobacco products

that are modified by adding or deleting a tobacco additive,

or increasing or decreasing the quantity of an existing

tobacco additive, if the Secretary determines that—

‘‘(i) such modification would be a minor modification

of a tobacco product that can be sold under this

Act;

‘‘(ii) a report under this subsection is not necessary

to ensure that permitting the tobacco product to be

marketed would be appropriate for protection of the

public health; and

‘‘(iii) an exemption is otherwise appropriate.

‘‘(B) REGULATIONS.—Not later than 15 months after

the date of enactment of the Family Smoking Prevention

and Tobacco Control Act, the Secretary shall issue regulations

to implement this paragraph.

**‘‘SEC. 906. GENERAL PROVISIONS RESPECTING CONTROL OF TOBACCO**

**PRODUCTS.**

‘‘(a) IN GENERAL.—Any requirement established by or under

section 902, 903, 905, or 909 applicable to a tobacco product shall

apply to such tobacco product until the applicability of the requirement

to the tobacco product has been changed by action taken

under section 907, section 910, section 911, or subsection (d) of

this section, and any requirement established by or under section

902, 903, 905, or 909 which is inconsistent with a requirement

imposed on such tobacco product under section 907, section 910,

section 911, or subsection (d) of this section shall not apply to

such tobacco product.

‘‘(b) INFORMATION ON PUBLIC ACCESS AND COMMENT.—Each

notice of proposed rulemaking or other notification under section

907, 908, 909, 910, or 911 or under this section, any other notice

which is published in the Federal Register with respect to any

other action taken under any such section and which states the

reasons for such action, and each publication of findings required

to be made in connection with rulemaking under any such section

shall set forth—

‘‘(1) the manner in which interested persons may examine

data and other information on which the notice or findings

is based; and

Notice.

Federal Register,

publication.

Applicability.

21 USC 387f.

Deadline.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00021 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

123 STAT. 1796 PUBLIC LAW 111–31—JUNE 22, 2009

‘‘(2) the period within which interested persons may present

their comments on the notice or findings (including the need

therefore) orally or in writing, which period shall be at least

60 days but may not exceed 90 days unless the time is extended

by the Secretary by a notice published in the Federal Register

stating good cause therefore.

‘‘(c) LIMITED CONFIDENTIALITY OF INFORMATION.—Any information

reported to or otherwise obtained by the Secretary or the

Secretary’s representative under section 903, 904, 907, 908, 909,

910, 911, or 704, or under subsection (e) or (f) of this section,

which is exempt from disclosure under subsection (a) of section

552 of title 5, United States Code, by reason of subsection (b)(4)

of that section shall be considered confidential and shall not be

disclosed, except that the information may be disclosed to other

officers or employees concerned with carrying out this chapter,

or when relevant in any proceeding under this chapter.

‘‘(d) RESTRICTIONS.—

‘‘(1) IN GENERAL.—The Secretary may by regulation require

restrictions on the sale and distribution of a tobacco product,

including restrictions on the access to, and the advertising

and promotion of, the tobacco product, if the Secretary determines

that such regulation would be appropriate for the protection

of the public health. The Secretary may by regulation

impose restrictions on the advertising and promotion of a

tobacco product consistent with and to full extent permitted

by the first amendment to the Constitution. The finding as

to whether such regulation would be appropriate for the protection

of the public health shall be determined with respect

to the risks and benefits to the population as a whole, including

users and nonusers of the tobacco product, and taking into

account—

‘‘(A) the increased or decreased likelihood that existing

users of tobacco products will stop using such products;

and

‘‘(B) the increased or decreased likelihood that those

who do not use tobacco products will start using such

products.

No such regulation may require that the sale or distribution

of a tobacco product be limited to the written or oral authorization

of a practitioner licensed by law to prescribe medical

products.

‘‘(2) LABEL STATEMENTS.—The label of a tobacco product

shall bear such appropriate statements of the restrictions

required by a regulation under subsection (a) as the Secretary

may in such regulation prescribe.

‘‘(3) LIMITATIONS.—

‘‘(A) IN GENERAL.—No restrictions under paragraph (1)

may—

‘‘(i) prohibit the sale of any tobacco product in

face-to-face transactions by a specific category of retail

outlets; or

‘‘(ii) establish a minimum age of sale of tobacco

products to any person older than 18 years of age.

‘‘(B) MATCHBOOKS.—For purposes of any regulations

issued by the Secretary, matchbooks of conventional size

containing not more than 20 paper matches, and which

are customarily given away for free with the purchase

Time period.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00022 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

PUBLIC LAW 111–31—JUNE 22, 2009 123 STAT. 1797

of tobacco products, shall be considered as adult-written

publications which shall be permitted to contain advertising.

Notwithstanding the preceding sentence, if the Secretary

finds that such treatment of matchbooks is not

appropriate for the protection of the public health, the

Secretary may determine by regulation that matchbooks

shall not be considered adult-written publications.

‘‘(4) REMOTE SALES.—

‘‘(A) IN GENERAL.—The Secretary shall—

‘‘(i) within 18 months after the date of enactment

of the Family Smoking Prevention and Tobacco Control

Act, promulgate regulations regarding the sale and

distribution of tobacco products that occur through

means other than a direct, face-to-face exchange

between a retailer and a consumer in order to prevent

the sale and distribution of tobacco products to individuals

who have not attained the minimum age established

by applicable law for the purchase of such products,

including requirements for age verification; and

‘‘(ii) within 2 years after such date of enactment,

issue regulations to address the promotion and marketing

of tobacco products that are sold or distributed

through means other than a direct, face-to-face

exchange between a retailer and a consumer in order

to protect individuals who have not attained the minimum

age established by applicable law for the purchase

of such products.

‘‘(B) RELATION TO OTHER AUTHORITY.—Nothing in this

paragraph limits the authority of the Secretary to take

additional actions under the other paragraphs of this subsection.

‘‘(e) GOOD MANUFACTURING PRACTICE REQUIREMENTS.—

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

‘‘(A) IN GENERAL.—In applying manufacturing restrictions

to tobacco, the Secretary shall, in accordance with

subparagraph (B), prescribe regulations (which may differ

based on the type of tobacco product involved) requiring

that the methods used in, and the facilities and controls

used for, the manufacture, preproduction design validation

(including a process to assess the performance of a tobacco

product), packing, and storage of a tobacco product conform

to current good manufacturing practice, or hazard analysis

and critical control point methodology, as prescribed in

such regulations to assure that the public health is protected

and that the tobacco product is in compliance with

this chapter. Such regulations may provide for the testing

of raw tobacco for pesticide chemical residues regardless

of whether a tolerance for such chemical residues has been

established.

‘‘(B) REQUIREMENTS.—The Secretary shall—

‘‘(i) before promulgating any regulation under

subparagraph (A), afford the Tobacco Products Scientific

Advisory Committee an opportunity to submit

recommendations with respect to the regulation proposed

to be promulgated;

Recommendations.

Regulations.

Deadlines.

Regulations.

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123 STAT. 1798 PUBLIC LAW 111–31—JUNE 22, 2009

‘‘(ii) before promulgating any regulation under

subparagraph (A), afford opportunity for an oral

hearing;

‘‘(iii) provide the Tobacco Products Scientific

Advisory Committee a reasonable time to make its

recommendation with respect to proposed regulations

under subparagraph (A);

‘‘(iv) in establishing the effective date of a regulation

promulgated under this subsection, take into

account the differences in the manner in which the

different types of tobacco products have historically

been produced, the financial resources of the different

tobacco product manufacturers, and the state of their

existing manufacturing facilities, and shall provide for

a reasonable period of time for such manufacturers

to conform to good manufacturing practices; and

‘‘(v) not require any small tobacco product manufacturer

to comply with a regulation under subparagraph

(A) for at least 4 years following the effective

date established by the Secretary for such regulation.

‘‘(2) EXEMPTIONS; VARIANCES.—

‘‘(A) PETITION.—Any person subject to any requirement

prescribed under paragraph (1) may petition the Secretary

for a permanent or temporary exemption or variance from

such requirement. Such a petition shall be submitted to

the Secretary in such form and manner as the Secretary

shall prescribe and shall—

‘‘(i) in the case of a petition for an exemption

from a requirement, set forth the basis for the petitioner’s

determination that compliance with the

requirement is not required to assure that the tobacco

product will be in compliance with this chapter;

‘‘(ii) in the case of a petition for a variance from

a requirement, set forth the methods proposed to be

used in, and the facilities and controls proposed to

be used for, the manufacture, packing, and storage

of the tobacco product in lieu of the methods, facilities,

and controls prescribed by the requirement; and

‘‘(iii) contain such other information as the Secretary

shall prescribe.

‘‘(B) REFERRAL TO THE TOBACCO PRODUCTS SCIENTIFIC

ADVISORY COMMITTEE.—The Secretary may refer to the

Tobacco Products Scientific Advisory Committee any petition

submitted under subparagraph (A). The Tobacco Products

Scientific Advisory Committee shall report its recommendations

to the Secretary with respect to a petition

referred to it within 60 days after the date of the petition’s

referral. Within 60 days after—

‘‘(i) the date the petition was submitted to the

Secretary under subparagraph (A); or

‘‘(ii) the day after the petition was referred to

the Tobacco Products Scientific Advisory Committee,

whichever occurs later, the Secretary shall by order either

deny the petition or approve it.

‘‘(C) APPROVAL.—The Secretary may approve—

‘‘(i) a petition for an exemption for a tobacco

product from a requirement if the Secretary determines

Reports.

Deadline.

Compliance date.

Hearings.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00024 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

PUBLIC LAW 111–31—JUNE 22, 2009 123 STAT. 1799

that compliance with such requirement is not required

to assure that the tobacco product will be in compliance

with this chapter; and

‘‘(ii) a petition for a variance for a tobacco product

from a requirement if the Secretary determines that

the methods to be used in, and the facilities and controls

to be used for, the manufacture, packing, and

storage of the tobacco product in lieu of the methods,

facilities, and controls prescribed by the requirement

are sufficient to assure that the tobacco product will

be in compliance with this chapter.

‘‘(D) CONDITIONS.—An order of the Secretary approving

a petition for a variance shall prescribe such conditions

respecting the methods used in, and the facilities and controls

used for, the manufacture, packing, and storage of

the tobacco product to be granted the variance under the

petition as may be necessary to assure that the tobacco

product will be in compliance with this chapter.

‘‘(E) HEARING.—After the issuance of an order under

subparagraph (B) respecting a petition, the petitioner shall

have an opportunity for an informal hearing on such order.

‘‘(3) COMPLIANCE.—Compliance with requirements under

this subsection shall not be required before the end of the

3-year period following the date of enactment of the Family

Smoking Prevention and Tobacco Control Act.

‘‘(f) RESEARCH AND DEVELOPMENT.—The Secretary may enter

into contracts for research, testing, and demonstrations respecting

tobacco products and may obtain tobacco products for research,

testing, and demonstration purposes.

**‘‘SEC. 907. TOBACCO PRODUCT STANDARDS.**

‘‘(a) IN GENERAL.—

‘‘(1) SPECIAL RULES.—

‘‘(A) SPECIAL RULE FOR CIGARETTES.—Beginning 3

months after the date of enactment of the Family Smoking

Prevention and Tobacco Control Act, a cigarette or any

of its component parts (including the tobacco, filter, or

paper) shall not contain, as a constituent (including a

smoke constituent) or additive, an artificial or natural

flavor (other than tobacco or menthol) or an herb or spice,

including strawberry, grape, orange, clove, cinnamon, pineapple,

vanilla, coconut, licorice, cocoa, chocolate, cherry,

or coffee, that is a characterizing flavor of the tobacco

product or tobacco smoke. Nothing in this subparagraph

shall be construed to limit the Secretary’s authority to

take action under this section or other sections of this

Act applicable to menthol or any artificial or natural flavor,

herb, or spice not specified in this subparagraph.

‘‘(B) ADDITIONAL SPECIAL RULE.—Beginning 2 years

after the date of enactment of the Family Smoking Prevention

and Tobacco Control Act, a tobacco product manufacturer

shall not use tobacco, including foreign grown tobacco,

that contains a pesticide chemical residue that is at a

level greater than is specified by any tolerance applicable

under Federal law to domestically grown tobacco.

Effective dates.

21 USC 387g.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00025 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

123 STAT. 1800 PUBLIC LAW 111–31—JUNE 22, 2009

‘‘(2) REVISION OF TOBACCO PRODUCT STANDARDS.—The Secretary

may revise the tobacco product standards in paragraph

(1) in accordance with subsection (c).

‘‘(3) TOBACCO PRODUCT STANDARDS.—

‘‘(A) IN GENERAL.—The Secretary may adopt tobacco

product standards in addition to those in paragraph (1)

if the Secretary finds that a tobacco product standard is

appropriate for the protection of the public health.

‘‘(B) DETERMINATIONS.—

‘‘(i) CONSIDERATIONS.—In making a finding

described in subparagraph (A), the Secretary shall consider

scientific evidence concerning—

‘‘(I) the risks and benefits to the population

as a whole, including users and nonusers of tobacco

products, of the proposed standard;

‘‘(II) the increased or decreased likelihood that

existing users of tobacco products will stop using

such products; and

‘‘(III) the increased or decreased likelihood

that those who do not use tobacco products will

start using such products.

‘‘(ii) ADDITIONAL CONSIDERATIONS.—In the event

that the Secretary makes a determination, set forth

in a proposed tobacco product standard in a proposed

rule, that it is appropriate for the protection of public

health to require the reduction or elimination of an

additive, constituent (including a smoke constituent),

or other component of a tobacco product because the

Secretary has found that the additive, constituent, or

other component is or may be harmful, any party

objecting to the proposed standard on the ground that

the proposed standard will not reduce or eliminate

the risk of illness or injury may provide for the Secretary’s

consideration scientific evidence that demonstrates

that the proposed standard will not reduce

or eliminate the risk of illness or injury.

‘‘(4) CONTENT OF TOBACCO PRODUCT STANDARDS.—A tobacco

product standard established under this section for a tobacco

product—

‘‘(A) shall include provisions that are appropriate for

the protection of the public health, including provisions,

where appropriate—

‘‘(i) for nicotine yields of the product;

‘‘(ii) for the reduction or elimination of other

constituents, including smoke constituents, or harmful

components of the product; or

‘‘(iii) relating to any other requirement under

subparagraph (B);

‘‘(B) shall, where appropriate for the protection of the

public health, include—

‘‘(i) provisions respecting the construction, components,

ingredients, additives, constituents, including

smoke constituents, and properties of the tobacco

product;

‘‘(ii) provisions for the testing (on a sample basis

or, if necessary, on an individual basis) of the tobacco

product;

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00026 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

PUBLIC LAW 111–31—JUNE 22, 2009 123 STAT. 1801

‘‘(iii) provisions for the measurement of the tobacco

product characteristics of the tobacco product;

‘‘(iv) provisions requiring that the results of each

or of certain of the tests of the tobacco product required

to be made under clause (ii) show that the tobacco

product is in conformity with the portions of the

standard for which the test or tests were required;

and

‘‘(v) a provision requiring that the sale and distribution

of the tobacco product be restricted but only

to the extent that the sale and distribution of a tobacco

product may be restricted under a regulation under

section 906(d);

‘‘(C) shall, where appropriate, require the use and prescribe

the form and content of labeling for the proper

use of the tobacco product; and

‘‘(D) shall require tobacco products containing foreigngrown

tobacco to meet the same standards applicable to

tobacco products containing domestically grown tobacco.

‘‘(5) PERIODIC REEVALUATION OF TOBACCO PRODUCT STANDARDS.—

The Secretary shall provide for periodic evaluation of

tobacco product standards established under this section to

determine whether such standards should be changed to reflect

new medical, scientific, or other technological data. The Secretary

may provide for testing under paragraph (4)(B) by any

person.

‘‘(6) INVOLVEMENT OF OTHER AGENCIES; INFORMED PERSONS.—

In carrying out duties under this section, the Secretary

shall endeavor to—

‘‘(A) use personnel, facilities, and other technical support

available in other Federal agencies;

‘‘(B) consult with other Federal agencies concerned with

standard setting and other nationally or internationally

recognized standard-setting entities; and

‘‘(C) invite appropriate participation, through joint or

other conferences, workshops, or other means, by informed

persons representative of scientific, professional, industry,

agricultural, or consumer organizations who in the Secretary’s

judgment can make a significant contribution.

‘‘(b) CONSIDERATIONS BY SECRETARY.—

‘‘(1) TECHNICAL ACHIEVABILITY.—The Secretary shall consider

information submitted in connection with a proposed

standard regarding the technical achievability of compliance

with such standard.

‘‘(2) OTHER CONSIDERATIONS.—The Secretary shall consider

all other information submitted in connection with a proposed

standard, including information concerning the countervailing

effects of the tobacco product standard on the health of adolescent

tobacco users, adult tobacco users, or nontobacco users,

such as the creation of a significant demand for contraband

or other tobacco products that do not meet the requirements

of this chapter and the significance of such demand.

‘‘(c) PROPOSED STANDARDS.—

‘‘(1) IN GENERAL.—The Secretary shall publish in the Federal

Register a notice of proposed rulemaking for the establishment,

amendment, or revocation of any tobacco product

standard.

Federal Register,

publication.

Notice.

Consultation.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00027 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

123 STAT. 1802 PUBLIC LAW 111–31—JUNE 22, 2009

‘‘(2) REQUIREMENTS OF NOTICE.—A notice of proposed rulemaking

for the establishment or amendment of a tobacco

product standard for a tobacco product shall—

‘‘(A) set forth a finding with supporting justification

that the tobacco product standard is appropriate for the

protection of the public health;

‘‘(B) invite interested persons to submit a draft or

proposed tobacco product standard for consideration by the

Secretary;

‘‘(C) invite interested persons to submit comments on

structuring the standard so that it does not advantage

foreign-grown tobacco over domestically grown tobacco; and

‘‘(D) invite the Secretary of Agriculture to provide any

information or analysis which the Secretary of Agriculture

believes is relevant to the proposed tobacco product

standard.

‘‘(3) FINDING.—A notice of proposed rulemaking for the

revocation of a tobacco product standard shall set forth a finding

with supporting justification that the tobacco product standard

is no longer appropriate for the protection of the public health.

‘‘(4) COMMENT.—The Secretary shall provide for a comment

period of not less than 60 days.

‘‘(d) PROMULGATION.—

‘‘(1) IN GENERAL.—After the expiration of the period for

comment on a notice of proposed rulemaking published under

subsection (c) respecting a tobacco product standard and after

consideration of comments submitted under subsections (b) and

(c) and any report from the Tobacco Products Scientific Advisory

Committee, the Secretary shall—

‘‘(A) if the Secretary determines that the standard

would be appropriate for the protection of the public health,

promulgate a regulation establishing a tobacco product

standard and publish in the Federal Register findings on

the matters referred to in subsection (c); or

‘‘(B) publish a notice terminating the proceeding for

the development of the standard together with the reasons

for such termination.

‘‘(2) EFFECTIVE DATE.—A regulation establishing a tobacco

product standard shall set forth the date or dates upon which

the standard shall take effect, but no such regulation may

take effect before 1 year after the date of its publication unless

the Secretary determines that an earlier effective date is necessary

for the protection of the public health. Such date or

dates shall be established so as to minimize, consistent with

the public health, economic loss to, and disruption or dislocation

of, domestic and international trade. In establishing such effective

date or dates, the Secretary shall consider information

submitted in connection with a proposed product standard by

interested parties, including manufacturers and tobacco

growers, regarding the technical achievability of compliance

with the standard, and including information concerning the

existence of patents that make it impossible to comply in the

timeframe envisioned in the proposed standard. If the Secretary

determines, based on the Secretary’s evaluation of submitted

comments, that a product standard can be met only by manufacturers

requiring substantial changes to the methods of farming

the domestically grown tobacco used by the manufacturer, the

Publication.

