EFFECTIVENESS/COMPLIANCE DATES FOR DEEMING AND ADDITIONAL PROVISIONS

EFFECTIVENESS/COMPLIANCE DATES FOR DEEMING PROVISIONS	
FD&C ACT CITATION	**EFFECTIVENESS DATE/COMPLIANCE PERIOD**
902(1)-(5), (8) **§387b 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 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 387s of this title by the date specified in section 387s of this title 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 387g of this title unless such tobacco product is in all respects in conformity with such standard; …. (8) it is in violation of section 387k of this title [modified tobacco products].	Effective date of part 1100, which is the publication date plus 90 days (**The final rule is scheduled to be published in the Federal Register on May 10, 2016, so August 8, 2016**).
903(a)(1)	Effective date of part 1100, which is the publication date plus 90

§ 387c - 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;	days (**August 8, 2016**).
903(a)(6)-(7) **§ 387c - Misbranded tobacco products** **(a)IN GENERAL-** A tobacco product shall be deemed to be misbranded— (6) if it was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 387e(b), 387e(c), 387e(d), or 387e(h) of this title, if it was not included in a list required bysection 387e(i) of this title, if a notice or other information respecting it was not provided as required by such section or section 387e(j) of this title, or if it does not bear such symbols from the uniform system for identification of tobacco products prescribed under section 387e(e) of this title 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 387f(d) of this title;	Effective date of part 1100, which is the publication date plus 90 days (**August 8, 2016**).
904(c)(2),(3) **§ 387d - Submission of health information to the Secretary** **(c)TIME FOR SUBMISSION** ***(2) Disclosure of additive***	Effective date of part 1100, which is the publication date plus 90 days (**August 8, 2016**).

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.	
911(a), 911(b) **[with the exception of products sold or distributed using the descriptors set forth in 911(b)(2)(A)(ii)[sold as "light," "mild," or "low"]]** **§387k. 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 tobacco-related disease associated with commercially marketed tobacco products.	Effective date of part 1100, which is the publication date plus 90 days (**August 8, 2016**).

(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 June 22, 2009, respecting the product 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 June 22, 2009, for those products whose label, labeling, or advertising contains the terms described in such paragraph on June 22, 2009. 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).	
919(a) **§387s. User fees** ***(a) Establishment of quarterly fee*** Beginning on June 22, 2009, 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 subchapter. 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	FDA issued a final rule revising the current user fee regulations concurrently with the final deeming rule. It is effective on the publication date plus 90 days (**August 8, 2016**).

specified in subsection (b)(1) for such year, subject to subsection (c).	

COMPLIANCE PERIODS FOR OTHER PROVISIONS	
FD&C ACT CITATION	**COMPLIANCE PERIOD**
903(a)(2) **§387c. Misbranded tobacco products** ***(a) In general*** A tobacco product shall be deemed to be misbranded- (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 387t(a) of this title, 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;	24 months after the publication of the final regulation (**May 10, 2018**). * This is designed to match the 24 month effective date of the health warnings.
903(a)(3) **§387c. Misbranded tobacco products** ***(a) In general*** A tobacco product shall be deemed to be misbranded- (3) if any word, statement, or other information required by or under authority of this subchapter to appear on the label or	Effective date of part 1100 PLUS 1 year. The effective date of part 1100 is the publication date plus 90 days (**August 8, 2017**). * This is designed to match the 1 year deadline in the FD&C Act for currently regulated products.

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;	
903(a)(4) **§387c. Misbranded tobacco products** ***(a) In general*** A tobacco product shall be deemed to be misbranded- (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;	24 months after the publication of this final regulation (**May 10, 2018**). * This is designed to match the 24 month effective date of the health warnings.
903(a)(8) **§387c. Misbranded tobacco products** ***(a) In general*** A tobacco product shall be deemed to be misbranded- (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	24 months after the publication of this final regulation (**May 10, 2018**). * This is designed to match the 24 month effective date of the health warnings.

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;	
904(a)(1), 904(c)(1) **§387d. 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 June 22, 2009, 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. ***(d) Data list*** ***(1) In general*** Not later than 3 years after June 22, 2009, 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).	Effective date of part 1100 PLUS 6 months (products on the market as of the effective date) (**February 8, 2017**), or 90 days before delivery for introduction into interstate commerce (products entering the market after the effective date). * This matches the timeframes provided in this section.
904(a)(3) **§387d. Submission of health information to the Secretary** ***(a) Requirement*** Each tobacco product manufacturer or importer, or agents	Effective date of part 1100 PLUS 3 years (**August 8, 2019**) or, for products delivered for introduction into interstate commerce later than 3 years after the effective date, 90 days before delivery for introduction into interstate commerce (products entering the

thereof, shall submit to the Secretary the following information: (3) Beginning 3 years after June 22, 2009, 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 June 22, 2009, the manufacturer, importer, or agent shall comply with regulations promulgated under section 387o of this title in reporting information under this paragraph, where applicable.	market after the effective date). * This matches the timeframes provided in this section.
904(a)(4) **§387d. 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: (4) Beginning 6 months after June 22, 2009, all documents developed after June 22, 2009 that relate to health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents (including smoke constituents), ingredients, components, and additives.	Effective date of part 1100 PLUS 6 months (**February 8, 2017**). * This matches the timeframes provided in this section.
905(b),(c),(d),(h) **§387e. Annual registration** ***(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	If the final rule publishes in the second half of the calendar year, FDA intends to issue a compliance policy with a compliance period for registration that is no later than 6 months into the subsequent calendar year. * This matches the timeframes provided in this section.

