



## The Deeming Regulation: The FDA's Questions for the Public Health Community

The FDA is accepting public comments on its proposed Deeming Regulation. In addition to allowing general comments on the proposal, the FDA is soliciting specific information that will help inform the final rule. Most of these specific requests fall into one of seven categories. A person who has relevant information to provide to the FDA in response to a specific question can submit that information without having to respond to all of the FDA's questions. We have listed the questions below, including the [Federal Register](#) page numbers in parentheses, to help readers find the original questions and view them in context. For more information about the proposed regulation and how to provide comments to the FDA, visit our [FDA Tobacco Action Center](#).

### I. Cigars

The FDA has proposed two different options for deeming cigars to be subject to the requirements found in the Family Smoking Prevention and Tobacco Control Act. Option 1 of the proposal would bring all cigars under the FDA's authority while Option 2 would exempt premium cigars from the Act.

Mechanically, Option 2 would extend the FDA's regulation to "covered cigars." It then would exempt premium cigars by explaining that a "covered cigar" is any cigar except one that:

- (1) Is wrapped in whole tobacco leaf;
- (2) Contains a 100 percent leaf tobacco binder;
- (3) Contains primarily long filler tobacco;
- (4) Is made by combining manually the wrapper, filler, and binder;
- (5) Has no filter, tip, or non-tobacco mouthpiece and is capped by hand;
- (6) Has a retail price (after any discounts or coupons) of no less than \$10 per cigar (adjusted, as necessary, every 2 years, effective July 1st, to account for any increases in the price of tobacco products since the last price adjustment);
- (7) Does not have a characterizing flavor other than tobacco; and
- (8) Weighs more than 6 pounds per 1000 units.

Regarding these two options, the FDA is soliciting the following information:

1. The FDA is requesting comments as to whether it is appropriate to deem premium cigars. (23,171)

2. The FDA seeks comment on the appropriateness of defining different categories of cigars, the proposed definition of “covered cigar,” and whether certain types of cigars should be subject to a different regulatory regime. (23,180)
3. How should the fact that studies indicate that young adults likely prefer cigarillos, as opposed to traditional large cigars, affect the FDA's decision about whether to regulate “premium” cigars? (23,150)
4. How could the FDA further refine this definition (of “covered cigar”), within the context of Option 2, to ensure that the exclusion would apply only to those cigars that, because of how they are used, may have less of a public health impact than other types of cigars? (23,150)
5. How should this proposed rule apply to cigars? The FDA is, therefore, also soliciting comment on how to further define categories of cigars, particularly premium cigars. (23,178)
6. Given that different kinds of cigars may have the potential for varying effects on public health, the FDA is proposing two options for the categories of cigars that would be covered by this rule. The FDA is specifically seeking comment on whether all cigars should be subject to deeming (in other words, under the FDA's jurisdiction) and what provisions of the proposed rule may be appropriate or not appropriate for different kinds of cigars. (23,144)
7. The FDA is seeking comment on the relative merits of Option 1 versus Option 2, taking into account what is appropriate for the public health, including possible benefits to the public health or possible negative public health consequences of adopting one Option or the other. (23,145)
8. Is this proposed definition of “covered cigar” appropriate to capture those products that, because of how they are used, may have less of a public health impact than other types of cigars? (23,150)
9. Should long filler tobacco content be included as one of required elements of a “premium” cigar (excluded from the definition of a “covered cigar”)? If so, what percentage of the tobacco contained in the cigar should be required to be long filler tobacco in order for the cigar to be considered “premium”? (23,150)
10. Is it appropriate to include the \$10 price point in differentiating “premium” cigars from other cigars? Please provide any data or information that supports the selection of a \$10 price point or, if you believe a different price point is more appropriate, that supports the selection of that price point. (23,150)
11. Should a volume/rate restriction (e.g., “is produced at a rate of no more than [insert number] units per minute”) be included as one of required elements of a “premium” cigar (excluded from the definition of a “covered cigar”)? If the FDA were to include this restriction, what should the rate be? How would the FDA determine compliance with such a restriction? (23,150)
12. Is it appropriate to include the proposed weight restriction (6 pounds per 1000 units) in differentiating “premium” cigars from other cigars? (23,150)
13. Would a different regulatory scheme for covered cigars, as defined here, or other category of cigars adequately address the dangers of tobacco use by adults or the proven dangers associated with use of cigars (such as increased risk of several cancers even among those users who do not inhale, and risk associated with lower levels of use as discussed in section VII)? (23,150)

Under the FDA's proposal, cigars that are sold individually are not required to bear a warning label but a retailer who sells individual cigars must display point-of-sale warnings.