Notice.

Regulations.

Federal Register,

publication.

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PUBLIC LAW 111–31—JUNE 22, 2009 123 STAT. 1803

effective date of that product standard shall be not less than

2 years after the date of publication of the final regulation

establishing the standard.

‘‘(3) LIMITATION ON POWER GRANTED TO THE FOOD AND

DRUG ADMINISTRATION.—Because of the importance of a decision

of the Secretary to issue a regulation—

‘‘(A) banning all cigarettes, all smokeless tobacco products,

all little cigars, all cigars other than little cigars,

all pipe tobacco, or all roll-your-own tobacco products; or

‘‘(B) requiring the reduction of nicotine yields of a

tobacco product to zero,

the Secretary is prohibited from taking such actions under

this Act.

‘‘(4) AMENDMENT; REVOCATION.—

‘‘(A) AUTHORITY.—The Secretary, upon the Secretary’s

own initiative or upon petition of an interested person,

may by a regulation, promulgated in accordance with the

requirements of subsection (c) and paragraph (2), amend

or revoke a tobacco product standard.

‘‘(B) EFFECTIVE DATE.—The Secretary may declare a

proposed amendment of a tobacco product standard to be

effective on and after its publication in the Federal Register

and until the effective date of any final action taken on

such amendment if the Secretary determines that making

it so effective is in the public interest.

‘‘(5) REFERRAL TO ADVISORY COMMITTEE.—

‘‘(A) IN GENERAL.—The Secretary may refer a proposed

regulation for the establishment, amendment, or revocation

of a tobacco product standard to the Tobacco Products

Scientific Advisory Committee for a report and recommendation

with respect to any matter involved in the

proposed regulation which requires the exercise of scientific

judgment.

‘‘(B) INITIATION OF REFERRAL.—The Secretary may

make a referral under this paragraph—

‘‘(i) on the Secretary’s own initiative; or

‘‘(ii) upon the request of an interested person

that—

‘‘(I) demonstrates good cause for the referral;

and

‘‘(II) is made before the expiration of the period

for submission of comments on the proposed regulation.

‘‘(C) PROVISION OF DATA.—If a proposed regulation is

referred under this paragraph to the Tobacco Products

Scientific Advisory Committee, the Secretary shall provide

the Advisory Committee with the data and information

on which such proposed regulation is based.

‘‘(D) REPORT AND RECOMMENDATION.—The Tobacco

Products Scientific Advisory Committee shall, within 60

days after the referral of a proposed regulation under this

paragraph and after independent study of the data and

information furnished to it by the Secretary and other

data and information before it, submit to the Secretary

a report and recommendation respecting such regulation,

together with all underlying data and information and

a statement of the reason or basis for the recommendation.

Statement.

Deadline.

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123 STAT. 1804 PUBLIC LAW 111–31—JUNE 22, 2009

‘‘(E) PUBLIC AVAILABILITY.—The Secretary shall make

a copy of each report and recommendation under subparagraph

(D) publicly available.

‘‘(e) MENTHOL CIGARETTES.—

‘‘(1) REFERRAL; CONSIDERATIONS.—Immediately upon the

establishment of the Tobacco Products Scientific Advisory Committee

under section 917(a), the Secretary shall refer to the

Committee for report and recommendation, under section

917(c)(4), the issue of the impact of the use of menthol in

cigarettes on the public health, including such use among children,

African-Americans, Hispanics, and other racial and ethnic

minorities. In its review, the Tobacco Products Scientific

Advisory Committee shall address the considerations listed in

subsections (a)(3)(B)(i) and (b).

‘‘(2) REPORT AND RECOMMENDATION.—Not later than 1 year

after its establishment, the Tobacco Product Scientific Advisory

Committee shall submit to the Secretary the report and recommendations

required pursuant to paragraph (1).

‘‘(3) RULE OF CONSTRUCTION.—Nothing in this subsection

shall be construed to limit the Secretary’s authority to take

action under this section or other sections of this Act applicable

to menthol.

‘‘(f) DISSOLVABLE TOBACCO PRODUCTS.—

‘‘(1) REFERRAL; CONSIDERATIONS.—The Secretary shall refer

to the Tobacco Products Scientific Advisory Committee for

report and recommendation, under section 917(c)(4), the issue

of the nature and impact of the use of dissolvable tobacco

products on the public health, including such use among children.

In its review, the Tobacco Products Scientific Advisory

Committee shall address the considerations listed in subsection

(a)(3)(B)(i).

‘‘(2) REPORT AND RECOMMENDATION.—Not later than 2

years after its establishment, the Tobacco Product Scientific

Advisory Committee shall submit to the Secretary the report

and recommendations required pursuant to paragraph (1).

‘‘(3) RULE OF CONSTRUCTION.—Nothing in this subsection

shall be construed to limit the Secretary’s authority to take

action under this section or other sections of this Act at any

time applicable to any dissolvable tobacco product.

**‘‘SEC. 908. NOTIFICATION AND OTHER REMEDIES.**

‘‘(a) NOTIFICATION.—If the Secretary determines that—

‘‘(1) a tobacco product which is introduced or delivered

for introduction into interstate commerce for commercial distribution

presents an unreasonable risk of substantial harm

to the public health; and

‘‘(2) notification under this subsection is necessary to eliminate

the unreasonable risk of such harm and no more practicable

means is available under the provisions of this chapter

(other than this section) to eliminate such risk,

the Secretary may issue such order as may be necessary to assure

that adequate notification is provided in an appropriate form, by

the persons and means best suited under the circumstances

involved, to all persons who should properly receive such notification

in order to eliminate such risk. The Secretary may order notification

by any appropriate means, including public service announcements.

21 USC 387h.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00030 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

PUBLIC LAW 111–31—JUNE 22, 2009 123 STAT. 1805

Before issuing an order under this subsection, the Secretary shall

consult with the persons who are to give notice under the order.

‘‘(b) NO EXEMPTION FROM OTHER LIABILITY.—Compliance with

an order issued under this section shall not relieve any person

from liability under Federal or State law. In awarding damages

for economic loss in an action brought for the enforcement of any

such liability, the value to the plaintiff in such action of any

remedy provided under such order shall be taken into account.

‘‘(c) RECALL AUTHORITY.—

‘‘(1) IN GENERAL.—If the Secretary finds that there is a

reasonable probability that a tobacco product contains a manufacturing

or other defect not ordinarily contained in tobacco

products on the market that would cause serious, adverse

health consequences or death, the Secretary shall issue an

order requiring the appropriate person (including the manufacturers,

importers, distributors, or retailers of the tobacco

product) to immediately cease distribution of such tobacco

product. The order shall provide the person subject to the

order with an opportunity for an informal hearing, to be held

not later than 10 days after the date of the issuance of the

order, on the actions required by the order and on whether

the order should be amended to require a recall of such tobacco

product. If, after providing an opportunity for such a hearing,

the Secretary determines that inadequate grounds exist to support

the actions required by the order, the Secretary shall

vacate the order.

‘‘(2) AMENDMENT OF ORDER TO REQUIRE RECALL.—

‘‘(A) IN GENERAL.—If, after providing an opportunity

for an informal hearing under paragraph (1), the Secretary

determines that the order should be amended to include

a recall of the tobacco product with respect to which the

order was issued, the Secretary shall, except as provided

in subparagraph (B), amend the order to require a recall.

The Secretary shall specify a timetable in which the tobacco

product recall will occur and shall require periodic reports

to the Secretary describing the progress of the recall.

‘‘(B) NOTICE.—An amended order under subparagraph

(A)—

‘‘(i) shall not include recall of a tobacco product

from individuals; and

‘‘(ii) shall provide for notice to persons subject to

the risks associated with the use of such tobacco

product.

In providing the notice required by clause (ii), the Secretary

may use the assistance of retailers and other persons who

distributed such tobacco product. If a significant number

of such persons cannot be identified, the Secretary shall

notify such persons under section 705(b).

‘‘(3) REMEDY NOT EXCLUSIVE.—The remedy provided by this

subsection shall be in addition to remedies provided by subsection

(a).

**‘‘SEC. 909. RECORDS AND REPORTS ON TOBACCO PRODUCTS.**

‘‘(a) IN GENERAL.—Every person who is a tobacco product manufacturer

or importer of a tobacco product shall establish and maintain

such records, make such reports, and provide such information,

as the Secretary may by regulation reasonably require to assure

Regulations.

21 USC 387i.

Notification.

Timetable.

Reports.

Deadline.

Order.

Consultation.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00031 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

123 STAT. 1806 PUBLIC LAW 111–31—JUNE 22, 2009

that such tobacco product is not adulterated or misbranded and

to otherwise protect public health. Regulations prescribed under

the preceding sentence—

‘‘(1) may require a tobacco product manufacturer or

importer to report to the Secretary whenever the manufacturer

or importer receives or otherwise becomes aware of information

that reasonably suggests that one of its marketed tobacco products

may have caused or contributed to a serious unexpected

adverse experience associated with the use of the product or

any significant increase in the frequency of a serious, expected

adverse product experience;

‘‘(2) shall require reporting of other significant adverse

tobacco product experiences as determined by the Secretary

to be necessary to be reported;

‘‘(3) shall not impose requirements unduly burdensome to

a tobacco product manufacturer or importer, taking into account

the cost of complying with such requirements and the need

for the protection of the public health and the implementation

of this chapter;

‘‘(4) when prescribing the procedure for making requests

for reports or information, shall require that each request made

under such regulations for submission of a report or information

to the Secretary state the reason or purpose for such request

and identify to the fullest extent practicable such report or

information;

‘‘(5) when requiring submission of a report or information

to the Secretary, shall state the reason or purpose for the

submission of such report or information and identify to the

fullest extent practicable such report or information; and

‘‘(6) may not require that the identity of any patient or

user be disclosed in records, reports, or information required

under this subsection unless required for the medical welfare

of an individual, to determine risks to public health of a tobacco

product, or to verify a record, report, or information submitted

under this chapter.

In prescribing regulations under this subsection, the Secretary shall

have due regard for the professional ethics of the medical profession

and the interests of patients. The prohibitions of paragraph (6)

continue to apply to records, reports, and information concerning

any individual who has been a patient, irrespective of whether

or when he ceases to be a patient.

‘‘(b) REPORTS OF REMOVALS AND CORRECTIONS.—

‘‘(1) IN GENERAL.—Except as provided in paragraph (2),

the Secretary shall by regulation require a tobacco product

manufacturer or importer of a tobacco product to report

promptly to the Secretary any corrective action taken or

removal from the market of a tobacco product undertaken by

such manufacturer or importer if the removal or correction

was undertaken—

‘‘(A) to reduce a risk to health posed by the tobacco

product; or

‘‘(B) to remedy a violation of this chapter caused by

the tobacco product which may present a risk to health.

A tobacco product manufacturer or importer of a tobacco

product who undertakes a corrective action or removal from

the market of a tobacco product which is not required to be

Applicability.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00032 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

PUBLIC LAW 111–31—JUNE 22, 2009 123 STAT. 1807

reported under this subsection shall keep a record of such

correction or removal.

‘‘(2) EXCEPTION.—No report of the corrective action or

removal of a tobacco product may be required under paragraph

(1) if a report of the corrective action or removal is required

and has been submitted under subsection (a).

**‘‘SEC. 910. APPLICATION FOR REVIEW OF CERTAIN TOBACCO PRODUCTS.**

‘‘(a) IN GENERAL.—

‘‘(1) NEW TOBACCO PRODUCT DEFINED.—For purposes of this

section the term ‘new tobacco product’ means—

‘‘(A) any tobacco product (including those products in

test markets) that was not commercially marketed in the

United States as of February 15, 2007; or

‘‘(B) any modification (including a change in design,

any component, any part, or any constituent, including

a smoke constituent, or in the content, delivery or form

of nicotine, or any other additive or ingredient) of a tobacco

product where the modified product was commercially marketed

in the United States after February 15, 2007.

‘‘(2) PREMARKET REVIEW REQUIRED.—

‘‘(A) NEW PRODUCTS.—An order under subsection

(c)(1)(A)(i) for a new tobacco product is required unless—

‘‘(i) the manufacturer has submitted a report under

section 905(j); and the Secretary has issued an order

that the tobacco product—

‘‘(I) is substantially equivalent to a tobacco

product commercially marketed (other than for test

marketing) in the United States as of February

15, 2007; and

‘‘(II) is in compliance with the requirements

of this Act; or

‘‘(ii) the tobacco product is exempt from the

requirements of section 905(j) pursuant to a regulation

issued under section 905(j)(3).

‘‘(B) APPLICATION TO CERTAIN POST-FEBRUARY 15, 2007,

PRODUCTS.—Subparagraph (A) shall not apply to a tobacco

product—

‘‘(i) that was first introduced or delivered for

introduction into interstate commerce for commercial

distribution in the United States after February 15,

2007, and prior to the date that is 21 months after

the date of enactment of the Family Smoking Prevention

and Tobacco Control Act; and

‘‘(ii) for which a report was submitted under section

905(j) within such 21-month period,

except that subparagraph (A) shall apply to the tobacco

product if the Secretary issues an order that the tobacco

product is not substantially equivalent.

‘‘(3) SUBSTANTIALLY EQUIVALENT DEFINED.—

‘‘(A) IN GENERAL.—In this section and section 905(j),

the term ‘substantially equivalent’ or ‘substantial equivalence’

means, with respect to the tobacco product being

compared to the predicate tobacco product, that the Secretary

by order has found that the tobacco product—

21 USC 387j.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00033 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

123 STAT. 1808 PUBLIC LAW 111–31—JUNE 22, 2009

‘‘(i) has the same characteristics as the predicate

tobacco product; or

‘‘(ii) has different characteristics and the information

submitted contains information, including clinical

data if deemed necessary by the Secretary, that demonstrates

that it is not appropriate to regulate the

product under this section because the product does

not raise different questions of public health.

‘‘(B) CHARACTERISTICS.—In subparagraph (A), the term

‘characteristics’ means the materials, ingredients, design,

composition, heating source, or other features of a tobacco

product.

‘‘(C) LIMITATION.—A tobacco product may not be found

to be substantially equivalent to a predicate tobacco product

that has been removed from the market at the initiative

of the Secretary or that has been determined by a judicial

order to be misbranded or adulterated.

‘‘(4) HEALTH INFORMATION.—

‘‘(A) SUMMARY.—As part of a submission under section

905(j) respecting a tobacco product, the person required

to file a premarket notification under such section shall

provide an adequate summary of any health information

related to the tobacco product or state that such information

will be made available upon request by any person.

‘‘(B) REQUIRED INFORMATION.—Any summary under

subparagraph (A) respecting a tobacco product shall contain

detailed information regarding data concerning adverse

health effects and shall be made available to the public

by the Secretary within 30 days of the issuance of a determination

that such tobacco product is substantially equivalent

to another tobacco product.

‘‘(b) APPLICATION.—

‘‘(1) CONTENTS.—An application under this section shall

contain—

‘‘(A) full reports of all information, published or known

to, or which should reasonably be known to, the applicant,

concerning investigations which have been made to show

the health risks of such tobacco product and whether such

tobacco product presents less risk than other tobacco products;

‘‘(B) a full statement of the components, ingredients,

additives, and properties, and of the principle or principles

of operation, of such tobacco product;

‘‘(C) a full description of the methods used in, and

the facilities and controls used for, the manufacture, processing,

and, when relevant, packing and installation of,

such tobacco product;

‘‘(D) an identifying reference to any tobacco product

standard under section 907 which would be applicable to

any aspect of such tobacco product, and either adequate

information to show that such aspect of such tobacco

product fully meets such tobacco product standard or adequate

information to justify any deviation from such

standard;

‘‘(E) such samples of such tobacco product and of

components thereof as the Secretary may reasonably

require;

Public

information.

Deadline.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00034 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

PUBLIC LAW 111–31—JUNE 22, 2009 123 STAT. 1809

‘‘(F) specimens of the labeling proposed to be used

for such tobacco product; and

‘‘(G) such other information relevant to the subject

matter of the application as the Secretary may require.

‘‘(2) REFERRAL TO TOBACCO PRODUCTS SCIENTIFIC ADVISORY

COMMITTEE.—Upon receipt of an application meeting the

requirements set forth in paragraph (1), the Secretary—

‘‘(A) may, on the Secretary’s own initiative; or

‘‘(B) may, upon the request of an applicant,

refer such application to the Tobacco Products Scientific

Advisory Committee for reference and for submission (within

such period as the Secretary may establish) of a report and

recommendation respecting the application, together with all

underlying data and the reasons or basis for the recommendation.

‘‘(c) ACTION ON APPLICATION.—

‘‘(1) DEADLINE.—

‘‘(A) IN GENERAL.—As promptly as possible, but in no

event later than 180 days after the receipt of an application

under subsection (b), the Secretary, after considering the

report and recommendation submitted under subsection

(b)(2), shall—

‘‘(i) issue an order that the new product may be

introduced or delivered for introduction into interstate

commerce if the Secretary finds that none of the

grounds specified in paragraph (2) of this subsection

applies; or

‘‘(ii) issue an order that the new product may

not be introduced or delivered for introduction into

interstate commerce if the Secretary finds (and sets

forth the basis for such finding as part of or accompanying

such denial) that 1 or more grounds for denial

specified in paragraph (2) of this subsection apply.

‘‘(B) RESTRICTIONS ON SALE AND DISTRIBUTION.—An

order under subparagraph (A)(i) may require that the sale

and distribution of the tobacco product be restricted but

only to the extent that the sale and distribution of a tobacco

product may be restricted under a regulation under section

906(d).

‘‘(2) DENIAL OF APPLICATION.—The Secretary shall deny

an application submitted under subsection (b) if, upon the

basis of the information submitted to the Secretary as part

of the application and any other information before the Secretary

with respect to such tobacco product, the Secretary finds

that—

‘‘(A) there is a lack of a showing that permitting such

tobacco product to be marketed would be appropriate for

the protection of the public health;

‘‘(B) the methods used in, or the facilities or controls

used for, the manufacture, processing, or packing of such

tobacco product do not conform to the requirements of

section 906(e);

‘‘(C) based on a fair evaluation of all material facts,

the proposed labeling is false or misleading in any particular;

or

‘‘(D) such tobacco product is not shown to conform

in all respects to a tobacco product standard in effect under

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00035 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

123 STAT. 1810 PUBLIC LAW 111–31—JUNE 22, 2009

section 907, and there is a lack of adequate information

to justify the deviation from such standard.

‘‘(3) DENIAL INFORMATION.—Any denial of an application

shall, insofar as the Secretary determines to be practicable,

be accompanied by a statement informing the applicant of

the measures required to remove such application from deniable

form (which measures may include further research by the

applicant in accordance with 1 or more protocols prescribed

by the Secretary).

‘‘(4) BASIS FOR FINDING.—For purposes of this section, the

finding as to whether the marketing of a tobacco product for

which an application has been submitted is appropriate for

the protection of the public health shall be determined with

respect to the risks and benefits to the population as a whole,

including users and nonusers of the tobacco product, and taking

into account—

‘‘(A) the increased or decreased likelihood that existing

users of tobacco products will stop using such products;

and

‘‘(B) the increased or decreased likelihood that those

who do not use tobacco products will start using such

products.