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. ***(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 381(a) of this title.	
905(i)(1) **§387e. Annual registration**	Same compliance period as that for initial registration; see date specified for 905(b).

(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 387g of this title or which is subject to section 387j of this title, 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 387g of this title, 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.	
907(a)(1)(B) **§387g. Tobacco product standards**	Effective date of part 1100 PLUS 2 years (**August 8, 2018**). * This matches the timeframe provided in this section

(a) In general ***(1) Special rules*** ***(B) Additional special rule*** Beginning 2 years after June 22, 2009, 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.	
911(a), (b)(1), (b)(2)(A)(ii), (b)(3) **§387k. 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 tobacco-related 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- (ii) the label, labeling, or advertising of which uses the	Use of "light," "low," and "mild" descriptors: Effective date of part 1100 PLUS 1 year (stop manufacture)(**August 8, 2017**); Effective date of part 1100 PLUS 13 months (stop distribution) (**September 8, 2017**). * This matches the timeframes provided in this section.

descriptors "light", "mild", or "low" or similar descriptors; ***(3) Effective date*** The provisions of paragraph (2)(A)(ii) shall take effect 12 months after June 22, 2009, for those products whose label, labeling, or advertising contains the terms described in such paragraph on June 22, 2009. 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).	
920(a)(1) **§387t. Labeling, recordkeeping, records inspection** ***(a) Origin labeling*** ***(1) Requirement*** Beginning 1 year after June 22, 2009, 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 1333(d) of title 15, as amended by section 201 of Family [1] 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".	Compliance period 24 months after the publication of this final regulation (**May 10, 2018**). * This is designed to match the 24 month effective date of the health warnings.

COMPLIANCE PERIODS FOR PRE-MARKET REVIEW SUBMISSIONS	
RULE	**COMPLIANCE PERIOD**
SE Exemption Requests	For newly deemed products that were on the market on the effective date of this final rule, but that were not on the market on February 15, 2007, FDA is providing two compliance periods: One for submission and FDA receipt of applications and one for obtaining premarket authorization. • The initial compliance period is 12 months from the effective date of the final rule (**August 8, 2017**) • Unless FDA has issued an order denying or refusing to accept the submission, products for which timely premarket submissions have been submitted will be subject to a continued compliance period for 12 months after the initial compliance period described previously, totaling 24 months from the effective date of the final rule (**August 8, 2018**).
SE Reports	For newly deemed products that were on the market on the effective date of this final rule, but that were not on the market on February 15, 2007, FDA is providing two compliance periods: One for submission and FDA receipt of applications and one for obtaining premarket authorization. • The initial compliance period is 18 months from the effective date of the final rule (**February 8, 2017**) • Unless FDA has issued an order denying or refusing to accept the submission, products for which timely premarket submissions have been submitted will be subject to a continued compliance period for 12 months after the initial compliance period described previously, totaling 30 months from the effective date of the final rule (**February 8, 2019**).
PMTAs	For newly deemed products that were on the market on the effective date of this final rule, but that were not on the market on February 15, 2007, FDA is providing two

	compliance periods: One for submission and FDA receipt of applications and one for obtaining premarket authorization. • The initial compliance period is 24 months from the effective date of the final rule (**August 8, 2018**) • Unless FDA has issued an order denying or refusing to accept the submission, products for which timely premarket submissions have been submitted will be subject to a continued compliance period for 12 months after the initial compliance period described previously, totaling 36 months from the effective date of the final rule (**August 8, 2019**).

EFFECTIVENESS DATES FOR ADDITIONAL PROVISIONS	
REGULATION	**EFFECTIVENESS DATES**
Minimum age and identification restrictions (21 CFR § 1140.14(b)(1) and (2)): Cigar retailers are prohibited from selling products to any person under the age of 18. Retailers are required to verify through photo identification that customers are not younger than 18 years of age, but are not required to verify age for persons over the age of 26.	Effective 90 days from the date of publication of the final rule (**August 8, 2016**).
Requirement to include health warnings (21 CFR § Part 1143): Cigar packages and advertisements are required to bear health warnings that must be randomly displayed on cigar product packages and rotated in advertisements.	Effective 24 months from the date of publication of the final rule (**May 10, 2018**), with an additional 30-day period during which manufacturers may continue to introduce into interstate commerce existing inventory without the required warning statements on packaging that was manufactured before the effective date. Requirement to submit a warning plan to FDA will take effect 12 months after the date of publication of the final rule (**May 10, 2017**).

Prohibition of vending machine sales, unless in a facility that excludes youth (21 CFR § 1140.14(b)(3)): Cigar retailers are prohibited from selling cigars through vending machines unless the vending machines are located in a facility where the retailer ensures that no-one under the age of 18 is present, or permitted to enter, at any time.	Effective 90 days from the date of publication of the final rule (**August 8, 2016**).