14. As stated throughout the proposed regulation, Option 2 would apply to a subset of cigars (defined as covered cigars). Therefore, under this option, this special rule (the point-of-sale warning requirement) would apply to only those *covered* cigars that are sold individually and not in a product package. Those cigars not meeting the definition of "covered cigars" would not be required to provide any warning statements on packages and in advertisements. The FDA requests comment about this special rule. (23,182)

The FDA's proposal includes information provided in a citizen petition submitted by the International Premium Cigar and Pipe Retailers Association (IPCPR). The petition asserts that premium cigars do not present a sufficient public health risk to warrant regulation, that most cigar users only smoke occasionally and thus the dose-response relationship is different than cigarette use, and that premium cigar users do not inhale and thus there is little public health benefit from the regulation of premium cigars.

15. The FDA requests any comments, data, and information regarding IPCPR's analysis of the National Cancer Institute's data or other data related to disease risk, nicotine addiction, and how premium cigars are used. (23,152)

## II. Flavored Tobacco Products

The FDA's proposal does not extend the current prohibition on characterizing flavors (except tobacco and menthol) in cigarettes to any of the newly-covered products. However, the FDA is soliciting the following information related to flavored tobacco products:

1. The prohibition against characterizing flavors established in the Tobacco Control Act applies to cigarettes only. Consequently, when this regulation is finalized and other tobacco products are deemed subject to the FDA's tobacco product authority, the statutory prohibition against characterizing flavors will not apply automatically to those products. However, once they are deemed, the FDA may establish a product standard prohibiting flavors in those products. The FDA requests information and data that would support establishing such a standard. (23,147)
2. Aside from this proposed rule, what additional actions, if any, should the FDA take to address the sale of candy and/or fruit-flavored tobacco products to children and young adults? For example, what data should the FDA request manufacturers submit in new tobacco product applications to establish that flavorants either do not raise different questions of public health, in the case of Substantial Equivalence reports, or are appropriate for the protection of public health in the case of premarket tobacco product applications? (23,147)
3. What is the likelihood that individuals who engage in flavored tobacco product use will initiate cigarette use and/or become dual users with cigarettes? (23,147)

4. Given the data showing a significant increase in e-cigarette usage among youth (Ref. 4) and the availability of fruit and candy-flavored nicotine liquids, what other regulatory actions should the FDA consider taking with respect to e-cigarettes? (23,157)
5. Does one's use of fruit and candy-flavored nicotine liquids impact the likelihood that such individual will initiate use of combustible tobacco products and/or become a dual user with combustible tobacco products? How should that affect the FDA's regulatory decisions regarding e-cigarettes? (23,157)

The FDA's proposal suggests that it may be possible that little cigars or e-cigarettes meet the statutory definition of the term "cigarette," which would allow the FDA to extend the current prohibition of characterizing flavors in cigarettes to little cigars or e-cigarettes.

Under Section 900(3) of the Food, Drug, and Cosmetic Act (FDCA) (the law amended by the Tobacco Control Act):

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.

This definition references the definition of 'cigarette' in the Federal Cigarette Labeling and Advertising Act. Under FCLAA:

(1) The term "cigarette" means--

(A) any roll of tobacco wrapped in paper or in any substance not containing tobacco, and

(B) any roll of tobacco wrapped in any substance containing tobacco 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 described in subparagraph (A).