‘‘(5) BASIS FOR ACTION.—

‘‘(A) INVESTIGATIONS.—For purposes of paragraph

(2)(A), whether permitting a tobacco product to be marketed

would be appropriate for the protection of the public health

shall, when appropriate, be determined on the basis of

well-controlled investigations, which may include 1 or more

clinical investigations by experts qualified by training and

experience to evaluate the tobacco product.

‘‘(B) OTHER EVIDENCE.—If the Secretary determines

that there exists valid scientific evidence (other than evidence

derived from investigations described in subparagraph

(A)) which is sufficient to evaluate the tobacco

product, the Secretary may authorize that the determination

for purposes of paragraph (2)(A) be made on the basis

of such evidence.

‘‘(d) WITHDRAWAL AND TEMPORARY SUSPENSION.—

‘‘(1) IN GENERAL.—The Secretary shall, upon obtaining,

where appropriate, advice on scientific matters from the

Tobacco Products Scientific Advisory Committee, and after due

notice and opportunity for informal hearing for a tobacco

product for which an order was issued under subsection

(c)(1)(A)(i), issue an order withdrawing the order if the Secretary

finds—

‘‘(A) that the continued marketing of such tobacco

product no longer is appropriate for the protection of the

public health;

‘‘(B) that the application contained or was accompanied

by an untrue statement of a material fact;

‘‘(C) that the applicant—

‘‘(i) has failed to establish a system for maintaining

records, or has repeatedly or deliberately failed to

maintain records or to make reports, required by an

applicable regulation under section 909;

Notice.

Hearings.

Statement.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00036 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

PUBLIC LAW 111–31—JUNE 22, 2009 123 STAT. 1811

‘‘(ii) has refused to permit access to, or copying

or verification of, such records as required by section

704; or

‘‘(iii) has not complied with the requirements of

section 905;

‘‘(D) on the basis of new information before the Secretary

with respect to such tobacco product, evaluated

together with the evidence before the Secretary when the

application was reviewed, that the methods used in, or

the facilities and controls used for, the manufacture, processing,

packing, or installation of such tobacco product

do not conform with the requirements of section 906(e)

and were not brought into conformity with such requirements

within a reasonable time after receipt of written

notice from the Secretary of nonconformity;

‘‘(E) on the basis of new information before the Secretary,

evaluated together with the evidence before the

Secretary when the application was reviewed, that the

labeling of such tobacco product, based on a fair evaluation

of all material facts, is false or misleading in any particular

and was not corrected within a reasonable time after receipt

of written notice from the Secretary of such fact; or

‘‘(F) on the basis of new information before the Secretary,

evaluated together with the evidence before the

Secretary when such order was issued, that such tobacco

product is not shown to conform in all respects to a tobacco

product standard which is in effect under section 907,

compliance with which was a condition to the issuance

of an order relating to the application, and that there

is a lack of adequate information to justify the deviation

from such standard.

‘‘(2) APPEAL.—The holder of an application subject to an

order issued under paragraph (1) withdrawing an order issued

pursuant to subsection (c)(1)(A)(i) may, by petition filed on

or before the 30th day after the date upon which such holder

receives notice of such withdrawal, obtain review thereof in

accordance with section 912.

‘‘(3) TEMPORARY SUSPENSION.—If, after providing an opportunity

for an informal hearing, the Secretary determines there

is reasonable probability that the continuation of distribution

of a tobacco product under an order would cause serious,

adverse health consequences or death, that is greater than

ordinarily caused by tobacco products on the market, the Secretary

shall by order temporarily suspend the authority of

the manufacturer to market the product. If the Secretary issues

such an order, the Secretary shall proceed expeditiously under

paragraph (1) to withdraw such application.

‘‘(e) SERVICE OF ORDER.—An order issued by the Secretary

under this section shall be served—

‘‘(1) in person by any officer or employee of the department

designated by the Secretary; or

‘‘(2) by mailing the order by registered mail or certified

mail addressed to the applicant at the applicant’s last known

address in the records of the Secretary.

‘‘(f) RECORDS.—

‘‘(1) ADDITIONAL INFORMATION.—In the case of any tobacco

product for which an order issued pursuant to subsection

Reports.

Order.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00037 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

123 STAT. 1812 PUBLIC LAW 111–31—JUNE 22, 2009

(c)(1)(A)(i) for an application filed under subsection (b) is in

effect, the applicant shall establish and maintain such records,

and make such reports to the Secretary, as the Secretary may

by regulation, or by order with respect to such application,

prescribe on the basis of a finding that such records and reports

are necessary in order to enable the Secretary to determine,

or facilitate a determination of, whether there is or may be

grounds for withdrawing or temporarily suspending such order.

‘‘(2) ACCESS TO RECORDS.—Each person required under this

section to maintain records, and each person in charge of custody

thereof, shall, upon request of an officer or employee

designated by the Secretary, permit such officer or employee

at all reasonable times to have access to and copy and verify

such records.

‘‘(g) INVESTIGATIONAL TOBACCO PRODUCT EXEMPTION FOR

INVESTIGATIONAL USE.—The Secretary may exempt tobacco products

intended for investigational use from the provisions of this

chapter under such conditions as the Secretary may by regulation

prescribe.

**‘‘SEC. 911. MODIFIED RISK TOBACCO PRODUCTS.**

‘‘(a) IN GENERAL.—No person may introduce or deliver for

introduction into interstate commerce any modified risk tobacco

product unless an order issued pursuant to subsection (g) is effective

with respect to such product.

‘‘(b) DEFINITIONS.—In this section:

‘‘(1) MODIFIED RISK TOBACCO PRODUCT.—The term ‘modified

risk tobacco product’ means any tobacco product that is sold

or distributed for use to reduce harm or the risk of tobaccorelated

disease associated with commercially marketed tobacco

products.

‘‘(2) SOLD OR DISTRIBUTED.—

‘‘(A) IN GENERAL.—With respect to a tobacco product,

the term ‘sold or distributed for use to reduce harm or

the risk of tobacco-related disease associated with commercially

marketed tobacco products’ means a tobacco

product—

‘‘(i) the label, labeling, or advertising of which represents

explicitly or implicitly that—

‘‘(I) the tobacco product presents a lower risk

of tobacco-related disease or is less harmful than

one or more other commercially marketed tobacco

products;

‘‘(II) the tobacco product or its smoke contains

a reduced level of a substance or presents a

reduced exposure to a substance; or

‘‘(III) the tobacco product or its smoke does

not contain or is free of a substance;

‘‘(ii) the label, labeling, or advertising of which

uses the descriptors ‘light’, ‘mild’, or ‘low’ or similar

descriptors; or

‘‘(iii) the tobacco product manufacturer of which

has taken any action directed to consumers through

the media or otherwise, other than by means of the

tobacco product’s label, labeling, or advertising, after

the date of enactment of the Family Smoking Prevention

and Tobacco Control Act, respecting the product

21 USC 387k.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00038 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

PUBLIC LAW 111–31—JUNE 22, 2009 123 STAT. 1813

that would be reasonably expected to result in consumers

believing that the tobacco product or its smoke

may present a lower risk of disease or is less harmful

than one or more commercially marketed tobacco products,

or presents a reduced exposure to, or does not

contain or is free of, a substance or substances.

‘‘(B) LIMITATION.—No tobacco product shall be considered

to be ‘sold or distributed for use to reduce harm

or the risk of tobacco-related disease associated with

commercially marketed tobacco products’, except as

described in subparagraph (A).

‘‘(C) SMOKELESS TOBACCO PRODUCT.—No smokeless

tobacco product shall be considered to be ‘sold or distributed

for use to reduce harm or the risk of tobacco-related disease

associated with commercially marketed tobacco products’

solely because its label, labeling, or advertising uses the

following phrases to describe such product and its use:

‘smokeless tobacco’, ‘smokeless tobacco product’, ‘not consumed

by smoking’, ‘does not produce smoke’, ‘smokefree’,

‘smoke-free’, ‘without smoke’, ‘no smoke’, or ‘not smoke’.

‘‘(3) EFFECTIVE DATE.—The provisions of paragraph

(2)(A)(ii) shall take effect 12 months after the date of enactment

of the Family Smoking Prevention and Tobacco Control Act

for those products whose label, labeling, or advertising contains

the terms described in such paragraph on such date of enactment.

The effective date shall be with respect to the date

of manufacture, provided that, in any case, beginning 30 days

after such effective date, a manufacturer shall not introduce

into the domestic commerce of the United States any product,

irrespective of the date of manufacture, that is not in conformance

with paragraph (2)(A)(ii).

‘‘(c) TOBACCO DEPENDENCE PRODUCTS.—A product that is

intended to be used for the treatment of tobacco dependence,

including smoking cessation, is not a modified risk tobacco product

under this section if it has been approved as a drug or device

by the Food and Drug Administration and is subject to the requirements

of chapter V.

‘‘(d) FILING.—Any person may file with the Secretary an application

for a modified risk tobacco product. Such application shall

include—

‘‘(1) a description of the proposed product and any proposed

advertising and labeling;

‘‘(2) the conditions for using the product;

‘‘(3) the formulation of the product;

‘‘(4) sample product labels and labeling;

‘‘(5) all documents (including underlying scientific information)

relating to research findings conducted, supported, or

possessed by the tobacco product manufacturer relating to the

effect of the product on tobacco-related diseases and healthrelated

conditions, including information both favorable and

unfavorable to the ability of the product to reduce risk or

exposure and relating to human health;

‘‘(6) data and information on how consumers actually use

the tobacco product; and

‘‘(7) such other information as the Secretary may require.

‘‘(e) PUBLIC AVAILABILITY.—The Secretary shall make the

application described in subsection (d) publicly available (except

Comment period.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00039 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

123 STAT. 1814 PUBLIC LAW 111–31—JUNE 22, 2009

matters in the application which are trade secrets or otherwise

confidential, commercial information) and shall request comments

by interested persons on the information contained in the application

and on the label, labeling, and advertising accompanying such

application.

‘‘(f) ADVISORY COMMITTEE.—

‘‘(1) IN GENERAL.—The Secretary shall refer to the Tobacco

Products Scientific Advisory Committee any application submitted

under this section.

‘‘(2) RECOMMENDATIONS.—Not later than 60 days after the

date an application is referred to the Tobacco Products Scientific

Advisory Committee under paragraph (1), the Advisory Committee

shall report its recommendations on the application

to the Secretary.

‘‘(g) MARKETING.—

‘‘(1) MODIFIED RISK PRODUCTS.—Except as provided in paragraph

(2), the Secretary shall, with respect to an application

submitted under this section, issue an order that a modified

risk product may be commercially marketed only if the Secretary

determines that the applicant has demonstrated that

such product, as it is actually used by consumers, will—

‘‘(A) significantly reduce harm and the risk of tobaccorelated

disease to individual tobacco users; and

‘‘(B) benefit the health of the population as a whole

taking into account both users of tobacco products and

persons who do not currently use tobacco products.

‘‘(2) SPECIAL RULE FOR CERTAIN PRODUCTS.—

‘‘(A) IN GENERAL.—The Secretary may issue an order

that a tobacco product may be introduced or delivered

for introduction into interstate commerce, pursuant to an

application under this section, with respect to a tobacco

product that may not be commercially marketed under

paragraph (1) if the Secretary makes the findings required

under this paragraph and determines that the applicant

has demonstrated that—

‘‘(i) such order would be appropriate to promote

the public health;

‘‘(ii) any aspect of the label, labeling, and advertising

for such product that would cause the tobacco

product to be a modified risk tobacco product under

subsection (b) is limited to an explicit or implicit representation

that such tobacco product or its smoke

does not contain or is free of a substance or contains

a reduced level of a substance, or presents a reduced

exposure to a substance in tobacco smoke;

‘‘(iii) scientific evidence is not available and, using

the best available scientific methods, cannot be made

available without conducting long-term epidemiological

studies for an application to meet the standards set

forth in paragraph (1); and

‘‘(iv) the scientific evidence that is available without

conducting long-term epidemiological studies demonstrates

that a measurable and substantial reduction

in morbidity or mortality among individual tobacco

users is reasonably likely in subsequent studies.

Order.

Deadline.

Reports.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00040 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

PUBLIC LAW 111–31—JUNE 22, 2009 123 STAT. 1815

‘‘(B) ADDITIONAL FINDINGS REQUIRED.—To issue an

order under subparagraph (A) the Secretary must also

find that the applicant has demonstrated that—

‘‘(i) the magnitude of the overall reductions in exposure

to the substance or substances which are the

subject of the application is substantial, such substance

or substances are harmful, and the product as actually

used exposes consumers to the specified reduced level

of the substance or substances;

‘‘(ii) the product as actually used by consumers

will not expose them to higher levels of other harmful

substances compared to the similar types of tobacco

products then on the market unless such increases

are minimal and the reasonably likely overall impact

of use of the product remains a substantial and measurable

reduction in overall morbidity and mortality

among individual tobacco users;

‘‘(iii) testing of actual consumer perception shows

that, as the applicant proposes to label and market

the product, consumers will not be misled into believing

that the product—

‘‘(I) is or has been demonstrated to be less

harmful; or

‘‘(II) presents or has been demonstrated to

present less of a risk of disease than 1 or more

other commercially marketed tobacco products;

and

‘‘(iv) issuance of an order with respect to the

application is expected to benefit the health of the

population as a whole taking into account both users

of tobacco products and persons who do not currently

use tobacco products.

‘‘(C) CONDITIONS OF MARKETING.—

‘‘(i) IN GENERAL.—Applications subject to an order

under this paragraph shall be limited to a term of

not more than 5 years, but may be renewed upon

a finding by the Secretary that the requirements of

this paragraph continue to be satisfied based on the

filing of a new application.

‘‘(ii) AGREEMENTS BY APPLICANT.—An order under

this paragraph shall be conditioned on the applicant’s

agreement to conduct postmarket surveillance and

studies and to submit to the Secretary the results

of such surveillance and studies to determine the

impact of the order on consumer perception, behavior,

and health and to enable the Secretary to review the

accuracy of the determinations upon which the order

was based in accordance with a protocol approved by

the Secretary.

‘‘(iii) ANNUAL SUBMISSION.—The results of such

postmarket surveillance and studies described in clause

(ii) shall be submitted annually.

‘‘(3) BASIS.—The determinations under paragraphs (1) and

(2) shall be based on—

‘‘(A) the scientific evidence submitted by the applicant;

and

Study.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00041 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

123 STAT. 1816 PUBLIC LAW 111–31—JUNE 22, 2009

‘‘(B) scientific evidence and other information that is

made available to the Secretary.

‘‘(4) BENEFIT TO HEALTH OF INDIVIDUALS AND OF POPULATION

AS A WHOLE.—In making the determinations under

paragraphs (1) and (2), the Secretary shall take into account—

‘‘(A) the relative health risks to individuals of the

tobacco product that is the subject of the application;

‘‘(B) the increased or decreased likelihood that existing

users of tobacco products who would otherwise stop using

such products will switch to the tobacco product that is

the subject of the application;

‘‘(C) the increased or decreased likelihood that persons

who do not use tobacco products will start using the tobacco

product that is the subject of the application;

‘‘(D) the risks and benefits to persons from the use

of the tobacco product that is the subject of the application

as compared to the use of products for smoking cessation

approved under chapter V to treat nicotine dependence;

and

‘‘(E) comments, data, and information submitted by

interested persons.

‘‘(h) ADDITIONAL CONDITIONS FOR MARKETING.—

‘‘(1) MODIFIED RISK PRODUCTS.—The Secretary shall require

for the marketing of a product under this section that any

advertising or labeling concerning modified risk products enable

the public to comprehend the information concerning modified

risk and to understand the relative significance of such information

in the context of total health and in relation to all of

the diseases and health-related conditions associated with the

use of tobacco products.

‘‘(2) COMPARATIVE CLAIMS.—

‘‘(A) IN GENERAL.—The Secretary may require for the

marketing of a product under this subsection that a claim

comparing a tobacco product to 1 or more other commercially

marketed tobacco products shall compare the tobacco

product to a commercially marketed tobacco product that

is representative of that type of tobacco product on the

market (for example the average value of the top 3 brands

of an established regular tobacco product).

‘‘(B) QUANTITATIVE COMPARISONS.—The Secretary may

also require, for purposes of subparagraph (A), that the

percent (or fraction) of change and identity of the reference

tobacco product and a quantitative comparison of the

amount of the substance claimed to be reduced shall be

stated in immediate proximity to the most prominent claim.

‘‘(3) LABEL DISCLOSURE.—

‘‘(A) IN GENERAL.—The Secretary may require the

disclosure on the label of other substances in the tobacco

product, or substances that may be produced by the

consumption of that tobacco product, that may affect a

disease or health-related condition or may increase the

risk of other diseases or health-related conditions associated

with the use of tobacco products.

‘‘(B) CONDITIONS OF USE.—If the conditions of use of

the tobacco product may affect the risk of the product

to human health, the Secretary may require the labeling

of conditions of use.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00042 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

PUBLIC LAW 111–31—JUNE 22, 2009 123 STAT. 1817

‘‘(4) TIME.—An order issued under subsection (g)(1) shall

be effective for a specified period of time.

‘‘(5) ADVERTISING.—The Secretary may require, with

respect to a product for which an applicant obtained an order

under subsection (g)(1), that the product comply with requirements

relating to advertising and promotion of the tobacco

product.

‘‘(i) POSTMARKET SURVEILLANCE AND STUDIES.—

‘‘(1) IN GENERAL.—The Secretary shall require, with respect

to a product for which an applicant obtained an order under

subsection (g)(1), that the applicant conduct postmarket surveillance

and studies for such a tobacco product to determine

the impact of the order issuance on consumer perception,

behavior, and health, to enable the Secretary to review the

accuracy of the determinations upon which the order was based,

and to provide information that the Secretary determines is

otherwise necessary regarding the use or health risks involving

the tobacco product. The results of postmarket surveillance

and studies shall be submitted to the Secretary on an annual

basis.

‘‘(2) SURVEILLANCE PROTOCOL.—Each applicant required to

conduct a surveillance of a tobacco product under paragraph

(1) shall, within 30 days after receiving notice that the applicant

is required to conduct such surveillance, submit, for the

approval of the Secretary, a protocol for the required surveillance.

The Secretary, within 60 days of the receipt of such

protocol, shall determine if the principal investigator proposed

to be used in the surveillance has sufficient qualifications and

experience to conduct such surveillance and if such protocol

will result in collection of the data or other information designated

by the Secretary as necessary to protect the public

health.

‘‘(j) WITHDRAWAL OF AUTHORIZATION.—The Secretary, after an

opportunity for an informal hearing, shall withdraw an order under

subsection (g) if the Secretary determines that—

‘‘(1) the applicant, based on new information, can no longer

make the demonstrations required under subsection (g), or

the Secretary can no longer make the determinations required

under subsection (g);

‘‘(2) the application failed to include material information

or included any untrue statement of material fact;

‘‘(3) any explicit or implicit representation that the product

reduces risk or exposure is no longer valid, including if—

‘‘(A) a tobacco product standard is established pursuant

to section 907;

‘‘(B) an action is taken that affects the risks presented

by other commercially marketed tobacco products that were

compared to the product that is the subject of the application;

or

‘‘(C) any postmarket surveillance or studies reveal that

the order is no longer consistent with the protection of

the public health;

‘‘(4) the applicant failed to conduct or submit the

postmarket surveillance and studies required under subsection

(g)(2)(C)(ii) or subsection (i); or

‘‘(5) the applicant failed to meet a condition imposed under

subsection (h).

Hearings.

Deadlines.

Notice.

Deadline.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00043 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

123 STAT. 1818 PUBLIC LAW 111–31—JUNE 22, 2009

‘‘(k) CHAPTER IV OR V.—A product for which the Secretary

has issued an order pursuant to subsection (g) shall not be subject

to chapter IV or V.

