Service, shall report to the Committee on Energy and Commerce and the Committee on Homeland Security of the House of Representatives and the Committee on Health, Education, Labor, and Pensions and the Committee on Homeland Security and Governmental Affairs of the Senate on the implementation of this section, including a summary of progress made toward near-real-time information sharing and the interoperability of such technologies.

(Pub. L. 115–271, title III, §3014, Oct. 24, 2018, 132 Stat. 3937.)

Statutory Notes and Related Subsidiaries

CODIFICATION

Section was enacted as part of the Stop Counterfeit Drugs by Regulating and Enhancing Enforcement Now Act, also known as the SCREEN Act, and also as part of the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, also known as the SUPPORT for Patients and Communities Act, and not as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

§ 384g. Restricting entrance of illicit drugs

(a) Food and Drug Administration and U.S. Customs and Border Protection cooperation

(1) In general

The Secretary of Health and Human Services (referred to in this section as the ''Secretary''), acting through the Commissioner of Food and Drugs and in consultation with the U.S. Customs and Border Protection, shall develop and periodically update a mutually agreed upon list of the controlled substances that the Secretary will refer to U.S. Customs and Border Protection, unless the Secretary and U.S. Customs and Border Protection agree otherwise, when such substances are offered for import via international mail and appear to violate the Controlled Substances Act (21 U.S.C. 801 et seq.), the Controlled Substances Import and Export Act (21 U.S.C. 951 et seq.), the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), or any other applicable law. The Secretary shall transfer controlled substances on such list to the U.S. Customs and Border Protection. If the Secretary identifies additional packages that appear to be the same as such package containing a controlled substance, such additional packages may also be transferred to U.S. Customs and Border Protection. The U.S. Customs and Border Protection shall receive such packages consistent with the requirements of the Controlled Substances Act (21 U.S.C. 801 et seq.).

(2) Report

Not later than 9 months after October 24, 2018, the Secretary, acting through the Commissioner of Food and Drugs and in consultation with the Secretary of Homeland Security, shall report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate on the implementation of this section.

(Pub. L. 115–271, title III, §3022(a), Oct. 24, 2018, 132 Stat. 3938.)

Editorial Notes

REFERENCES IN TEXT

The Controlled Substances Act, referred to in subsec. (a)(1), is title II of Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1242, which is classified principally to subchapter I (§801 et seq.) of chapter 13 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 801 of this title and Tables.

The Controlled Substances Import and Export Act, referred to in subsec. (a)(1), is title III of Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1285, which is classified principally to subchapter II (§951 et seq.) of chapter 13 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 951 of this title and Tables.

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (a)(1), is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to this chapter. For complete classification of this Act to the Code, see section 301 of this title and Tables.

Statutory Notes and Related Subsidiaries

CODIFICATION

Section was enacted as part of the Stop Counterfeit Drugs by Regulating and Enhancing Enforcement Now Act, also known as the SCREEN Act, and also as part of the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, also known as the SUPPORT for Patients and Communities Act, and not as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

SUBCHAPTER IX—TOBACCO PRODUCTS

Editorial Notes

PRIOR PROVISIONS

A prior subchapter IX of this chapter, consisting of sections 391 to 399a of this title, was redesignated subchapter X by Pub. L. 111–31, div. A, title I, §101(b)(1), June 22, 2009, 123 Stat. 1784.

§ 387. Definitions

In this subchapter:

(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 1332(1) of title 15; 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 subchapter shall also apply to cigarette tobacco.

(5) Commerce

The term ''commerce'' has the meaning given that term by section 1332(2) of title 15.

(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 387e(i)(1) of this title.

(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 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 subchapter.

(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.

(10) Indian tribe

The term ''Indian tribe'' has the meaning given such term in section 5304(e) of title 25.

(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 1332(7) of title 15.

(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 321 of this title.

(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 chapter.

(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 subchapter 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.

(June 25, 1938, ch. 675, §900, as added Pub. L. 111–31, div. A, title I, §101(b)(3), June 22, 2009, 123 Stat. 1784.)

Statutory Notes and Related Subsidiaries

SEVERABILITY

Pub. L. 111–31, div. A, §5, June 22, 2009, 123 Stat. 1782, provided that: ''If any provision of this division [see Short Title of 2009 Amendment note set out under section 301 of this title], 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.''