Regarding these definitions, the FDA solicits the following information:

6. The FDA is aware that some tobacco products, such as e-cigarettes and certain cigars, are being marketed with characterizing flavors, and that these flavors can be especially attractive to youth. The prohibition against characterizing flavors established in the Tobacco Control Act applies to cigarettes only. The FDA requests comments on the characteristics or other factors it should consider in determining whether a particular tobacco product is a "cigarette" as defined in section 900(3) of the FDCA and, consequently, subject to the prohibition against characterizing flavors, despite being labelled as a little cigar or other non-cigarette tobacco product. The FDA is also seeking research regarding the long-term effects of flavored tobacco product usage including data as to the likelihood of whether users of flavored tobacco products initiate cigarette usage and/or become dual users with cigarettes. (23,144)

7. The FDA requests comments on the characteristics or other factors it should consider in determining whether a particular tobacco product is a "cigarette" as defined in section 900(3) of the FDCA and, consequently, subject to the prohibition against characterizing flavors, despite being labelled as a little cigar or other non-cigarette tobacco product. (23,147)

### **III. E-cigarettes**

The FDA's proposal makes no distinctions in the regulation of different product categories but given the relatively short period of time that e-cigarettes have been available in the United States, the FDA solicits the following information specific to e-cigarettes:

1. As noted in the proposed regulation, some have advanced views that certain new tobacco products that are noncombustible (such as e-cigarettes) may be less hazardous, at least in certain respects, than combustible products given the carcinogens in smoke and the dangers of secondhand smoke. The FDA also notes the increase in e-cigarette use by youth and the availability of fruit and candy-flavored e-cigarette liquid. The FDA does not currently have sufficient data about these products to determine what effects e-cigarettes have on the public health. Accordingly, the FDA is seeking comment as to how such products should be regulated. It particularly requests comments on behavioral data related to co-use of e-cigarettes and more traditional tobacco products, including data on the effects of e-cigarettes on the initiation and continuation of use of other tobacco products. (23,144)
2. The FDA is seeking comments, including supporting research, facts, and other evidence, as to how e-cigarettes should be regulated based on the continuum of nicotine-delivering products (as discussed in section III) and the potential benefits associated with e-cigarettes. (23,152)
3. Given the data showing a significant increase in e-cigarette usage among youth (Ref. 4) and the availability of fruit and candy-flavored nicotine liquids, what other regulatory actions should the FDA consider taking with respect to e-cigarettes? (23,157)

### **IV. Components, Parts & Accessories**

The FDCA's definition of the term "tobacco product" allows the FDA to regulate components, parts and accessories of tobacco products. The FDA has proposed that its statutory authority, such as the power to establish product standards, require registration by manufacturers and compile ingredient lists, cover all components and parts of tobacco products. However, the FDA has proposed to extend other requirements, such as the minimum purchase age requirements and the prohibition on sales through vending machines, to only those components and parts that contain nicotine. Moreover, the FDA's proposal would only require components and parts to be subject to the Act and the FDA would not regulate accessories. The proposal does not define the terms "component," "part," or "accessory." However, the proposal does explain how the FDA is interpreting these terms.

Components and Parts, as interpreted by the FDA:

Components and parts are included as part of a finished tobacco product or intended for consumer use in the consumption of a tobacco product. Components and parts that would be covered under this proposal include those items sold separately or as part of kits sold or distributed for consumer use or further manufacturing or included as part of a finished tobacco product. Such examples would include air/smoke filters, tubes, papers, pouches, or flavorings used for any of the proposed deemed tobacco products (such as flavored hookah charcoals and hookah flavor enhancers) or cartridges for e-cigarettes. (23,143)

Accessories, as interpreted by the FDA:

The FDA considers accessories of proposed deemed products to be those items that are not included as part of a finished tobacco product or intended or expected to be used by consumers in the consumption of a tobacco product. The FDA expects that they will not have a significant impact on the public health. In addition, the FDA considers accessories to be those items that may be used in the storage or personal possession of a proposed deemed product. Therefore, items such as hookah tongs, bags, cases, charcoal burners and holders, as well as cigar foil cutters, humidors, carriers, and lighters would be considered accessories and would not fall within the scope of the proposed rule.