‘‘(l) IMPLEMENTING REGULATIONS OR GUIDANCE.—

‘‘(1) SCIENTIFIC EVIDENCE.—Not later than 2 years after

the date of enactment of the Family Smoking Prevention and

Tobacco Control Act, the Secretary shall issue regulations or

guidance (or any combination thereof) on the scientific evidence

required for assessment and ongoing review of modified risk

tobacco products. Such regulations or guidance shall—

‘‘(A) to the extent that adequate scientific evidence

exists, establish minimum standards for scientific studies

needed prior to issuing an order under subsection (g) to

show that a substantial reduction in morbidity or mortality

among individual tobacco users occurs for products

described in subsection (g)(1) or is reasonably likely for

products described in subsection (g)(2);

‘‘(B) include validated biomarkers, intermediate clinical

endpoints, and other feasible outcome measures, as appropriate;

‘‘(C) establish minimum standards for postmarket

studies, that shall include regular and long-term assessments

of health outcomes and mortality, intermediate clinical

endpoints, consumer perception of harm reduction, and

the impact on quitting behavior and new use of tobacco

products, as appropriate;

‘‘(D) establish minimum standards for required

postmarket surveillance, including ongoing assessments of

consumer perception;

‘‘(E) require that data from the required studies and

surveillance be made available to the Secretary prior to

the decision on renewal of a modified risk tobacco product;

and

‘‘(F) establish a reasonable timetable for the Secretary

to review an application under this section.

‘‘(2) CONSULTATION.—The regulations or guidance issued

under paragraph (1) shall be developed in consultation with

the Institute of Medicine, and with the input of other appropriate

scientific and medical experts, on the design and conduct

of such studies and surveillance.

‘‘(3) REVISION.—The regulations or guidance under paragraph

(1) shall be revised on a regular basis as new scientific

information becomes available.

‘‘(4) NEW TOBACCO PRODUCTS.—Not later than 2 years after

the date of enactment of the Family Smoking Prevention and

Tobacco Control Act, the Secretary shall issue a regulation

or guidance that permits the filing of a single application for

any tobacco product that is a new tobacco product under section

910 and which the applicant seeks to commercially market

under this section.

‘‘(m) DISTRIBUTORS.—Except as provided in this section, no

distributor may take any action, after the date of enactment of

the Family Smoking Prevention and Tobacco Control Act, with

respect to a tobacco product that would reasonably be expected

to result in consumers believing that the tobacco product or its

smoke may present a lower risk of disease or is less harmful

Deadline.

Deadline.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00044 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

PUBLIC LAW 111–31—JUNE 22, 2009 123 STAT. 1819

than one or more commercially marketed tobacco products, or presents

a reduced exposure to, or does not contain or is free of,

a substance or substances.

**‘‘SEC. 912. JUDICIAL REVIEW.**

‘‘(a) RIGHT TO REVIEW.—

‘‘(1) IN GENERAL.—Not later than 30 days after—

‘‘(A) the promulgation of a regulation under section

907 establishing, amending, or revoking a tobacco product

standard; or

‘‘(B) a denial of an application under section 910(c),

any person adversely affected by such regulation or denial

may file a petition for judicial review of such regulation or

denial with the United States Court of Appeals for the District

of Columbia or for the circuit in which such person resides

or has their principal place of business.

‘‘(2) REQUIREMENTS.—

‘‘(A) COPY OF PETITION.—A copy of the petition filed

under paragraph (1) shall be transmitted by the clerk

of the court involved to the Secretary.

‘‘(B) RECORD OF PROCEEDINGS.—On receipt of a petition

under subparagraph (A), the Secretary shall file in the

court in which such petition was filed—

‘‘(i) the record of the proceedings on which the

regulation or order was based; and

‘‘(ii) a statement of the reasons for the issuance

of such a regulation or order.

‘‘(C) DEFINITION OF RECORD.—In this section, the term

‘record’ means—

‘‘(i) all notices and other matter published in the

Federal Register with respect to the regulation or order

reviewed;

‘‘(ii) all information submitted to the Secretary

with respect to such regulation or order;

‘‘(iii) proceedings of any panel or advisory committee

with respect to such regulation or order;

‘‘(iv) any hearing held with respect to such regulation

or order; and

‘‘(v) any other information identified by the Secretary,

in the administrative proceeding held with

respect to such regulation or order, as being relevant

to such regulation or order.

‘‘(b) STANDARD OF REVIEW.—Upon the filing of the petition

under subsection (a) for judicial review of a regulation or order,

the court shall have jurisdiction to review the regulation or order

in accordance with chapter 7 of title 5, United States Code, and

to grant appropriate relief, including interim relief, as provided

for in such chapter. A regulation or denial described in subsection

(a) shall be reviewed in accordance with section 706(2)(A) of title

5, United States Code.

‘‘(c) FINALITY OF JUDGMENT.—The judgment of the court

affirming or setting aside, in whole or in part, any regulation

or order shall be final, subject to review by the Supreme Court

of the United States upon certiorari or certification, as provided

in section 1254 of title 28, United States Code.

Statement.

Deadline.

21 USC 387*l*.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00045 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

123 STAT. 1820 PUBLIC LAW 111–31—JUNE 22, 2009

‘‘(d) OTHER REMEDIES.—The remedies provided for in this section

shall be in addition to, and not in lieu of, any other remedies

provided by law.

‘‘(e) REGULATIONS AND ORDERS MUST RECITE BASIS IN

RECORD.—To facilitate judicial review, a regulation or order issued

under section 906, 907, 908, 909, 910, or 916 shall contain a

statement of the reasons for the issuance of such regulation or

order in the record of the proceedings held in connection with

its issuance.

**‘‘SEC. 913. EQUAL TREATMENT OF RETAIL OUTLETS.**

‘‘The Secretary shall issue regulations to require that retail

establishments for which the predominant business is the sale

of tobacco products comply with any advertising restrictions

applicable to retail establishments accessible to individuals under

the age of 18.

**‘‘SEC. 914. JURISDICTION OF AND COORDINATION WITH THE FEDERAL**

**TRADE COMMISSION.**

‘‘(a) JURISDICTION.—

‘‘(1) IN GENERAL.—Except where expressly provided in this

chapter, nothing in this chapter shall be construed as limiting

or diminishing the authority of the Federal Trade Commission

to enforce the laws under its jurisdiction with respect to the

advertising, sale, or distribution of tobacco products.

‘‘(2) ENFORCEMENT.—Any advertising that violates this

chapter or a provision of the regulations referred to in section

102 of the Family Smoking Prevention and Tobacco Control

Act, is an unfair or deceptive act or practice under section

5(a) of the Federal Trade Commission Act and shall be considered

a violation of a rule promulgated under section 18 of

that Act.

‘‘(b) COORDINATION.—With respect to the requirements of section

4 of the Federal Cigarette Labeling and Advertising Act and

section 3 of the Comprehensive Smokeless Tobacco Health Education

Act of 1986—

‘‘(1) the Chairman of the Federal Trade Commission shall

coordinate with the Secretary concerning the enforcement of

such Act as such enforcement relates to unfair or deceptive

acts or practices in the advertising of cigarettes or smokeless

tobacco; and

‘‘(2) the Secretary shall consult with the Chairman of such

Commission in revising the label statements and requirements

under such sections.

**‘‘SEC. 915. REGULATION REQUIREMENT.**

‘‘(a) TESTING, REPORTING, AND DISCLOSURE.—Not later than

36 months after the date of enactment of the Family Smoking

Prevention and Tobacco Control Act, the Secretary shall promulgate

regulations under this Act that meet the requirements of subsection

(b).

‘‘(b) CONTENTS OF RULES.—The regulations promulgated under

subsection (a)—

‘‘(1) shall require testing and reporting of tobacco product

constituents, ingredients, and additives, including smoke

constituents, by brand and subbrand that the Secretary determines

should be tested to protect the public health, provided

that, for purposes of the testing requirements of this paragraph,

21 USC 387o.

Consultation.

21 USC 387n.

Regulations.

21 USC 387m.

Statement.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00046 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

PUBLIC LAW 111–31—JUNE 22, 2009 123 STAT. 1821

tobacco products manufactured and sold by a single tobacco

product manufacturer that are identical in all respects except

the labels, packaging design, logo, trade dress, trademark,

brand name, or any combination thereof, shall be considered

as a single brand; and

‘‘(2) may require that tobacco product manufacturers, packagers,

or importers make disclosures relating to the results

of the testing of tar and nicotine through labels or advertising

or other appropriate means, and make disclosures regarding

the results of the testing of other constituents, including smoke

constituents, ingredients, or additives, that the Secretary determines

should be disclosed to the public to protect the public

health and will not mislead consumers about the risk of tobaccorelated

disease.

‘‘(c) AUTHORITY.—The Secretary shall have the authority under

this chapter to conduct or to require the testing, reporting, or

disclosure of tobacco product constituents, including smoke constituents.

‘‘(d) SMALL TOBACCO PRODUCT MANUFACTURERS.—

‘‘(1) FIRST COMPLIANCE DATE.—The initial regulations

promulgated under subsection (a) shall not impose requirements

on small tobacco product manufacturers before the later

of—

‘‘(A) the end of the 2-year period following the final

promulgation of such regulations; and

‘‘(B) the initial date set by the Secretary for compliance

with such regulations by manufacturers that are not small

tobacco product manufacturers.

‘‘(2) TESTING AND REPORTING INITIAL COMPLIANCE PERIOD.—

‘‘(A) 4-YEAR PERIOD.—The initial regulations promulgated

under subsection (a) shall give each small tobacco

product manufacturer a 4-year period over which to conduct

testing and reporting for all of its tobacco products. Subject

to paragraph (1), the end of the first year of such 4-

year period shall coincide with the initial date of compliance

under this section set by the Secretary with respect to

manufacturers that are not small tobacco product manufacturers

or the end of the 2-year period following the final

promulgation of such regulations, as described in paragraph

(1)(A). A small tobacco product manufacturer shall

be required—

‘‘(i) to conduct such testing and reporting for 25

percent of its tobacco products during each year of

such 4-year period; and

‘‘(ii) to conduct such testing and reporting for its

largest-selling tobacco products (as determined by the

Secretary) before its other tobacco products, or in such

other order of priority as determined by the Secretary.

‘‘(B) CASE-BY-CASE DELAY.—Notwithstanding subparagraph

(A), the Secretary may, on a case-by-case basis,

delay the date by which an individual small tobacco product

manufacturer must conduct testing and reporting for its

tobacco products under this section based upon a showing

of undue hardship to such manufacturer. Notwithstanding

the preceding sentence, the Secretary shall not extend the

deadline for a small tobacco product manufacturer to conduct

testing and reporting for all of its tobacco products

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00047 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

123 STAT. 1822 PUBLIC LAW 111–31—JUNE 22, 2009

beyond a total of 5 years after the initial date of compliance

under this section set by the Secretary with respect to

manufacturers that are not small tobacco product manufacturers.

‘‘(3) SUBSEQUENT AND ADDITIONAL TESTING AND

REPORTING.—The regulations promulgated under subsection (a)

shall provide that, with respect to any subsequent or additional

testing and reporting of tobacco products required under this

section, such testing and reporting by a small tobacco product

manufacturer shall be conducted in accordance with the timeframes

described in paragraph (2)(A), except that, in the case

of a new product, or if there has been a modification described

in section 910(a)(1)(B) of any product of a small tobacco product

manufacturer since the last testing and reporting required

under this section, the Secretary shall require that any subsequent

or additional testing and reporting be conducted in

accordance with the same timeframe applicable to manufacturers

that are not small tobacco product manufacturers.

‘‘(4) JOINT LABORATORY TESTING SERVICES.—The Secretary

shall allow any 2 or more small tobacco product manufacturers

to join together to purchase laboratory testing services required

by this section on a group basis in order to ensure that such

manufacturers receive access to, and fair pricing of, such testing

services.

‘‘(e) EXTENSIONS FOR LIMITED LABORATORY CAPACITY.—

‘‘(1) IN GENERAL.—The regulations promulgated under subsection

(a) shall provide that a small tobacco product manufacturer

shall not be considered to be in violation of this section

before the deadline applicable under paragraphs (3) and (4),

if—

‘‘(A) the tobacco products of such manufacturer are

in compliance with all other requirements of this chapter;

and

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

‘‘(2) CONDITIONS.—Notwithstanding the requirements of

this section, the Secretary may delay the date by which a

small tobacco product manufacturer must be in compliance

with the testing and reporting required by this section until

such time as the testing is reported if, not later than 90

days before the deadline for reporting in accordance with this

section, a small tobacco product manufacturer provides evidence

to the Secretary demonstrating that—

‘‘(A) the manufacturer has submitted the required products

for testing to a laboratory and has done so sufficiently

in advance of the deadline to create a reasonable expectation

of completion by the deadline;

‘‘(B) the products currently are awaiting testing by

the laboratory; and

‘‘(C) neither that laboratory nor any other laboratory

is able to complete testing by the deadline at customary,

nonexpedited testing fees.

‘‘(3) EXTENSION.—The Secretary, taking into account the

laboratory testing capacity that is available to tobacco product

manufacturers, shall review and verify the evidence submitted

by a small tobacco product manufacturer in accordance with

paragraph (2). If the Secretary finds that the conditions

described in such paragraph are met, the Secretary shall notify

Notification.

Deadline.

Evidence.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00048 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

PUBLIC LAW 111–31—JUNE 22, 2009 123 STAT. 1823

the small tobacco product manufacturer that the manufacturer

shall not be considered to be in violation of the testing and

reporting requirements of this section until the testing is

reported or until 1 year after the reporting deadline has passed,

whichever occurs sooner. If, however, the Secretary has not

made a finding before the reporting deadline, the manufacturer

shall not be considered to be in violation of such requirements

until the Secretary finds that the conditions described in paragraph

(2) have not been met, or until 1 year after the reporting

deadline, whichever occurs sooner.

‘‘(4) ADDITIONAL EXTENSION.—In addition to the time that

may be provided under paragraph (3), the Secretary may provide

further extensions of time, in increments of no more than

1 year, for required testing and reporting to occur if the Secretary

determines, based on evidence properly and timely submitted

by a small tobacco product manufacturer in accordance

with paragraph (2), that a lack of available laboratory capacity

prevents the manufacturer from completing the required testing

during the period described in paragraph (3).

‘‘(f) RULE OF CONSTRUCTION.—Nothing in subsection (d) or (e)

shall be construed to authorize the extension of any deadline, or

to otherwise affect any timeframe, under any provision of this

Act or the Family Smoking Prevention and Tobacco Control Act

other than this section.

**‘‘SEC. 916. PRESERVATION OF STATE AND LOCAL AUTHORITY.**

‘‘(a) IN GENERAL.—

‘‘(1) PRESERVATION.—Except as provided in paragraph

(2)(A), nothing in this chapter, or rules promulgated under

this chapter, shall be construed to limit the authority of a

Federal agency (including the Armed Forces), a State or political

subdivision of a State, or the government of an Indian

tribe to enact, adopt, promulgate, and enforce any law, rule,

regulation, or other measure with respect to tobacco products

that is in addition to, or more stringent than, requirements

established under this chapter, including a law, rule, regulation,

or other measure relating to or prohibiting the sale, distribution,

possession, exposure to, access to, advertising and promotion

of, or use of tobacco products by individuals of any

age, information reporting to the State, or measures relating

to fire safety standards for tobacco products. No provision of

this chapter shall limit or otherwise affect any State, tribal,

or local taxation of tobacco products.

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

‘‘(A) IN GENERAL.—No State or political subdivision

of a State may establish or continue in effect with respect

to a tobacco product any requirement which is different

from, or in addition to, any requirement under the provisions

of this chapter relating to tobacco product standards,

premarket review, adulteration, misbranding, labeling, registration,

good manufacturing standards, or modified risk

tobacco products.

‘‘(B) EXCEPTION.—Subparagraph (A) does not apply to

requirements relating to the sale, distribution, possession,

information reporting to the State, exposure to, access to,

the advertising and promotion of, or use of, tobacco products

21 USC 387p.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00049 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

123 STAT. 1824 PUBLIC LAW 111–31—JUNE 22, 2009

by individuals of any age, or relating to fire safety standards

for tobacco products. Information disclosed to a State

under subparagraph (A) that is exempt from disclosure

under section 552(b)(4) of title 5, United States Code, shall

be treated as a trade secret and confidential information

by the State.

‘‘(b) RULE OF CONSTRUCTION REGARDING PRODUCT LIABILITY.—

No provision of this chapter relating to a tobacco product shall

be construed to modify or otherwise affect any action or the liability

of any person under the product liability law of any State.

**‘‘SEC. 917. TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE.**

‘‘(a) ESTABLISHMENT.—Not later than 6 months after the date

of enactment of the Family Smoking Prevention and Tobacco Control

Act, the Secretary shall establish a 12-member advisory committee,

to be known as the Tobacco Products Scientific Advisory

Committee (in this section referred to as the ‘Advisory Committee’).

‘‘(b) MEMBERSHIP.—

‘‘(1) IN GENERAL.—

‘‘(A) MEMBERS.—The Secretary shall appoint as members

of the Tobacco Products Scientific Advisory Committee

individuals who are technically qualified by training and

experience in medicine, medical ethics, science, or technology

involving the manufacture, evaluation, or use of

tobacco products, who are of appropriately diversified

professional backgrounds. The committee shall be composed

of—

‘‘(i) 7 individuals who are physicians, dentists, scientists,

or health care professionals practicing in the

area of oncology, pulmonology, cardiology, toxicology,

pharmacology, addiction, or any other relevant specialty;

‘‘(ii) 1 individual who is an officer or employee

of a State or local government or of the Federal Government;

‘‘(iii) 1 individual as a representative of the general

public;

‘‘(iv) 1 individual as a representative of the

interests of the tobacco manufacturing industry;

‘‘(v) 1 individual as a representative of the interests

of the small business tobacco manufacturing industry,

which position may be filled on a rotating, sequential

basis by representatives of different small business

tobacco manufacturers based on areas of expertise relevant

to the topics being considered by the Advisory

Committee; and

‘‘(vi) 1 individual as a representative of the

interests of the tobacco growers.

‘‘(B) NONVOTING MEMBERS.—The members of the committee

appointed under clauses (iv), (v), and (vi) of subparagraph

(A) shall serve as consultants to those described

in clauses (i) through (iii) of subparagraph (A) and shall

be nonvoting representatives.

‘‘(C) CONFLICTS OF INTEREST.—No members of the committee,

other than members appointed pursuant to clauses

(iv), (v), and (vi) of subparagraph (A) shall, during the

member’s tenure on the committee or for the 18-month

Deadline.

21 USC 387q.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00050 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

PUBLIC LAW 111–31—JUNE 22, 2009 123 STAT. 1825

period prior to becoming such a member, receive any salary,

grants, or other payments or support from any business

that manufactures, distributes, markets, or sells cigarettes

or other tobacco products.

‘‘(2) LIMITATION.—The Secretary may not appoint to the

Advisory Committee any individual who is in the regular fulltime

employ of the Food and Drug Administration or any agency

responsible for the enforcement of this Act. The Secretary may

appoint Federal officials as ex officio members.

‘‘(3) CHAIRPERSON.—The Secretary shall designate 1 of the

members appointed under clauses (i), (ii), and (iii) of paragraph

(1)(A) to serve as chairperson.