CONSTRUCTION

Pub. L. 111–31, div. A, §4, June 22, 2009, 123 Stat. 1782, provided that:

''(a) INTENDED EFFECT.—Nothing in this division [see Short Title of 2009 Amendment note set out under section 301 of this title] (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 [26 U.S.C. 5701 et seq.].''

FINDINGS

Pub. L. 111–31, div. A, §2, June 22, 2009, 123 Stat. 1776, provided that: ''The Congress finds the following:

''(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 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 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 [probably means this division, see Short Title of 2009 Amendment note set out under section 301 of this title] 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 [been] 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.

''(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 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 [div. A of Pub. L. 111–31, see Short Title of 2009 Amendment note set out under section 301 of this title].

''(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 nicotine-related research. USA v. Philip Morris, USA, Inc., et al. (Civil Action No. 99–2496 (GK), August 17, 2006).''

PURPOSE

Pub. L. 111–31, div. A, §3, June 22, 2009, 123 Stat. 1781, provided that: ''The purposes of this division [see Short Title of 2009 Amendment note set out under section 301 of this title] 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;

''(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.''

MODIFICATION OF DEADLINES FOR SECRETARIAL ACTION

Pub. L. 111–31, div. A, §6, June 22, 2009, 123 Stat. 1783, provided that:

''(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 [see Short Title of 2009 Amendment note set out under section 301 of this title] (or in an amendment made by this division) that begin on the date of enactment of this Act [June 22, 2009], 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 [21 U.S.C. 387s] (as added by section 101).

''(c) EXCEPTION.—Subsection (a) shall not apply to any time period (or date) contained—

''(1) in section 102 [21 U.S.C. 387a–1], 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 [amending sections 1333, 1334, and 4402 of Title 15, Commerce and Trade, and enacting provisions set out as notes under sections 1333 and 4402 of Title 15] (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 [sic], except that no such period shall be extended for more than 90 days.''

§ 387a. 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 387k of this title, shall be regulated by the Secretary under this subchapter and shall not be subject to the provisions of subchapter V.

(b) Applicability

This subchapter 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 subchapter. This subchapter shall also apply to any tobacco product containing nicotine that is not made or derived from tobacco.

(c) Scope

(1) In general

Nothing in this subchapter, or any policy issued or regulation promulgated thereunder, or in sections 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 chapter that are not tobacco products under subchapter V or any other subchapter.

(2) Limitation of authority

(A) In general

The provisions of this subchapter 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 subchapter 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 subchapter 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 subchapter shall be in accordance with chapter 5 of title 5. This subsection shall not be construed to affect the rulemaking provisions of section 102(a) of the Family Smoking Prevention and Tobacco Control Act [21 U.S.C. 387a–1(a)].

(e) Center for tobacco products

Not later than 90 days after June 22, 2009, 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 subchapter 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 chapter.

(g) Consultation prior to rulemaking

Prior to promulgating rules under this subchapter, the Secretary shall endeavor to consult with other Federal agencies as appropriate.

(June 25, 1938, ch. 675, § 901, as added Pub. L. 111–31, div. A, title I, § 101(b)(3), June 22, 2009, 123 Stat. 1786; amended Pub. L. 117–103, div. P, title I, § 111(b), Mar. 15, 2022, 136 Stat. 789.)

Editorial Notes

REFERENCES IN TEXT

The Family Smoking Prevention and Tobacco Control Act, referred to in subsec. (c)(1), is div. A of Pub. L. 111–31, June 22, 2009, 123 Stat. 1776. Section 101(a) of title I of the Act amended section 321 of this title. Section 102 of title I of the Act enacted section 387a–1 of this title. Section 103 of title I of the Act amended sections 331, 333, 334, 355, 360m, 372 to 374, 375, 379a, 381, 393, 399, and 679 of this title and enacted provisions set out as notes under sections 331, 333, and 387c of this title. Title II of the Act amended sections 1333, 1334, 4402, and 4406 of Title 15, Commerce and Trade, and enacted provisions set out as notes under sections 1333 and 4402 of Title 15. Title III of the Act enacted section 387t of this title. For complete classification of this Act to the Code, see Short Title of 2009 Amendment note set out under section 301 of this title and Tables.