Regarding these terms, the FDA is soliciting the following information:

1. The FDA is seeking comment on how its proposal to exclude accessories from the scope of the deeming rule would impact the public health. It is asking for comments, including supporting facts, research, and other evidence, as to whether the FDA should define components and parts of tobacco products and how those items might be distinguished from accessories of tobacco products. (23,144)
2. The FDA believes that applying the minimum age and identification restrictions to covered tobacco products only (and not to the components and parts that do not contain nicotine or tobacco) would be sufficient to protect the public health, because youth will not be able to use such components and parts and potentially suffer the consequences *without also* obtaining the covered tobacco product. In the event that the FDA determines it is appropriate for the protection of the public health to extend the restrictions in part 1140 (e.g. the minimum purchase age requirements) to components and parts that do *not* contain nicotine or tobacco in the future, the FDA will issue a new rulemaking and provide notice and opportunity to comment on such proceeding. The FDA seeks comment on this approach. Further, as stated throughout the proposed regulation, the FDA is not proposing to cover accessories of proposed deemed products within the scope of the deeming regulation and, therefore, accessories would not be subject to the additional restrictions in part 1140. (23,178)

## V. Premarket Review

The FDA's proposal would delay the enforcement of premarket review until twenty-four months after the rule would take effect. During that time period, manufacturers would be free to market new products so long as they submit an application to the FDA. After that time period ends, manufacturers could continue to market those products until the FDA issues an order prohibiting the marketing. (A similar process was established during the passage of the Tobacco Control Act

in 2009. As of the date of this publication, the FDA has only acted on the applications for 4 products; there are 3,396 outstanding applications pending at the FDA.)

The FDA solicits the following information regarding its enforcement of premarket review:

1. The statute establishes a “substantial equivalence” (SE) pathway for a new tobacco product to enter the market if it is substantially equivalent to a “predicate product,” meaning a product commercially marketed in the United States as of February 15, 2007. The FDA is aware of new product category entrants into the market after the February 15, 2007, reference date and that the SE pathway may not be available to these newer products. Because this date is written into the statute, the FDA does not believe that it has the authority to amend it with respect to e-cigarettes or other products. The FDA is proposing to extend the compliance period for submitting a marketing application under this pathway to 24 months following the effective date of a final rule. The FDA is also proposing a 24-month compliance period for the submission of premarket tobacco applications (PMTAs). In addition, the FDA intends to continue the compliance policy pending review of marketing applications if those applications are submitted within the 24 months after the final rule's effective date. The FDA is specifically seeking comment on whether and, if so, how the FDA should consider a different regulatory mechanism for newer proposed deemed tobacco products that cannot, as a practical matter, use the SE pathway. (23,144)
2. The FDA also is soliciting comment on what FDA actions or regulatory approaches, if any, should be taken for proposed deemed tobacco products that are “new tobacco products” under section 910(a)(1) of the FDCA. (23,174)
3. The FDA requests comment on whether there are ways that it might provide additional flexibility with respect to PMTAs that would still be appropriately protective of the public health. (23,175)
4. Should the FDA consider a different compliance policy for proposed deemed tobacco products that cannot, as a practical matter, use the SE pathway? If so, what should the compliance policy entail and would it benefit public health? Instead of, or in addition to, such a policy, should the FDA consider ways to expedite the review of some or all premarket applications for proposed deemed products? (23,176)
5. If the FDA does establish a compliance policy or an expedited review process, should the policy or expedited process apply to all proposed deemed products or only to certain categories of products, such as based on their relative impact on public health? Why or why not? For example, the FDA could establish factors based on certain categories of products and their relative impact on public health. The FDA could use these factors in guiding its enforcement policy. Examples of factors the FDA might take into account include whether the product is “non-combusted;” contains no tobacco leaf, but contains nicotine, such as some electronic cigarettes; is nonflavored; or is no or low nicotine. (23,176)
6. What other FDA actions or regulatory approaches, if any, should the FDA consider for products it is now proposing to regulate (“deemed tobacco products”) that are “new tobacco products” under section 910(a)(1) of the FDCA and why? (23,176)
7. The FDA is collecting information as to how it can streamline review of new product applications. The FDA expects that, in certain instances, it would be able to determine