‘‘(c) DUTIES.—The Tobacco Products Scientific Advisory Committee

shall provide advice, information, and recommendations to

the Secretary—

‘‘(1) as provided in this chapter;

‘‘(2) on the effects of the alteration of the nicotine yields

from tobacco products;

‘‘(3) on whether there is a threshold level below which

nicotine yields do not produce dependence on the tobacco

product involved; and

‘‘(4) on its review of other safety, dependence, or health

issues relating to tobacco products as requested by the Secretary.

‘‘(d) COMPENSATION; SUPPORT; FACA.—

‘‘(1) COMPENSATION AND TRAVEL.—Members of the Advisory

Committee who are not officers or employees of the United

States, while attending conferences or meetings of the committee

or otherwise engaged in its business, shall be entitled

to receive compensation at rates to be fixed by the Secretary,

which may not exceed the daily equivalent of the rate in effect

under the Senior Executive Schedule under section 5382 of

title 5, United States Code, for each day (including travel

time) they are so engaged; and while so serving away from

their homes or regular places of business each member may

be allowed travel expenses, including per diem in lieu of subsistence,

as authorized by section 5703 of title 5, United States

Code, for persons in the Government service employed intermittently.

‘‘(2) ADMINISTRATIVE SUPPORT.—The Secretary shall furnish

the Advisory Committee clerical and other assistance.

‘‘(3) NONAPPLICATION OF FACA.—Section 14 of the Federal

Advisory Committee Act does not apply to the Advisory Committee.

‘‘(e) PROCEEDINGS OF ADVISORY PANELS AND COMMITTEES.—

The Advisory Committee shall make and maintain a transcript

of any proceeding of the panel or committee. Each such panel

and committee shall delete from any transcript made under this

subsection information which is exempt from disclosure under section

552(b) of title 5, United States Code.

**‘‘SEC. 918. DRUG PRODUCTS USED TO TREAT TOBACCO DEPENDENCE.**

‘‘(a) IN GENERAL.—The Secretary shall—

‘‘(1) at the request of the applicant, consider designating

products for smoking cessation, including nicotine replacement

products as fast track research and approval products within

the meaning of section 506;

21 USC 387r.

Records.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00051 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

123 STAT. 1826 PUBLIC LAW 111–31—JUNE 22, 2009

‘‘(2) consider approving the extended use of nicotine replacement

products (such as nicotine patches, nicotine gum, and

nicotine lozenges) for the treatment of tobacco dependence;

and

‘‘(3) review and consider the evidence for additional indications

for nicotine replacement products, such as for craving

relief or relapse prevention.

‘‘(b) REPORT ON INNOVATIVE PRODUCTS.—

‘‘(1) IN GENERAL.—Not later than 3 years after the date

of enactment of the Family Smoking Prevention and Tobacco

Control Act, the Secretary, after consultation with recognized

scientific, medical, and public health experts (including both

Federal agencies and nongovernmental entities, the Institute

of Medicine of the National Academy of Sciences, and the

Society for Research on Nicotine and Tobacco), shall submit

to the Congress a report that examines how best to regulate,

promote, and encourage the development of innovative products

and treatments (including nicotine-based and non-nicotinebased

products and treatments) to better achieve, in a manner

that best protects and promotes the public health—

‘‘(A) total abstinence from tobacco use;

‘‘(B) reductions in consumption of tobacco; and

‘‘(C) reductions in the harm associated with continued

tobacco use.

‘‘(2) RECOMMENDATIONS.—The report under paragraph (1)

shall include the recommendations of the Secretary on how

the Food and Drug Administration should coordinate and facilitate

the exchange of information on such innovative products

and treatments among relevant offices and centers within the

Administration and within the National Institutes of Health,

the Centers for Disease Control and Prevention, and other

relevant agencies.

**‘‘SEC. 919. USER FEES.**

‘‘(a) ESTABLISHMENT OF QUARTERLY FEE.—Beginning on the

date of enactment of the Family Smoking Prevention and Tobacco

Control Act, the Secretary shall in accordance with this section

assess user fees on, and collect such fees from, each manufacturer

and importer of tobacco products subject to this chapter. The fees

shall be assessed and collected with respect to each quarter of

each fiscal year, and the total amount assessed and collected for

a fiscal year shall be the amount specified in subsection (b)(1)

for such year, subject to subsection (c).

‘‘(b) ASSESSMENT OF USER FEE.—

‘‘(1) AMOUNT OF ASSESSMENT.—The total amount of user

fees authorized to be assessed and collected under subsection

(a) for a fiscal year is the following, as applicable to the fiscal

year involved:

‘‘(A) For fiscal year 2009, $85,000,000 (subject to subsection

(e)).

‘‘(B) For fiscal year 2010, $235,000,000.

‘‘(C) For fiscal year 2011, $450,000,000.

‘‘(D) For fiscal year 2012, $477,000,000.

‘‘(E) For fiscal year 2013, $505,000,000.

‘‘(F) For fiscal year 2014, $534,000,000.

‘‘(G) For fiscal year 2015, $566,000,000.

‘‘(H) For fiscal year 2016, $599,000,000.

Effective date.

21 USC 387s.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00052 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

PUBLIC LAW 111–31—JUNE 22, 2009 123 STAT. 1827

‘‘(I) For fiscal year 2017, $635,000,000.

‘‘(J) For fiscal year 2018, $672,000,000.

‘‘(K) For fiscal year 2019 and each subsequent fiscal

year, $712,000,000.

‘‘(2) ALLOCATIONS OF ASSESSMENT BY CLASS OF TOBACCO

PRODUCTS.—

‘‘(A) IN GENERAL.—The total user fees assessed and

collected under subsection (a) each fiscal year with respect

to each class of tobacco products shall be an amount that

is equal to the applicable percentage of each class for

the fiscal year multiplied by the amount specified in paragraph

(1) for the fiscal year.

‘‘(B) APPLICABLE PERCENTAGE.—

‘‘(i) IN GENERAL.—For purposes of subparagraph

(A), the applicable percentage for a fiscal year for each

of the following classes of tobacco products shall be

determined in accordance with clause (ii):

‘‘(I) Cigarettes.

‘‘(II) Cigars, including small cigars and cigars

other than small cigars.

‘‘(III) Snuff.

‘‘(IV) Chewing tobacco.

‘‘(V) Pipe tobacco.

‘‘(VI) Roll-your-own tobacco.

‘‘(ii) ALLOCATIONS.—The applicable percentage of

each class of tobacco product described in clause (i)

for a fiscal year shall be the percentage determined

under section 625(c) of Public Law 108–357 for each

such class of product for such fiscal year.

‘‘(iii) REQUIREMENT OF REGULATIONS.—Notwithstanding

clause (ii), no user fees shall be assessed

on a class of tobacco products unless such class of

tobacco products is listed in section 901(b) or is deemed

by the Secretary in a regulation under section 901(b)

to be subject to this chapter.

‘‘(iv) REALLOCATIONS.—In the case of a class of

tobacco products that is not listed in section 901(b)

or deemed by the Secretary in a regulation under section

901(b) to be subject to this chapter, the amount

of user fees that would otherwise be assessed to such

class of tobacco products shall be reallocated to the

classes of tobacco products that are subject to this

chapter in the same manner and based on the same

relative percentages otherwise determined under

clause (ii).

‘‘(3) DETERMINATION OF USER FEE BY COMPANY.—

‘‘(A) IN GENERAL.—The total user fee to be paid by

each manufacturer or importer of a particular class of

tobacco products shall be determined for each quarter by

multiplying—

‘‘(i) such manufacturer’s or importer’s percentage

share as determined under paragraph (4); by

‘‘(ii) the portion of the user fee amount for the

current quarter to be assessed on all manufacturers

and importers of such class of tobacco products as

determined under paragraph (2).

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00053 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

123 STAT. 1828 PUBLIC LAW 111–31—JUNE 22, 2009

‘‘(B) NO FEE IN EXCESS OF PERCENTAGE SHARE.—No

manufacturer or importer of tobacco products shall be

required to pay a user fee in excess of the percentage

share of such manufacturer or importer.

‘‘(4) ALLOCATION OF ASSESSMENT WITHIN EACH CLASS OF

TOBACCO PRODUCT.—The percentage share of each manufacturer

or importer of a particular class of tobacco products

of the total user fee to be paid by all manufacturers or importers

of that class of tobacco products shall be the percentage determined

for purposes of allocations under subsections (e) through

(h) of section 625 of Public Law 108–357.

‘‘(5) ALLOCATION FOR CIGARS.—Notwithstanding paragraph

(4), if a user fee assessment is imposed on cigars, the percentage

share of each manufacturer or importer of cigars shall be based

on the excise taxes paid by such manufacturer or importer

during the prior fiscal year.

‘‘(6) TIMING OF ASSESSMENT.—The Secretary shall notify

each manufacturer and importer of tobacco products subject

to this section of the amount of the quarterly assessment

imposed on such manufacturer or importer under this subsection

for each quarter of each fiscal year. Such notifications

shall occur not later than 30 days prior to the end of the

quarter for which such assessment is made, and payments

of all assessments shall be made by the last day of the quarter

involved.

‘‘(7) MEMORANDUM OF UNDERSTANDING.—

‘‘(A) IN GENERAL.—The Secretary shall request the

appropriate Federal agency to enter into a memorandum

of understanding that provides for the regular and timely

transfer from the head of such agency to the Secretary

of the information described in paragraphs (2)(B)(ii) and

(4) and all necessary information regarding all tobacco

product manufacturers and importers required to pay user

fees. The Secretary shall maintain all disclosure restrictions

established by the head of such agency regarding

the information provided under the memorandum of understanding.

‘‘(B) ASSURANCES.—Beginning not later than fiscal year

2015, and for each subsequent fiscal year, the Secretary

shall ensure that the Food and Drug Administration is

able to determine the applicable percentages described in

paragraph (2) and the percentage shares described in paragraph

(4). The Secretary may carry out this subparagraph

by entering into a contract with the head of the Federal

agency referred to in subparagraph (A) to continue to provide

the necessary information.

‘‘(c) CREDITING AND AVAILABILITY OF FEES.—

‘‘(1) IN GENERAL.—Fees authorized under subsection (a)

shall be collected and available for obligation only to the extent

and in the amount provided in advance in appropriations Acts,

subject to paragraph (2)(D). Such fees are authorized to remain

available until expended. Such sums as may be necessary may

be transferred from the Food and Drug Administration salaries

and expenses appropriation account without fiscal year limitation

to such appropriation account for salaries and expenses

with such fiscal year limitation.

‘‘(2) AVAILABILITY.—

Effective dates.

Disclosure.

Deadlines.

Notification.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00054 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

PUBLIC LAW 111–31—JUNE 22, 2009 123 STAT. 1829

‘‘(A) IN GENERAL.—Fees appropriated under paragraph

(3) are available only for the purpose of paying the costs

of the activities of the Food and Drug Administration

related to the regulation of tobacco products under this

chapter and the Family Smoking Prevention and Tobacco

Control Act (referred to in this subsection as ‘tobacco regulation

activities’), except that such fees may be used for

the reimbursement specified in subparagraph (C).

‘‘(B) PROHIBITION AGAINST USE OF OTHER FUNDS.—

‘‘(i) IN GENERAL.—Except as provided in clause

(ii), fees collected under subsection (a) are the only

funds authorized to be made available for tobacco regulation

activities.

‘‘(ii) STARTUP COSTS.—Clause (i) does not apply

until October 1, 2009. Until such date, any amounts

available to the Food and Drug Administration

(excluding user fees) shall be available and allocated

as needed to pay the costs of tobacco regulation activities.

‘‘(C) REIMBURSEMENT OF START-UP AMOUNTS.—

‘‘(i) IN GENERAL.—Any amounts allocated for the

start-up period pursuant to subparagraph (B)(ii) shall

be reimbursed through any appropriated fees collected

under subsection (a), in such manner as the Secretary

determines appropriate to ensure that such allocation

results in no net change in the total amount of funds

otherwise available, for the period from October 1,

2008, through September 30, 2010, for Food and Drug

Administration programs and activities (other than

tobacco regulation activities) for such period.

‘‘(ii) TREATMENT OF REIMBURSED AMOUNTS.—

Amounts reimbursed under clause (i) shall be available

for the programs and activities for which funds allocated

for the start-up period were available, prior to

such allocation, until September 30, 2010, notwithstanding

any otherwise applicable limits on amounts

for such programs or activities for a fiscal year.

‘‘(D) FEE COLLECTED DURING START-UP PERIOD.—Notwithstanding

the first sentence of paragraph (1), fees under

subsection (a) may be collected through September 30, 2009

under subparagraph (B)(ii) and shall be available for obligation

and remain available until expended. Such offsetting

collections shall be credited to the salaries and expenses

account of the Food and Drug Administration.

‘‘(E) OBLIGATION OF START-UP COSTS IN ANTICIPATION

OF AVAILABLE FEE COLLECTIONS.—Notwithstanding any

other provision of law, following the enactment of an appropriation

for fees under this section for fiscal year 2010,

or any portion thereof, obligations for costs of tobacco regulation

activities during the start-up period may be incurred

in anticipation of the receipt of offsetting fee collections

through procedures specified in section 1534 of title 31,

United States Code.

‘‘(3) AUTHORIZATION OF APPROPRIATIONS.—For fiscal year

2009 and each subsequent fiscal year, there is authorized to

be appropriated for fees under this section an amount equal

to the amount specified in subsection (b)(1) for the fiscal year.

Deadline.

Deadline.

Effective date.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00055 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

123 STAT. 1830 PUBLIC LAW 111–31—JUNE 22, 2009

‘‘(d) COLLECTION OF UNPAID FEES.—In any case where the

Secretary does not receive payment of a fee assessed under subsection

(a) within 30 days after it is due, such fee shall be treated

as a claim of the United States Government subject to subchapter

II of chapter 37 of title 31, United States Code.

‘‘(e) APPLICABILITY TO FISCAL YEAR 2009.—If the date of enactment

of the Family Smoking Prevention and Tobacco Control Act

occurs during fiscal year 2009, the following applies, subject to

subsection (c):

‘‘(1) The Secretary shall determine the fees that would

apply for a single quarter of such fiscal year according to

the application of subsection (b) to the amount specified in

paragraph (1)(A) of such subsection (referred to in this subsection

as the ‘quarterly fee amounts’).

‘‘(2) For the quarter in which such date of enactment occurs,

the amount of fees assessed shall be a pro rata amount, determined

according to the number of days remaining in the quarter

(including such date of enactment) and according to the daily

equivalent of the quarterly fee amounts. Fees assessed under

the preceding sentence shall not be collected until the next

quarter.

‘‘(3) For the quarter following the quarter to which paragraph

(2) applies, the full quarterly fee amounts shall be

assessed and collected, in addition to collection of the pro rata

fees assessed under paragraph (2).’’.

(c) CONFORMING AMENDMENT.—Section 9(1) of the Comprehensive

Smokeless Tobacco Health Education Act of 1986 (15 U.S.C.

4408(i)) is amended to read as follows:

‘‘(1) The term ‘smokeless tobacco’ has the meaning given

such term by section 900(18) of the Federal Food, Drug, and

Cosmetic Act.’’.

**SEC. 102. FINAL RULE.**

(a) CIGARETTES AND SMOKELESS TOBACCO.—

(1) IN GENERAL.—On the first day of publication of the

Federal Register that is 180 days or more after the date of

enactment of this Act, the Secretary of Health and Human

Services shall publish in the Federal Register a final rule

regarding cigarettes and smokeless tobacco, which—

(A) is deemed to be issued under chapter 9 of the

Federal Food, Drug, and Cosmetic Act, as added by section

101 of this division; and

(B) shall be deemed to be in compliance with all

applicable provisions of chapter 5 of title 5, United States

Code, and all other provisions of law relating to rulemaking

procedures.

(2) CONTENTS OF RULE.—Except as provided in this subsection,

the final rule published under paragraph (1), shall

be identical in its provisions to part 897 of the regulations

promulgated by the Secretary of Health and Human Services

in the August 28, 1996, issue of the Federal Register (61

Fed. Reg. 44615–44618). Such rule shall—

(A) provide for the designation of jurisdictional

authority that is in accordance with this subsection in

accordance with this division and the amendments made

by this division;

(B) strike Subpart C—Labels and section 897.32(c);

Deadline.

Federal Register,

publication.

21 USC 387a–1.

Fees.

Deadline.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00056 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

PUBLIC LAW 111–31—JUNE 22, 2009 123 STAT. 1831

(C) strike paragraphs (a), (b), and (i) of section 897.3

and insert definitions of the terms ‘‘cigarette’’, ‘‘cigarette

tobacco’’, and ‘‘smokeless tobacco’’ as defined in section

900 of the Federal Food, Drug, and Cosmetic Act;

(D) insert ‘‘or roll-your-own paper’’ in section 897.34(a)

after ‘‘other than cigarettes or smokeless tobacco’’;

(E) include such modifications to section 897.30(b), if

any, that the Secretary determines are appropriate in light

of governing First Amendment case law, including the decision

of the Supreme Court of the United States in Lorillard

Tobacco Co. v. Reilly (533 U.S. 525 (2001));

(F) become effective on the date that is 1 year after

the date of enactment of this Act; and

(G) amend paragraph (d) of section 897.16 to read

as follows:

‘‘(d)(1) Except as provided in subparagraph (2), no manufacturer,

distributor, or retailer may distribute or cause to be distributed

any free samples of cigarettes, smokeless tobacco, or other

tobacco products (as such term is defined in section 201 of the

Federal Food, Drug, and Cosmetic Act).

‘‘(2)(A) Subparagraph (1) does not prohibit a manufacturer,

distributor, or retailer from distributing or causing to be distributed

free samples of smokeless tobacco in a qualified adult-only facility.

‘‘(B) This subparagraph does not affect the authority of a State

or local government to prohibit or otherwise restrict the distribution

of free samples of smokeless tobacco.

‘‘(C) For purposes of this paragraph, the term ‘qualified adultonly

facility’ means a facility or restricted area that—

‘‘(i) requires each person present to provide to a law enforcement

officer (whether on or off duty) or to a security guard

licensed by a governmental entity government-issued identification

showing a photograph and at least the minimum age

established by applicable law for the purchase of smokeless

tobacco;

‘‘(ii) does not sell, serve, or distribute alcohol;

‘‘(iii) is not located adjacent to or immediately across from

(in any direction) a space that is used primarily for youthoriented

marketing, promotional, or other activities;

‘‘(iv) is a temporary structure constructed, designated, and

operated as a distinct enclosed area for the purpose of distributing

free samples of smokeless tobacco in accordance with

this subparagraph;

‘‘(v) is enclosed by a barrier that—

‘‘(I) is constructed of, or covered with, an opaque material

(except for entrances and exits);

‘‘(II) extends from no more than 12 inches above the

ground or floor (which area at the bottom of the barrier

must be covered with material that restricts visibility but

may allow airflow) to at least 8 feet above the ground

or floor (or to the ceiling); and

‘‘(III) prevents persons outside the qualified adult-only

facility from seeing into the qualified adult-only facility,

unless they make unreasonable efforts to do so; and

‘‘(vi) does not display on its exterior—

‘‘(I) any tobacco product advertising;

Effective date.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00057 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

123 STAT. 1832 PUBLIC LAW 111–31—JUNE 22, 2009

‘‘(II) a brand name other than in conjunction with

words for an area or enclosure to identify an adult-only

facility; or

‘‘(III) any combination of words that would imply to

a reasonable observer that the manufacturer, distributor,

or retailer has a sponsorship that would violate section

897.34(c).