that a product meets the requirements of section 910 of the FDCA using information that might be less burdensome for a manufacturer to gather and submit to the FDA. For example, in some cases, it is possible that an applicant may not need to conduct any new nonclinical or clinical studies, while in other cases, such as where there is little to no understanding of a product's potential impact, several nonclinical and clinical studies may be required for market authorization. Toward that end, the FDA is seeking comment on whether manufacturers of certain categories of products (e.g., those that contain fewer or substantially lower levels of toxicants, consistent with the continuum of nicotine-delivering products as discussed in section III) could support their applications, and allow the FDA to make its required findings under section 910 of the FDCA, with types of information that would be less burdensome to collect than information needed for other product categories. (23,176-77)

8. Is there anything else the FDA should consider to help expedite the application review for products that have fewer or substantially lower levels of toxicants that are seeking a marketing authorization under section 910 of the FDCA? (23,177)
9. The FDA is considering possible additional approaches to address this issue, including increasing the compliance policy period for SEs or PMTAs for new tobacco products. The FDA would also consider revising its compliance policy should the FDA find that doing so is warranted, such as to better protect the public health. In addition, the FDA may choose to implement this approach for only certain categories of proposed deemed products based on their impact on public health. It is considering other options as well to best address this issue in a manner that is appropriate for the protection of the public health. The FDA is seeking data, research, information, and comments on the previously referenced possible approaches. (23,177)

## VI. Compliance Dates

All of the statutory provisions of the FDCA will apply automatically upon the effective date of the final rule for the Deeming Regulation. The FDA has proposed to delay enforcement of many of these statutory provisions.

The FDA has created a table with all of the proposed delayed enforcement dates that begins on page 23,172 of the Federal Register Notice and is reproduced in the appendix to this document. The FDA solicits the following information regarding the delay in enforcing the Act:

1. The FDA recognizes that there may be the potential for varying levels of harm and negative effects on public health for different categories of tobacco products. The FDA is considering whether it might be appropriate for the protection of the public health to stagger the compliance dates for certain provisions for different categories of products. The FDA seeks comment on this issue. (23,144)
2. The FDA is seeking comment on the proposed compliance dates for the provisions listed in table 1B. (23,172)
3. Different categories of tobacco products may have the potential for varying levels of harm and negative effects on public health. As a result of the potential for differing effects on public health, the FDA is considering whether it might be appropriate to stagger the compliance dates for certain provisions for different categories of products.

For example, the FDA may opt to provide different compliance dates for certain automatic provisions (e.g., ingredient listing under section 904 of the FDCA, registration and listing under section 905, and hazardous and potentially hazardous constituent reporting under section 915) based on the negative public health effects known to be associated with certain products. In such cases, products with fewer known negative impacts might have additional time to comply with such provisions when compared with products with greater negative public health effects. The FDA requests comments, including supporting facts, research, and other evidence, regarding such an approach. (23,177)

4. The FDA would like comments on the following options that may help lessen the time and resources needed to comply with certain requirements:
  - a. Extending the compliance period to provide more time to gather the required information to be included in a regulatory submission information
  - b. If extending the compliance period would be beneficial, which provisions should be extended and why? Are there any public health concerns that would outweigh any delay in compliance dates?
  - c. If extending the compliance period is appropriate, how much more time should the FDA provide and why? (23,177)

## VII. Warning Labels

Current law requires nine rotating warnings for cigarettes and four rotating warnings for smokeless tobacco. The FDA's proposal establishes five new warning labels. All five would appear on any cigars that become the subject of FDA regulation while only one of those five would appear on all tobacco products that are not cigars, cigarettes or smokeless tobacco. The new proposed warning statements for cigars are:

WARNING: Cigar smoking can cause cancers of the mouth and throat, even if you do not inhale.

WARNING: Cigar smoking can cause lung cancer and heart disease.

WARNING: Cigars are not a safe alternative to cigarettes.

WARNING: Tobacco smoke increases the risk of lung cancer and heart disease, even in nonsmokers.

WARNING: This product contains nicotine derived from tobacco. Nicotine is an addictive chemical.

All tobacco products other than cigarettes and smokeless tobacco, will bear the following warning statement:

WARNING: This product contains nicotine derived from tobacco. Nicotine is an addictive chemical.