‘‘(D) Distribution of samples of smokeless tobacco under this

subparagraph permitted to be taken out of the qualified adultonly

facility shall be limited to 1 package per adult consumer

containing no more than 0.53 ounces (15 grams) of smokeless

tobacco. If such package of smokeless tobacco contains individual

portions of smokeless tobacco, the individual portions of smokeless

tobacco shall not exceed 8 individual portions and the collective

weight of such individual portions shall not exceed 0.53 ounces

(15 grams). Any manufacturer, distributor, or retailer who distributes

or causes to be distributed free samples also shall take reasonable

steps to ensure that the above amounts are limited to one

such package per adult consumer per day.

‘‘(3) Notwithstanding subparagraph (2), no manufacturer, distributor,

or retailer may distribute or cause to be distributed any

free samples of smokeless tobacco—

‘‘(A) to a sports team or entertainment group; or

‘‘(B) at any football, basketball, baseball, soccer, or hockey

event or any other sporting or entertainment event determined

by the Secretary to be covered by this subparagraph.

‘‘(4) The Secretary shall implement a program to ensure compliance

with this paragraph and submit a report to the Congress

on such compliance not later than 18 months after the date of

enactment of the Family Smoking Prevention and Tobacco Control

Act.

‘‘(5) Nothing in this paragraph shall be construed to authorize

any person to distribute or cause to be distributed any sample

of a tobacco product to any individual who has not attained the

minimum age established by applicable law for the purchase of

such product.’’.

(3) AMENDMENTS TO RULE.—Prior to making amendments

to the rule published under paragraph (1), the Secretary shall

promulgate a proposed rule in accordance with chapter 5 of

title 5, United States Code.

(4) RULE OF CONSTRUCTION.—Except as provided in paragraph

(3), nothing in this section shall be construed to limit

the authority of the Secretary to amend, in accordance with

chapter 5 of title 5, United States Code, the regulation promulgated

pursuant to this section, including the provisions of such

regulation relating to distribution of free samples.

(5) ENFORCEMENT OF RETAIL SALE PROVISIONS.—The Secretary

of Health and Human Services shall ensure that the

provisions of this division, the amendments made by this division,

and the implementing regulations (including such provisions,

amendments, and regulations relating to the retail sale

of tobacco products) are enforced with respect to the United

States and Indian tribes.

(6) QUALIFIED ADULT-ONLY FACILITY.—A qualified adultonly

facility (as such term is defined in section 897.16(d) of

the final rule published under paragraph (1)) that is also a

retailer and that commits a violation as a retailer shall not

Penalties.

Reports.

Deadline.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00058 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

PUBLIC LAW 111–31—JUNE 22, 2009 123 STAT. 1833

be subject to the limitations in section 103(q) and shall be

subject to penalties applicable to a qualified adult-only facility.

(7) CONGRESSIONAL REVIEW PROVISIONS.—Section 801 of

title 5, United States Code, shall not apply to the final rule

published under paragraph (1).

(b) LIMITATION ON ADVISORY OPINIONS.—As of the date of enactment

of this Act, the following documents issued by the Food

and Drug Administration shall not constitute advisory opinions

under section 10.85(d)(1) of title 21, Code of Federal Regulations,

except as they apply to tobacco products, and shall not be cited

by the Secretary of Health and Human Services or the Food and

Drug Administration as binding precedent:

(1) The preamble to the proposed rule in the document

titled ‘‘Regulations Restricting the Sale and Distribution of

Cigarettes and Smokeless Tobacco Products to Protect Children

and Adolescents’’ (60 Fed. Reg. 41314–41372 (August 11, 1995)).

(2) The document titled ‘‘Nicotine in Cigarettes and Smokeless

Tobacco Products is a Drug and These Products Are Nicotine

Delivery Devices Under the Federal Food, Drug, and Cosmetic

Act’’ (60 Fed. Reg. 41453–41787 (August 11, 1995)).

(3) The preamble to the final rule in the document titled

‘‘Regulations Restricting the Sale and Distribution of Cigarettes

and Smokeless Tobacco to Protect Children and Adolescents’’

(61 Fed. Reg. 44396–44615 (August 28, 1996)).

(4) The document titled ‘‘Nicotine in Cigarettes and Smokeless

Tobacco is a Drug and These Products are Nicotine Delivery

Devices Under the Federal Food, Drug, and Cosmetic Act; Jurisdictional

Determination’’ (61 Fed. Reg. 44619–45318 (August

28, 1996)).

**SEC. 103. CONFORMING AND OTHER AMENDMENTS TO GENERAL**

**PROVISIONS.**

(a) AMENDMENT OF FEDERAL FOOD, DRUG, AND COSMETIC

ACT.—Except as otherwise expressly provided, whenever in this

section an amendment is expressed in terms of an amendment

to, or repeal of, a section or other provision, the reference is to

a section or other provision of the Federal Food, Drug, and Cosmetic

Act (21 U.S.C. 301 et seq.).

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

(1) in subsection (a), by inserting ‘‘tobacco product,’’ after

‘‘device,’’;

(2) in subsection (b), by inserting ‘‘tobacco product,’’ after

‘‘device,’’;

(3) in subsection (c), by inserting ‘‘tobacco product,’’ after

‘‘device,’’;

(4) in subsection (e)—

(A) by striking the period after ‘‘572(i)’’; and

(B) by striking ‘‘or 761 or the refusal to permit access

to’’ and inserting ‘‘761, 909, or 920 or the refusal to permit

access to’’;

(5) in subsection (g), by inserting ‘‘tobacco product,’’ after

‘‘device,’’;

(6) in subsection (h), by inserting ‘‘tobacco product,’’ after

‘‘device,’’;

(7) in subsection (j)—

(A) by striking the period after ‘‘573’’; and

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00059 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

123 STAT. 1834 PUBLIC LAW 111–31—JUNE 22, 2009

(B) by striking ‘‘708, or 721’’ and inserting ‘‘708, 721,

904, 905, 906, 907, 908, 909, or 920(b)’’;

(8) in subsection (k), by inserting ‘‘tobacco product,’’ after

‘‘device,’’;

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

‘‘(p) The failure to register in accordance with section 510

or 905, the failure to provide any information required by section

510(j), 510(k), 905(i), or 905(j), or the failure to provide a notice

required by section 510(j)(2) or 905(i)(3).’’;

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

‘‘(q)(1) The failure or refusal—

‘‘(A) to comply with any requirement prescribed under section

518, 520(g), 903(b), 907, 908, or 915;

‘‘(B) to furnish any notification or other material or information

required by or under section 519, 520(g), 904, 909, or

920; or

‘‘(C) to comply with a requirement under section 522 or

913.’’;

(11) in subsection (q)(2), by striking ‘‘device,’’ and inserting

‘‘device or tobacco product,’’;

(12) in subsection (r), by inserting ‘‘or tobacco product’’

after the term ‘‘device’’ each time that such term appears;

and

(13) by adding at the end the following:

‘‘(oo) The sale of tobacco products in violation of a no-tobaccosale

order issued under section 303(f).

‘‘(pp) The introduction or delivery for introduction into interstate

commerce of a tobacco product in violation of section 911.

‘‘(qq)(1) Forging, counterfeiting, simulating, or falsely representing,

or without proper authority using any mark, stamp

(including tax stamp), tag, label, or other identification device upon

any tobacco product or container or labeling thereof so as to render

such tobacco product a counterfeit tobacco product.

‘‘(2) Making, selling, disposing of, or keeping in possession,

control, or custody, or concealing any punch, die, plate, stone, or

other item that is designed to print, imprint, or reproduce the

trademark, trade name, or other identifying mark, imprint, or device

of another or any likeness of any of the foregoing upon any tobacco

product or container or labeling thereof so as to render such tobacco

product a counterfeit tobacco product.

‘‘(3) The doing of any act that causes a tobacco product to

be a counterfeit tobacco product, or the sale or dispensing, or

the holding for sale or dispensing, of a counterfeit tobacco product.

‘‘(rr) The charitable distribution of tobacco products.

‘‘(ss) The failure of a manufacturer or distributor to notify

the Attorney General and the Secretary of the Treasury of their

knowledge of tobacco products used in illicit trade.

‘‘(tt) Making any express or implied statement or representation

directed to consumers with respect to a tobacco product, in a label

or labeling or through the media or advertising, that either conveys,

or misleads or would mislead consumers into believing, that—

‘‘(1) the product is approved by the Food and Drug Administration;

‘‘(2) the Food and Drug Administration deems the product

to be safe for use by consumers;

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00060 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

PUBLIC LAW 111–31—JUNE 22, 2009 123 STAT. 1835

‘‘(3) the product is endorsed by the Food and Drug Administration

for use by consumers; or

‘‘(4) the product is safe or less harmful by virtue of—

‘‘(A) its regulation or inspection by the Food and Drug

Administration; or

‘‘(B) its compliance with regulatory requirements set

by the Food and Drug Administration;

including any such statement or representation rendering the

product misbranded under section 903.’’.

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

(1) in paragraph (5)—

(A) by striking ‘‘paragraph (1), (2), (3), or (4)’’ each

place such appears and inserting ‘‘paragraph (1), (2), (3),

(4), or (9)’’;

(B) in subparagraph (A)—

(i) by striking ‘‘assessed’’ the first time it appears

and inserting ‘‘assessed, or a no-tobacco-sale order may

be imposed,’’; and

(ii) by striking ‘‘penalty’’ the second time it appears

and inserting ‘‘penalty, or upon whom a no-tobaccosale

order is to be imposed,’’;

(C) in subparagraph (B)—

(i) by inserting after ‘‘penalty,’’ the following: ‘‘or

the period to be covered by a no-tobacco-sale order,’’;

and

(ii) by adding at the end the following: ‘‘A notobacco-

sale order permanently prohibiting an individual

retail outlet from selling tobacco products shall

include provisions that allow the outlet, after a specified

period of time, to request that the Secretary compromise,

modify, or terminate the order.’’; and

(D) by adding at the end the following:

‘‘(D) The Secretary may compromise, modify, or terminate, with

or without conditions, any no-tobacco-sale order.’’;

(2) in paragraph (6)—

(A) by inserting ‘‘or the imposition of a no-tobaccosale

order’’ after the term ‘‘penalty’’ each place such term

appears; and

(B) by striking ‘‘issued.’’ and inserting ‘‘issued, or on

which the no-tobacco-sale order was imposed, as the case

may be.’’; and

(3) by adding at the end the following:

‘‘(8) If the Secretary finds that a person has committed repeated

violations of restrictions promulgated under section 906(d) at a

particular retail outlet then the Secretary may impose a no-tobaccosale

order on that person prohibiting the sale of tobacco products

in that outlet. A no-tobacco-sale order may be imposed with a

civil penalty under paragraph (1). Prior to the entry of a nosale

order under this paragraph, a person shall be entitled to

a hearing pursuant to the procedures established through regulations

of the Food and Drug Administration for assessing civil money

penalties, including at a retailer’s request a hearing by telephone,

or at the nearest regional or field office of the Food and Drug

Administration, or at a Federal, State, or county facility within

100 miles from the location of the retail outlet, if such a facility

is available.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00061 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

123 STAT. 1836 PUBLIC LAW 111–31—JUNE 22, 2009

‘‘(9) CIVIL MONETARY PENALTIES FOR VIOLATION OF TOBACCO

PRODUCT REQUIREMENTS.—

‘‘(A) IN GENERAL.—Subject to subparagraph (B), any person

who violates a requirement of this Act which relates to tobacco

products shall be liable to the United States for a civil penalty

in an amount not to exceed $15,000 for each such violation,

and not to exceed $1,000,000 for all such violations adjudicated

in a single proceeding.

‘‘(B) ENHANCED PENALTIES.—

‘‘(i) Any person who intentionally violates a requirement

of section 902(5), 902(6), 904, 908(c), or 911(a), shall

be subject to a civil monetary penalty of—

‘‘(I) not to exceed $250,000 per violation, and not

to exceed $1,000,000 for all such violations adjudicated

in a single proceeding; or

‘‘(II) in the case of a violation that continues after

the Secretary provides written notice to such person,

$250,000 for the first 30-day period (or any portion

thereof) that the person continues to be in violation,

and such amount shall double for every 30-day period

thereafter that the violation continues, not to exceed

$1,000,000 for any 30-day period, and not to exceed

$10,000,000 for all such violations adjudicated in a

single proceeding.

‘‘(ii) Any person who violates a requirement of section

911(g)(2)(C)(ii) or 911(i)(1), shall be subject to a civil monetary

penalty of—

‘‘(I) not to exceed $250,000 per violation, and not

to exceed $1,000,000 for all such violations adjudicated

in a single proceeding; or

‘‘(II) in the case of a violation that continues after

the Secretary provides written notice to such person,

$250,000 for the first 30-day period (or any portion

thereof) that the person continues to be in violation,

and such amount shall double for every 30-day period

thereafter that the violation continues, not to exceed

$1,000,000 for any 30-day period, and not to exceed

$10,000,000 for all such violations adjudicated in a

single proceeding.

‘‘(iii) In determining the amount of a civil penalty

under clause (i)(II) or (ii)(II), the Secretary shall take into

consideration whether the person is making efforts toward

correcting the violation of the requirements of the section

for which such person is subject to such civil penalty.’’.

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

(1) in subsection (a)(2)—

(A) by striking ‘‘and’’ before ‘‘(D)’’; and

(B) by striking ‘‘device.’’ and inserting the following:

‘‘device, and (E) Any adulterated or misbranded tobacco

product.’’;

(2) in subsection (d)(1), by inserting ‘‘tobacco product,’’ after

‘‘device,’’;

(3) in subsection (g)(1), by inserting ‘‘or tobacco product’’

after the term ‘‘device’’ each place such term appears; and

(4) in subsection (g)(2)(A), by inserting ‘‘or tobacco product’’

after ‘‘device’’.

Notice.

Notice.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00062 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

PUBLIC LAW 111–31—JUNE 22, 2009 123 STAT. 1837

(e) SECTION 505.—Section 505(n)(2) (21 U.S.C. 355(n)(2)) is

amended by striking ‘‘section 904’’ and inserting ‘‘section 1004’’.

(f) SECTION 523.—Section 523(b)(2)(D) (21 U.S.C. 360m(b)(2)(D))

is amended by striking ‘‘section 903(g)’’ and inserting ‘‘section

1003(g)’’.

(g) SECTION 702.—Section 702(a)(1) (U.S.C. 372(a)(1)) is

amended—

(1) by striking ‘‘(a)(1)’’ and inserting ‘‘(a)(1)(A)’’; and

(2) by adding at the end the following:

‘‘(B)(i) For a tobacco product, to the extent feasible, the Secretary

shall contract with the States in accordance with this paragraph

to carry out inspections of retailers within that State in

connection with the enforcement of this Act.

‘‘(ii) The Secretary shall not enter into any contract under

clause (i) with the government of any of the several States to

exercise enforcement authority under this Act on Indian country

without the express written consent of the Indian tribe involved.’’.

(h) SECTION 703.—Section 703 (21 U.S.C. 373) is amended—

(1) by inserting ‘‘tobacco product,’’ after the term ‘‘device,’’

each place such term appears; and

(2) by inserting ‘‘tobacco products,’’ after the term ‘‘devices,’’

each place such term appears.

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

(1) in subsection (a)(1)—

(A) by striking ‘‘devices, or cosmetics’’ each place it

appears and inserting ‘‘devices, tobacco products, or cosmetics’’;

(B) by striking ‘‘or restricted devices’’ each place it

appears and inserting ‘‘restricted devices, or tobacco products’’;

and

(C) by striking ‘‘and devices and subject to’’ and all

that follows through ‘‘other drugs or devices’’ and inserting

‘‘devices, and tobacco products and subject to reporting

and inspection under regulations lawfully issued pursuant

to section 505 (i) or (k), section 519, section 520(g), or

chapter IX and data relating to other drugs, devices, or

tobacco products’’;

(2) in subsection (b), by inserting ‘‘tobacco product,’’ after

‘‘device,’’; and

(3) in subsection (g)(13), by striking ‘‘section 903(g)’’ and

inserting ‘‘section 1003(g)’’.

(j) SECTION 705.—Section 705(b) (21 U.S.C. 375(b)) is amended

by inserting ‘‘tobacco products,’’ after ‘‘devices,’’.

(k) SECTION 709.—Section 709 (21 U.S.C. 379a) is amended

by inserting ‘‘tobacco product,’’ after ‘‘device,’’.

(l) SECTION 801.—Section 801 (21 U.S.C. 381) is amended—

(1) in subsection (a)—

(A) by inserting ‘‘tobacco products,’’ after the term

‘‘devices,’’;

(B) by inserting ‘‘or section 905(h)’’ after ‘‘section 510’’;

and

(C) by striking the term ‘‘drugs or devices’’ each time

such term appears and inserting ‘‘drugs, devices, or tobacco

products’’;

(2) in subsection (e)(1)—

(A) by inserting ‘‘tobacco product’’ after ‘‘drug, device,’’;

and

Contracts.

Intergovernmental

relations.

21 USC 372.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00063 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

123 STAT. 1838 PUBLIC LAW 111–31—JUNE 22, 2009

(B) by inserting ‘‘, and a tobacco product intended

for export shall not be deemed to be in violation of section

906(e), 907, 911, or 920(a),’’ before ‘‘if it—’’; and

(3) by adding at the end the following:

‘‘(p)(1) Not later than 36 months after the date of enactment

of the Family Smoking Prevention and Tobacco Control Act, and

annually thereafter, the Secretary shall submit to the Committee

on Health, Education, Labor, and Pensions of the Senate and the

Committee on Energy and Commerce of the House of Representatives,

a report regarding—

‘‘(A) the nature, extent, and destination of United States

tobacco product exports that do not conform to tobacco product

standards established pursuant to this Act;

‘‘(B) the public health implications of such exports,

including any evidence of a negative public health impact;

and

‘‘(C) recommendations or assessments of policy alternatives

available to Congress and the executive branch to reduce any

negative public health impact caused by such exports.

‘‘(2) The Secretary is authorized to establish appropriate

information disclosure requirements to carry out this subsection.’’.

(m) SECTION 1003.—Section 1003(d)(2)(C) (as redesignated by

section 101(b)) is amended—

(1) by striking ‘‘and’’ after ‘‘cosmetics,’’; and

(2) inserting ‘‘, and tobacco products’’ after ‘‘devices’’.

(n) SECTION 1009.—Section 1009(b) (as redesignated by section

101(b)) is amended by striking ‘‘section 908’’ and inserting ‘‘section

1008’’.

(o) SECTION 409 OF THE FEDERAL MEAT INSPECTION ACT.—

Section 409(a) of the Federal Meat Inspection Act (21 U.S.C. 679(a))

is amended by striking ‘‘section 902(b)’’ and inserting ‘‘section

1002(b)’’.

(p) RULE OF CONSTRUCTION.—Nothing in this section is

intended or shall be construed to expand, contract, or otherwise

modify or amend the existing limitations on State government

authority over tribal restricted fee or trust lands.

(q) GUIDANCE AND EFFECTIVE DATES.—

(1) IN GENERAL.—The Secretary of Health and Human

Services shall issue guidance—

(A) defining the term ‘‘repeated violation’’, as used

in section 303(f)(8) of the Federal Food, Drug, and Cosmetic

Act (21 U.S.C. 333(f)(8)) as amended by subsection (c),

as including at least 5 violations of particular requirements

over a 36-month period at a particular retail outlet that

constitute a repeated violation and providing for civil penalties

in accordance with paragraph (2);

(B) providing for timely and effective notice by certified

or registered mail or personal delivery to the retailer of

each alleged violation at a particular retail outlet prior

to conducting a followup compliance check, such notice

to be sent to the location specified on the retailer’s registration

or to the retailer’s registered agent if the retailer

has provider such agent information to the Food and Drug

Administration prior to the violation;

(C) providing for a hearing pursuant to the procedures

established through regulations of the Food and Drug

Administration for assessing civil money penalties,

21 USC 333 note.

21 USC 331 note.

21 USC 399.

21 USC 393.

Requirements.

Deadline.

Reports.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00064 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

PUBLIC LAW 111–31—JUNE 22, 2009 123 STAT. 1839

including at a retailer’s request a hearing by telephone

or at the nearest regional or field office of the Food and

Drug Administration, and providing for an expedited procedure

for the administrative appeal of an alleged violation;

(D) providing that a person may not be charged with

a violation at a particular retail outlet unless the Secretary

has provided notice to the retailer of all previous violations

at that outlet;

(E) establishing that civil money penalties for multiple

violations shall increase from one violation to the next

violation pursuant to paragraph (2) within the time periods

provided for in such paragraph;

(F) providing that good faith reliance on the presentation

of a false government-issued photographic identification

that contains a date of birth does not constitute a

violation of any minimum age requirement for the sale

of tobacco products if the retailer has taken effective steps

to prevent such violations, including—

(i) adopting and enforcing a written policy against

sales to minors;

(ii) informing its employees of all applicable laws;

(iii) establishing disciplinary sanctions for

employee noncompliance; and

(iv) requiring its employees to verify age by way

of photographic identification or electronic scanning

device; and

(G) providing for the Secretary, in determining whether

to impose a no-tobacco-sale order and in determining

whether to compromise, modify, or terminate such an order,

to consider whether the retailer has taken effective steps

to prevent violations of the minimum age requirements

for the sale of tobacco products, including the steps listed

in subparagraph (F).

(2) PENALTIES FOR VIOLATIONS.—

(A) IN GENERAL.—The amount of the civil penalty to

be applied for violations of restrictions promulgated under

section 906(d), as described in paragraph (1), shall be as

follows:

(i) With respect to a retailer with an approved

training program, the amount of the civil penalty shall

not exceed—

(I) in the case of the first violation, $0.00

together with the issuance of a warning letter

to the retailer;

(II) in the case of a second violation within

a 12-month period, $250;

(III) in the case of a third violation within

a 24-month period, $500;

(IV) in the case of a fourth violation within

a 24-month period, $2,000;

(V) in the case of a fifth violation within a

36-month period, $5,000; and

(VI) in the case of a sixth or subsequent violation

within a 48-month period, $10,000 as determined

by the Secretary on a case-by-case basis.

21 USC 333 note.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00065 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

123 STAT. 1840 PUBLIC LAW 111–31—JUNE 22, 2009

(ii) With respect to a retailer that does not have

an approved training program, the amount of the civil

penalty shall not exceed—

(I) in the case of the first violation, $250;

(II) in the case of a second violation within

a 12-month period, $500;

(III) in the case of a third violation within

a 24-month period, $1,000;

(IV) in the case of a fourth violation within

a 24-month period, $2,000;

(V) in the case of a fifth violation within a

36-month period, $5,000; and

(VI) in the case of a sixth or subsequent violation

within a 48-month period, $10,000 as determined

by the Secretary on a case-by-case basis.

(B) TRAINING PROGRAM.—For purposes of subparagraph

(A), the term ‘‘approved training program’’ means a training

program that complies with standards developed by the

Food and Drug Administration for such programs.

(C) CONSIDERATION OF STATE PENALTIES.—The Secretary

shall coordinate with the States in enforcing the

provisions of this Act and, for purposes of mitigating a

civil penalty to be applied for a violation by a retailer

of any restriction promulgated under section 906(d), shall

consider the amount of any penalties paid by the retailer

to a State for the same violation.

(3) GENERAL EFFECTIVE DATE.—The amendments made by

paragraphs (2), (3), and (4) of subsection (c) shall take effect

upon the issuance of guidance described in paragraph (1) of

this subsection.

(4) SPECIAL EFFECTIVE DATE.—The amendment made by

subsection (c)(1) shall take effect on the date of enactment

of this Act.

(5) PACKAGE LABEL REQUIREMENTS.—The package label

requirements of paragraphs (3) and (4) of section 903(a) of

the Federal Food, Drug, and Cosmetic Act (as amended by

this division) shall take effect on the date that is 12 months

after the date of enactment of this Act. The package label

requirements of paragraph (2) of such section 903(a) for cigarettes

shall take effect on the date that is 15 months after

the issuance of the regulations required by section 4(d) of

the Federal Cigarette Labeling and Advertising Act (15 U.S.C.

1333), as amended by section 201 of this division. The package

label requirements of paragraph (2) of such section 903(a) for

tobacco products other than cigarettes shall take effect on the

date that is 12 months after the date of enactment of this

Act. The effective date shall be with respect to the date of

manufacture, provided that, in any case, beginning 30 days

after such effective date, a manufacturer shall not introduce

into the domestic commerce of the United States any product,

irrespective of the date of manufacture, that is not in conformance

with section 903(a) (2), (3), and (4) and section 920(a)

of the Federal Food, Drug, and Cosmetic Act.

(6) ADVERTISING REQUIREMENTS.—The advertising requirements

of section 903(a)(8) of the Federal Food, Drug, and Cosmetic

Act (as amended by this division) shall take effect on

21 USC 387c

note.

21 USC 333 note.

21 USC 333 note.

VerDate Nov 24 2008 15:14 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00066 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

PUBLIC LAW 111–31—JUNE 22, 2009 123 STAT. 1841

the date that is 12 months after the date of enactment of

this Act.

**SEC. 104. STUDY ON RAISING THE MINIMUM AGE TO PURCHASE**

**TOBACCO PRODUCTS.**

The Secretary of Health and Human Services shall—

(1) convene an expert panel to conduct a study on the

public health implications of raising the minimum age to purchase

tobacco products; and

(2) not later than 5 years after the date of enactment

of this Act, submit a report to the Congress on the results

of such study.

**SEC. 105. ENFORCEMENT ACTION PLAN FOR ADVERTISING AND PROMOTION**

**RESTRICTIONS.**

(a) ACTION PLAN.—

(1) DEVELOPMENT.—Not later than 6 months after the date

of enactment of this Act, the Secretary of Health and Human

Services (in this section referred to as the ‘‘Secretary’’) shall

develop and publish an action plan to enforce restrictions

adopted pursuant to section 906 of the Federal Food, Drug,

and Cosmetic Act, as added by section 101(b) of this division,

or pursuant to section 102(a) of this division, on promotion

and advertising of menthol and other cigarettes to youth.

(2) CONSULTATION.—The action plan required by paragraph

(1) shall be developed in consultation with public health

organizations and other stakeholders with demonstrated expertise

and experience in serving minority communities.

(3) PRIORITY.—The action plan required by paragraph (1)

shall include provisions designed to ensure enforcement of the

restrictions described in paragraph (1) in minority communities.

(b) STATE AND LOCAL ACTIVITIES.—

(1) INFORMATION ON AUTHORITY.—Not later than 3 months

after the date of enactment of this Act, the Secretary shall

inform State, local, and tribal governments of the authority

provided to such entities under section 5(c) of the Federal

Cigarette Labeling and Advertising Act, as added by section

203 of this division, or preserved by such entities under section

916 of the Federal Food, Drug, and Cosmetic Act, as added

by section 101(b) of this division.

(2) COMMUNITY ASSISTANCE.—At the request of communities

seeking assistance to prevent underage tobacco use, the

Secretary shall provide such assistance, including assistance

with strategies to address the prevention of underage tobacco

use in communities with a disproportionate use of menthol

cigarettes by minors.

**SEC. 106. STUDIES OF PROGRESS AND EFFECTIVENESS.**

(a) FDA REPORT.—Not later than 3 years after the date of

enactment of this Act, and not less than every 2 years thereafter,

the Secretary of Health and Human Services shall submit to the

Committee on Health, Education, Labor, and Pensions of the Senate

and the Committee on Energy and Commerce of the House of

Representatives, a report concerning—

(1) the progress of the Food and Drug Administration in

implementing this division, including major accomplishments,

objective measurements of progress, and the identification of

any areas that have not been fully implemented;

21 USC 387u.

Deadline.

Deadline.

Publication.

21 USC 387f–1.

Deadline.

Reports.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00067 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

123 STAT. 1842 PUBLIC LAW 111–31—JUNE 22, 2009

(2) impediments identified by the Food and Drug Administration

to progress in implementing this division and to meeting

statutory timeframes;

(3) data on the number of new product applications received

under section 910 of the Federal Food, Drug, and Cosmetic

Act and modified risk product applications received under section

911 of such Act, and the number of applications acted

on under each category; and

(4) data on the number of full time equivalents engaged

in implementing this division.

(b) GAO REPORT.—Not later than 5 years after the date of

enactment of this Act, the Comptroller General of the United States

shall conduct a study of, and submit to the Committees described

in subsection (a) a report concerning—

(1) the adequacy of the authority and resources provided

to the Secretary of Health and Human Services for this division

to carry out its goals and purposes; and

(2) any recommendations for strengthening that authority

to more effectively protect the public health with respect to

the manufacture, marketing, and distribution of tobacco products.

(c) PUBLIC AVAILABILITY.—The Secretary of Health and Human

Services and the Comptroller General of the United States, respectively,

shall make the reports required under subsection (a) and

(b) available to the public, including by posting such reports on

the respective Internet websites of the Food and Drug Administration

and the Government Accountability Office.

**TITLE II—TOBACCO PRODUCT WARNINGS;**

**CONSTITUENT AND SMOKE**

**CONSTITUENT DISCLOSURE**

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

(a) AMENDMENT.—Section 4 of the Federal Cigarette Labeling

and Advertising Act (15 U.S.C. 1333) is amended to read as follows:

**‘‘SEC. 4. LABELING.**

‘‘(a) LABEL REQUIREMENTS.—

‘‘(1) IN GENERAL.—It shall be unlawful for any person to

manufacture, package, sell, offer to sell, distribute, or import

for sale or distribution within the United States any cigarettes

the package of which fails to bear, in accordance with the

requirements of this section, one of the following labels:

‘‘WARNING: Cigarettes are addictive.

‘‘WARNING: Tobacco smoke can harm your children.

‘‘WARNING: Cigarettes cause fatal lung disease.

‘‘WARNING: Cigarettes cause cancer.

‘‘WARNING: Cigarettes cause strokes and heart disease.

‘‘WARNING: Smoking during pregnancy can harm your

baby.

‘‘WARNING: Smoking can kill you.

‘‘WARNING: Tobacco smoke causes fatal lung disease

in nonsmokers.

Web posting.

Study.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00068 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

PUBLIC LAW 111–31—JUNE 22, 2009 123 STAT. 1843

‘‘WARNING: Quitting smoking now greatly reduces

serious risks to your health.

‘‘(2) PLACEMENT; TYPOGRAPHY; ETC.—Each label statement

required by paragraph (1) shall be located in the upper portion

of the front and rear panels of the package, directly on the

package underneath the cellophane or other clear wrapping.

Each label statement shall comprise the top 50 percent of

the front and rear panels of the package. The word ‘WARNING’

shall appear in capital letters and all text shall be in conspicuous

and legible 17-point type, unless the text of the label

statement would occupy more than 70 percent of such area,

in which case the text may be in a smaller conspicuous and

legible type size, provided that at least 60 percent of such

area is occupied by required text. The text shall be black

on a white background, or white on a black background, in

a manner that contrasts, by typography, layout, or color, with

all other printed material on the package, in an alternating

fashion under the plan submitted under subsection (c).

‘‘(3) DOES NOT APPLY TO FOREIGN DISTRIBUTION.—The provisions

of this subsection do not apply to a tobacco product

manufacturer or distributor of cigarettes which does not manufacture,

package, or import cigarettes for sale or distribution

within the United States.

‘‘(4) APPLICABILITY TO RETAILERS.—A retailer of cigarettes

shall not be in violation of this subsection for packaging that—

‘‘(A) contains a warning label;

‘‘(B) is supplied to the retailer by a license- or permitholding

tobacco product manufacturer, importer, or distributor;

and

‘‘(C) is not altered by the retailer in a way that is

material to the requirements of this subsection.

‘‘(b) ADVERTISING REQUIREMENTS.—

‘‘(1) IN GENERAL.—It shall be unlawful for any tobacco

product manufacturer, importer, distributor, or retailer of cigarettes

to advertise or cause to be advertised within the United

States any cigarette unless its advertising bears, in accordance

with the requirements of this section, one of the labels specified

in subsection (a).

‘‘(2) TYPOGRAPHY, ETC.—Each label statement required by

subsection (a) in cigarette advertising shall comply with the

standards set forth in this paragraph. For press and poster

advertisements, each such statement and (where applicable)

any required statement relating to tar, nicotine, or other constituent

(including a smoke constituent) yield shall comprise

at least 20 percent of the area of the advertisement and shall

appear in a conspicuous and prominent format and location

at the top of each advertisement within the trim area. The

Secretary may revise the required type sizes in such area

in such manner as the Secretary determines appropriate. The

word ‘WARNING’ shall appear in capital letters, and each

label statement shall appear in conspicuous and legible type.

The text of the label statement shall be black if the background

is white and white if the background is black, under the plan

submitted under subsection (c). The label statements shall be

enclosed by a rectangular border that is the same color as

the letters of the statements and that is the width of the

first downstroke of the capital ‘W’ of the word ‘WARNING’

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00069 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

123 STAT. 1844 PUBLIC LAW 111–31—JUNE 22, 2009

in the label statements. The text of such label statements

shall be in a typeface pro rata to the following requirements:

45-point type for a whole-page broadsheet newspaper advertisement;

39-point type for a half-page broadsheet newspaper

advertisement; 39-point type for a whole-page tabloid newspaper

advertisement; 27-point type for a half-page tabloid newspaper

advertisement; 31.5-point type for a double page spread

magazine or whole-page magazine advertisement; 22.5-point

type for a 28 centimeter by 3 column advertisement; and 15-

point type for a 20 centimeter by 2 column advertisement.

The label statements shall be in English, except that—

‘‘(A) in the case of an advertisement that appears in

a newspaper, magazine, periodical, or other publication

that is not in English, the statements shall appear in

the predominant language of the publication; and

‘‘(B) in the case of any other advertisement that is

not in English, the statements shall appear in the same

language as that principally used in the advertisement.

‘‘(3) MATCHBOOKS.—Notwithstanding paragraph (2), for

matchbooks (defined as containing not more than 20 matches)

customarily given away with the purchase of tobacco products,

each label statement required by subsection (a) may be printed

on the inside cover of the matchbook.

‘‘(4) ADJUSTMENT BY SECRETARY.—The Secretary may,

through a rulemaking under section 553 of title 5, United

States Code, adjust the format and type sizes for the label

statements required by this section; the text, format, and type

sizes of any required tar, nicotine yield, or other constituent

(including smoke constituent) disclosures; or the text, format,

and type sizes for any other disclosures required under the

Federal Food, Drug, and Cosmetic Act. The text of any such

label statements or disclosures shall be required to appear

only within the 20 percent area of cigarette advertisements

provided by paragraph (2). The Secretary shall promulgate

regulations which provide for adjustments in the format and

type sizes of any text required to appear in such area to

ensure that the total text required to appear by law will fit

within such area.

‘‘(c) MARKETING REQUIREMENTS.—

‘‘(1) RANDOM DISPLAY.—The label statements specified in

subsection (a)(1) shall be randomly displayed in each 12-month

period, in as equal a number of times as is possible on each

brand of the product and be randomly distributed in all areas

of the United States in which the product is marketed in

accordance with a plan submitted by the tobacco product manufacturer,

importer, distributor, or retailer and approved by the

Secretary.

‘‘(2) ROTATION.—The label statements specified in subsection

(a)(1) shall be rotated quarterly in alternating sequence

in advertisements for each brand of cigarettes in accordance

with a plan submitted by the tobacco product manufacturer,

importer, distributor, or retailer to, and approved by, the Secretary.

‘‘(3) REVIEW.—The Secretary shall review each plan submitted

under paragraph (2) and approve it if the plan—

Deadline.

Time period.

Regulations.

VerDate Nov 24 2008 08:41 Jun 25, 2009 Jkt 079139 PO 00031 Frm 00070 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL031.111 APPS06 PsN: PUBL031 dkrause on GSDDPC29 with PUBLIC LAWS

PUBLIC LAW 111–31—JUNE 22, 2009 123 STAT. 1845

‘‘(A) will provide for the equal distribution and display

on packaging and the rotation required in advertising

under this subsection; and

‘‘(B) assures that all of the labels required under this

section will be displayed by the tobacco product manufacturer,

importer, distributor, or retailer at the same time.

‘‘(4) APPLICABILITY TO RETAILERS.—This subsection and subsection

(b) apply to a retailer only if that retailer is responsible

for or directs the label statements required under this section

except that this paragraph shall not relieve a retailer of liability

if the retailer displays, in a location open to the public, an

advertisement that does not contain a warning label or has

been altered by the retailer in a way that is material to the

requirements of this subsection and subsection (b).

‘‘(d) GRAPHIC LABEL STATEMENTS.—Not later than 24 months

after the date of enactment of the Family Smoking Prevention

and Tobacco Control Act, the Secretary shall issue regulations that

require color graphics depicting the negative health consequences

of smoking to accompany the label statements specified in subsection

(a)(1). The Secretary may adjust the type size, text and

format of the label statements specified in subsections (a)(2) and

(b)(2) as the Secretary determines appropriate so that both the

graphics and the accompanying label statements are clear, conspicuous,

legible and appear within the specified area.’’.

(b) EFFECTIVE DATE.—The amendment made by subsection (a)

shall take effect 15 months after the issuance of the regulations

required by subsection (a). Such effective date shall be with respect

to the date of manufacture, provided that, in any case, beginning

30 days after such effective date, a manufacturer shall not introduce

into the domestic commerce of the United States any product,

irrespective of the date of manufacture, that is not in conformance

with section 4 of the Federal Cigarette Labeling and Advertising

Act (15 U.S.C. 1333), as amended by subsection (a).

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

(a) PREEMPTION.—Section 5(a) of the Federal Cigarette Labeling

and Advertising Act (15 U.S.C. 1334(a)) is amended by striking

‘‘No’’ and inserting ‘‘Except to the extent the Secretary requires

additional or different statements on any cigarette package by

a regulation, by an order, by a standard, by an authorization

to market a product, or by a condition of marketing a product,

pursuant to the Family Smoking Prevention and Tobacco Control

Act (and the amendments made by that Act), or as required under

section 903(a)(2) or section 920(a) of the Federal Food, Drug, and

Cosmetic Act, no’’.

(b) CHANGE IN REQUIRED STATEMENTS.—Section 4 of the Federal

Cigarette Labeling and Advertising Act (15 U.S.C. 1333), as

amended by section 201, is further amended by adding at the

end the following:

‘‘(d) CHANGE IN REQUIRED STATEMENTS.—The Secretary

through a rulemaking conducted under section 553 of title 5, United

States Code, may adjust the format, type size, color graphics, and

text of any of the label requirements, or establish the format,

type size, and text of any other disclosures required under the

Federal Food, Drug, and Cosmetic Act, if the Secretary finds that

15 USC 1333

note.

Deadline.

Regulations.

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123 STAT. 1846 PUBLIC LAW 111–31—JUNE 22, 2009

such a change would promote greater public understanding of the

risks associated with the use of tobacco products.’’.

**SEC. 203. STATE REGULATION OF CIGARETTE ADVERTISING AND PROMOTION.**

Section 5 of the Federal Cigarette Labeling and Advertising

Act (15 U.S.C. 1334) is amended by adding at the end the following:

‘‘(c) EXCEPTION.—Notwithstanding subsection (b), a State or

locality may enact statutes and promulgate regulations, based on

smoking and health, that take effect after the effective date of

the Family Smoking Prevention and Tobacco Control Act, imposing

specific bans or restrictions on the time, place, and manner, but

not content, of the advertising or promotion of any cigarettes.’’.

**SEC. 204. SMOKELESS TOBACCO LABELS AND ADVERTISING**

**WARNINGS.**

(a) AMENDMENT.—Section 3 of the Comprehensive Smokeless

Tobacco Health Education Act of 1986 (15 U.S.C. 4402) is amended

to read as follows:

**‘‘SEC. 3. SMOKELESS TOBACCO WARNING.**

‘‘(a) GENERAL RULE.—

‘‘(1) It shall be unlawful for any person to manufacture,

package, sell, offer to sell, distribute, or import for sale or

distribution within the United States any smokeless tobacco

product unless the product package bears, in accordance with

the requirements of this Act, one of the following labels:

‘‘WARNING: This product can cause mouth cancer.

‘‘WARNING: This product can cause gum disease and

tooth loss.

‘‘WARNING: This product is not a safe alternative

to cigarettes.

‘‘WARNING: Smokeless tobacco is addictive.

‘‘(2) Each label statement required by paragraph (1) shall

be—

‘‘(A) located on the 2 principal display panels of the

package, and each label statement shall comprise at least

30 percent of each such display panel; and

‘‘(B) in 17-point conspicuous and legible type and in

black text on a white background, or white text on a

black background, in a manner that contrasts by typography,

layout, or color, with all other printed material

on the package, in an alternating fashion under the plan

submitted under subsection (b)(3), except that if the text

of a label statement would occupy more than 70 percent

of the area specified by subparagraph (A), such text may

appear in a smaller type size, so long as at least 60 percent

of such warning area is occupied by the label statement.

‘‘(3) The label statements required by paragraph (1) shall

be introduced by each tobacco product manufacturer, packager,

importer, distributor, or retailer of smokeless tobacco products

concurrently into the distribution chain of such products.

‘‘(4) The provisions of this subsection do not apply to a

tobacco product manufacturer or distributor of any smokeless

tobacco product that does not manufacture, package, or import

smokeless tobacco products for sale or distribution within the

United States.

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PUBLIC LAW 111–31—JUNE 22, 2009 123 STAT. 1847

‘‘(5) A retailer of smokeless tobacco products shall not be

in violation of this subsection for packaging that—

‘‘(A) contains a warning label;

‘‘(B) is supplied to the retailer by a license- or permitholding

tobacco product manufacturer, importer, or distributor;

and

‘‘(C) is not altered by the retailer in a way that is

material to the requirements of this subsection.

‘‘(b) REQUIRED LABELS.—

‘‘(1) It shall be unlawful for any tobacco product manufacturer,

packager, importer, distributor, or retailer of smokeless

tobacco products to advertise or cause to be advertised within

the United States any smokeless tobacco product unless its

advertising bears, in accordance with the requirements of this

section, one of the labels specified in subsection (a).

‘‘(2)(A) Each label statement required by subsection (a)

in smokeless tobacco advertising shall comply with the standards

set forth in this paragraph.

‘‘(B) For press and poster advertisements, each such statement

and (where applicable) any required statement relating

to tar, nicotine, or other constituent yield shall comprise at

least 20 percent of the area of the advertisement.

‘‘(C) The word ‘WARNING’ shall appear in capital letters,

and each label statement shall appear in conspicuous and legible

type.

‘‘(D) The text of the label statement shall be black on

a white background, or white on a black background, in an

alternating fashion under the plan submitted under paragraph

(3).

‘‘(E) The label statements shall be enclosed by a rectangular

border that is the same color as the letters of the statements

and that is the width of the first downstroke of the capital

‘W’ of the word ‘WARNING’ in the label statements.

‘‘(F) The text of such label statements shall be in a typeface

pro rata to the following requirements: 45-point type for a

whole-page broadsheet newspaper advertisement; 39-point type

for a half-page broadsheet newspaper advertisement; 39-point

type for a whole-page tabloid newspaper advertisement; 27-

point type for a half-page tabloid newspaper advertisement;

31.5-point type for a double page spread magazine or wholepage

magazine advertisement; 22.5-point type for a 28 centimeter

by 3 column advertisement; and 15-point type for a

20 centimeter by 2 column advertisement.

‘‘(G) The label statements shall be in English, except that—

‘‘(i) in the case of an advertisement that appears in

a newspaper, magazine, periodical, or other publication

that is not in English, the statements shall appear in

the predominant language of the publication; and

‘‘(ii) in the case of any other advertisement that is

not in English, the statements shall appear in the same

language as that principally used in the advertisement.

‘‘(3)(A) The label statements specified in subsection (a)(1)

shall be randomly displayed in each 12-month period, in as

equal a number of times as is possible on each brand of the

product and be randomly distributed in all areas of the United

States in which the product is marketed in accordance with

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123 STAT. 1848 PUBLIC LAW 111–31—JUNE 22, 2009

a plan submitted by the tobacco product manufacturer,

importer, distributor, or retailer and approved by the Secretary.

‘‘(B) The label statements specified in subsection (a)(1)

shall be rotated quarterly in alternating sequence in

advertisements for each brand of smokeless tobacco product

in accordance with a plan submitted by the tobacco product

manufacturer, importer, distributor, or retailer to, and approved

by, the Secretary.

‘‘(C) The Secretary shall review each plan submitted under

subparagraphs (A) and (B) and approve it if the plan—

‘‘(i) will provide for the equal distribution and display

on packaging and the rotation required in advertising

under this subsection; and

‘‘(ii) assures that all of the labels required under this

section will be displayed by the tobacco product manufacturer,

importer, distributor, or retailer at the same time.

‘‘(D) This paragraph applies to a retailer only if that retailer

is responsible for or directs the label statements under this

section, unless the retailer displays, in a location open to the

public, an advertisement that does not contain a warning label

or has been altered by the retailer in a way that is material

to the requirements of this subsection.

‘‘(4) The Secretary may, through a rulemaking under section

553 of title 5, United States Code, adjust the format

and type sizes for the label statements required by this section;

the text, format, and type sizes of any required tar, nicotine

yield, or other constituent disclosures; or the text, format, and

type sizes for any other disclosures required under the Federal

Food, Drug, and Cosmetic Act. The text of any such label

statements or disclosures shall be required to appear only

within the 20 percent area of advertisements provided by paragraph

(2). The Secretary shall promulgate regulations which

provide for adjustments in the format and type sizes of any

text required to appear in such area to ensure that the total

text required to appear by law will fit within such area.

‘‘(c) TELEVISION AND RADIO ADVERTISING.—It is unlawful to

advertise smokeless tobacco on any medium of electronic communications

subject to the jurisdiction of the Federal Communications

Commission.’’.

(b) EFFECTIVE DATE.—The amendment made by subsection (a)

shall take effect 12 months after the date of enactment of this

Act. Such effective date shall be with respect to the date of manufacture,

provided that, in any case, beginning 30 days after such

effective date, a manufacturer shall not introduce into the domestic

commerce of the United States any product, irrespective of the

date of manufacture, that is not in conformance with section 3

of the Comprehensive Smokeless Tobacco Health Education Act

of 1986 (15 U.S.C. 4402), as amended by subsection (a).

**SEC. 205. AUTHORITY TO REVISE SMOKELESS TOBACCO PRODUCT**

**WARNING LABEL STATEMENTS.**

(a) IN GENERAL.—Section 3 of the Comprehensive Smokeless

Tobacco Health Education Act of 1986 (15 U.S.C. 4402), as amended

by section 204, is further amended by adding at the end the following:

‘‘(d) AUTHORITY TO REVISE WARNING LABEL STATEMENTS.—

The Secretary may, by a rulemaking conducted under section 553

15 USC 4402

note.

Regulations.

Applicability.

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PUBLIC LAW 111–31—JUNE 22, 2009 123 STAT. 1849

of title 5, United States Code, adjust the format, type size, and

text of any of the label requirements, require color graphics to

accompany the text, increase the required label area from 30 percent

up to 50 percent of the front and rear panels of the package,

or establish the format, type size, and text of any other disclosures

required under the Federal Food, Drug, and Cosmetic Act, if the

Secretary finds that such a change would promote greater public

understanding of the risks associated with the use of smokeless

tobacco products.’’.

(b) PREEMPTION.—Section 7(a) of the Comprehensive Smokeless

Tobacco Health Education Act of 1986 (15 U.S.C. 4406(a)) is

amended by striking ‘‘No’’ and inserting ‘‘Except as provided in

the Family Smoking Prevention and Tobacco Control Act (and the

amendments made by that Act), no’’.

**SEC. 206. TAR, NICOTINE, AND OTHER SMOKE CONSTITUENT DISCLOSURE**

**TO THE PUBLIC.**

Section 4 of the Federal Cigarette Labeling and Advertising

Act (15 U.S.C. 1333), as amended by sections 201 and 202, is

further amended by adding at the end the following:

‘‘(e) TAR, NICOTINE, AND OTHER SMOKE CONSTITUENT DISCLOSURE.—

‘‘(1) IN GENERAL.—The Secretary shall, by a rulemaking

conducted under section 553 of title 5, United States Code,

determine (in the Secretary’s sole discretion) whether cigarette

and other tobacco product manufacturers shall be required

to include in the area of each cigarette advertisement specified

by subsection (b) of this section, or on the package label, or

both, the tar and nicotine yields of the advertised or packaged

brand. Any such disclosure shall be in accordance with the

methodology established under such regulations, shall conform

to the type size requirements of subsection (b) of this section,

and shall appear within the area specified in subsection (b)

of this section.

‘‘(2) RESOLUTION OF DIFFERENCES.—Any differences

between the requirements established by the Secretary under

paragraph (1) and tar and nicotine yield reporting requirements

established by the Federal Trade Commission shall be resolved

by a memorandum of understanding between the Secretary

and the Federal Trade Commission.

‘‘(3) CIGARETTE AND OTHER TOBACCO PRODUCT CONSTITUENTS.—

In addition to the disclosures required by paragraph

(1), the Secretary may, under a rulemaking conducted under

section 553 of title 5, United States Code, prescribe disclosure

requirements regarding the level of any cigarette or other

tobacco product constituent including any smoke constituent.

Any such disclosure may be required if the Secretary determines

that disclosure would be of benefit to the public health,

or otherwise would increase consumer awareness of the health

consequences of the use of tobacco products, except that no

such prescribed disclosure shall be required on the face of

any cigarette package or advertisement. Nothing in this section

shall prohibit the Secretary from requiring such prescribed

disclosure through a cigarette or other tobacco product package

or advertisement insert, or by any other means under the

Federal Food, Drug, and Cosmetic Act.

Memorandum.

Regulations.

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123 STAT. 1850 PUBLIC LAW 111–31—JUNE 22, 2009

‘‘(4) RETAILERS.—This subsection applies to a retailer only

if that retailer is responsible for or directs the label statements

required under this section.’’.

**TITLE III—PREVENTION OF ILLICIT**

**TRADE IN TOBACCO PRODUCTS**

**SEC. 301. LABELING, RECORDKEEPING, RECORDS INSPECTION.**

Chapter IX of the Federal Food, Drug, and Cosmetic Act, as

added by section 101, is further amended by adding at the end

the following:

**‘‘SEC. 920. LABELING, RECORDKEEPING, RECORDS INSPECTION.**

‘‘(a) ORIGIN LABELING.—

‘‘(1) REQUIREMENT.—Beginning 1 year after the date of

enactment of the Family Smoking Prevention and Tobacco Control

Act, the label, packaging, and shipping containers of tobacco

products other than cigarettes for introduction or delivery for

introduction into interstate commerce in the United States

shall bear the statement ‘sale only allowed in the United

States’. Beginning 15 months after the issuance of the regulations

required by section 4(d) of the Federal Cigarette Labeling

and Advertising Act (15 U.S.C. 1333), as amended by section

201 of Family Smoking Prevention and Tobacco Control Act,

the label, packaging, and shipping containers of cigarettes for

introduction or delivery for introduction into interstate commerce

in the United States shall bear the statement ‘Sale

only allowed in the United States’.

‘‘(2) EFFECTIVE DATE.—The effective date specified in paragraph

(1) shall be with respect to the date of manufacture,

provided that, in any case, beginning 30 days after such effective

date, a manufacturer shall not introduce into the domestic

commerce of the United States any product, irrespective of

the date of manufacture, that is not in conformance with such

paragraph.

‘‘(b) REGULATIONS CONCERNING RECORDKEEPING FOR TRACKING

AND TRACING.—

‘‘(1) IN GENERAL.—The Secretary shall promulgate regulations

regarding the establishment and maintenance of records

by any person who manufactures, processes, transports, distributes,

receives, packages, holds, exports, or imports tobacco products.

‘‘(2) INSPECTION.—In promulgating the regulations

described in paragraph (1), the Secretary shall consider which

records are needed for inspection to monitor the movement

of tobacco products from the point of manufacture through

distribution to retail outlets to assist in investigating potential

illicit trade, smuggling, or counterfeiting of tobacco products.

‘‘(3) CODES.—The Secretary may require codes on the labels

of tobacco products or other designs or devices for the purpose

of tracking or tracing the tobacco product through the distribution

system.

‘‘(4) SIZE OF BUSINESS.—The Secretary shall take into

account the size of a business in promulgating regulations

under this section.

Effective dates.

21 USC 387t.

Applicability.

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PUBLIC LAW 111–31—JUNE 22, 2009 123 STAT. 1851

‘‘(5) RECORDKEEPING BY RETAILERS.—The Secretary shall

not require any retailer to maintain records relating to individual

purchasers of tobacco products for personal consumption.

‘‘(c) RECORDS INSPECTION.—If the Secretary has a reasonable

belief that a tobacco product is part of an illicit trade or smuggling

or is a counterfeit product, each person who manufactures, processes,

transports, distributes, receives, holds, packages, exports,

or imports tobacco products shall, at the request of an officer

or employee duly designated by the Secretary, permit such officer

or employee, at reasonable times and within reasonable limits and

in a reasonable manner, upon the presentation of appropriate

credentials and a written notice to such person, to have access

to and copy all records (including financial records) relating to

such article that are needed to assist the Secretary in investigating

potential illicit trade, smuggling, or counterfeiting of tobacco products.

The Secretary shall not authorize an officer or employee

of the government of any of the several States to exercise authority

under the preceding sentence on Indian country without the express

written consent of the Indian tribe involved.

‘‘(d) KNOWLEDGE OF ILLEGAL TRANSACTION.—

‘‘(1) NOTIFICATION.—If the manufacturer or distributor of

a tobacco product has knowledge which reasonably supports

the conclusion that a tobacco product manufactured or distributed

by such manufacturer or distributor that has left the

control of such person may be or has been—

‘‘(A) imported, exported, distributed, or offered for sale

in interstate commerce by a person without paying duties

or taxes required by law; or

‘‘(B) imported, exported, distributed, or diverted for

possible illicit marketing,

the manufacturer or distributor shall promptly notify the

Attorney General and the Secretary of the Treasury of such

knowledge.

‘‘(2) KNOWLEDGE DEFINED.—For purposes of this subsection,

the term ‘knowledge’ as applied to a manufacturer or distributor

means—

‘‘(A) the actual knowledge that the manufacturer or

distributor had; or

‘‘(B) the knowledge which a reasonable person would

have had under like circumstances or which would have

been obtained upon the exercise of due care.

‘‘(e) CONSULTATION.—In carrying out this section, the Secretary

shall consult with the Attorney General of the United States and

the Secretary of the Treasury, as appropriate.’’.

**SEC. 302. STUDY AND REPORT.**

(a) STUDY.—The Comptroller General of the United States shall

conduct a study of cross-border trade in tobacco products to—

(1) collect data on cross-border trade in tobacco products,

including illicit trade and trade of counterfeit tobacco products

and make recommendations on the monitoring of such trade;

(2) collect data on cross-border advertising (any advertising

intended to be broadcast, transmitted, or distributed from the

United States to another country) of tobacco products and make

recommendations on how to prevent or eliminate, and what

technologies could help facilitate the elimination of, cross-border

advertising; and

Notice.

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123 STAT. 1852 PUBLIC LAW 111–31—JUNE 22, 2009

(3) collect data on the health effects (particularly with

respect to individuals under 18 years of age) resulting from

cross-border trade in tobacco products, including the health

effects resulting from—

(A) the illicit trade of tobacco products and the trade

of counterfeit tobacco products; and

(B) the differing tax rates applicable to tobacco products.

(b) REPORT.—Not later than 18 months after the date of enactment

of this Act, the Comptroller General of the United States

shall submit to the Committee on Health, Education, Labor, and

Pensions of the Senate and the Committee on Energy and Commerce

of the House of Representatives a report on the study

described in subsection (a).

(c) DEFINITION.—In this section:

(1) The term ‘‘cross-border trade’’ means trade across a

border of the United States, a State or Territory, or Indian

country.

(2) The term ‘‘Indian country’’ has the meaning given to

such term in section 1151 of title 18, United States Code.

(3) The terms ‘‘State’’ and ‘‘Territory’’ have the meanings

given to those terms in section 201 of the Federal Food, Drug,

and Cosmetic Act (21 U.S.C. 321).

From the U.S. House of Representatives Downloadable U.S. Code [[uscode. house.gov](http://uscode.house.gov/)]

[Laws in effect as of January 5, 1999]

[Document affected by Public Law 104-134 Section 101(d)]

[Document affected by Public Law 104-140 Section 1(a)]

[CITE: 42USC241]

TITLE 42 - THE PUBLIC HEALTH AND WELFARE CHAPTER 6A - PUBLIC HEALTH SERVICE

SUBCHAPTER II - GENERAL POWERS AND DUTIES Part A - Research and Investigations

HEAD-Sec. 241. Research and investigations generally STATUTE

(a) Authority of Secretary

The Secretary shall conduct in the Service, and encourage, cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man, including water purification, sewage treatment, and pollution of lakes and streams. In carrying out the foregoing the Secretary is authorized to - (1)     collect and make available through publications and other appropriate means, information as to, and the practical application of, such research and other activities; (2)     make available research facilities of the Service to appropriate public authorities, and to health officials and scientists engaged in special study; (3)     make grants-in-aid to universities, hospitals, laboratories, and other public or private institutions, and to individuals for such research projects as are recommended by the advisory council to the entity of the Department supporting such projects and make, upon recommendation of the advisory council to the appropriate entity of the Department, grants-in-aid to public or nonprofit universities, hospitals, laboratories, and other institutions for the general support of their research; (4)   secure from time to time and for such periods as he deems advisable, the assistance and advice of experts, scholars, and consultants from the United States or abroad; (5)   for purposes of study, admit and treat at institutions, hospitals, and stations of the Service, persons not otherwise eligible for such treatment; (6)   make available, to health officials, scientists, and appropriate public and other nonprofit institutions and organizations, technical advice and assistance on the application of statistical methods to experiments, studies, and surveys in health and medical fields; (7)   enter into contracts, including contracts for research in accordance with and subject to the provisions of law applicable to contracts entered into by the military departments under sections 2353 and 2354 of title 10, except that determination, approval, and certification required thereby shall be by the Secretary of Health and Human Services; and (8)   adopt, upon recommendations of the advisory councils to the appropriate entities of the Department or, with respect to mental health, the National Advisory Mental Health Council, such additional means as the Secretary considers necessary or appropriate to carry out the purposes of this section.  The Secretary may make available to individuals and entities, for biomedical and behavioral research, substances and living organisms. Such substances and organisms shall be made available under such terms and conditions (including payment for them) as the Secretary determines appropriate.