The FDA is soliciting the following information about these warning statements:

1. Some have advanced views that certain new tobacco products that are non-combustible (such as e-cigarettes) may be less hazardous, at least in certain respects,

- than combustible products given the carcinogens in smoke and the dangers of secondhand smoke. Nevertheless, all tobacco products containing nicotine are addictive, and the FDA is not currently aware of any tobacco products that do not contain nicotine. Thus, the FDA is seeking comments, including supporting research, facts, and other evidence, as to whether all tobacco products should be required to carry an addiction warning and, if yes, whether different warnings should be placed on different categories of products. (23,144)
2. The FDA is not proposing the fifth FTC warning (Tobacco Use Increases The Risk Of Infertility, Stillbirth And Low Birth Weight), because although cigarette smoke causes these health effects (and cigar smoke is similar to cigarette smoke), the FDA is not aware of studies specifically linking cigars to these reproductive effects. The FDA requests comment on its proposal to require the use of only four of the five current FTC warnings for cigars. (23,144)
  3. The FDA is proposing that any cigar that is sold in product packaging bear a health warning that would be randomly displayed and distributed on cigar product packages and rotated in advertisements. In addition, the FDA is proposing that warnings for cigars sold individually and not within product packages all be included on a sign located at the point-of-sale at each cash register in any retail establishment where such cigars are sold. The FDA requests comment as to whether all cigars sold without product packaging, including those cigars it refers to as “premium cigars,” should be exempt from the warning requirements. (23,145)
  4. The FDA is also seeking comment on the proposed addictiveness warning and any potential for consumer confusion, the proposed size of the health warnings that would be required by this rule, and on the role that the size of such warnings has in helping to convey consumer information. (23,145)
  5. The FDA requests comments on other possible methods (e.g., randomly assigning warning statements per individual cigar or Universal Product Code) to ensure that the warnings have a maximum public health impact by reaching as many individuals as possible yet do not grow stale from overuse. (23,163)
  6. The FDA is seeking comments, including supporting research, facts, and other evidence, as to whether all tobacco products should be required to carry the proposed addictiveness warning and if different warnings should be placed on different categories of products. (23,166)
  7. Do the words “tobacco product” in this proposed warning have the potential to cause confusion for consumers? If so, what are the product types where such a warning could potentially confuse consumers? (23,167)
  8. If there are concerns about the use of the word “tobacco product,” what other language should the FDA consider utilizing in this proposed warning? (23,167)
  9. Would such other proposed language still have the ability to notify consumers that certain products (especially those that look like candy) are, in fact, tobacco products and potentially harmful and/or addictive? (23,167)
  10. The FDA requests comment as to whether the proposed addictiveness warning also should cover other substances that may cause addiction. (23,180)

## Appendix

**Table 1B—Compliance Dates for Various Provisions**

FDCA citation	Provision	Compliance date
903(a)(2)	A tobacco product shall be deemed misbranded if in package form unless it bears a label containing—	24 months after the issuance of the final regulation.
	(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.	
903(a)(3)	A tobacco product is misbranded—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	Effective date of part 1100 PLUS 1 year.
903(a)(4)	A tobacco product is 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	Effective date of part 1100 PLUS 1 year.
903(a)(8)	A tobacco product is 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 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	Effective date of part 1100 PLUS 1 year.

FDCA citation	Provision	Compliance date
	product to the extent required in regulations which shall be issued by the Secretary after an opportunity for a hearing	
904(a)(1) and 904(c)(1)	(a)(1) 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(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).	Effective date of part 1100 PLUS 6 months (products on the market as of the effective date) or 90 days before delivery for introduction into interstate commerce (products entering the market after the effective date).
904(a)(3)	REQUIREMENT.—Each tobacco product manufacturer or importer, or agents thereof, shall submit to the Secretary the following information: (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 date of part 1100 PLUS 3 years.
904(a)(4)	REQUIREMENT.—Each tobacco product manufacturer or importer, or agents thereof, shall submit to the Secretary the following information: (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	Effective date of part 1100 PLUS 6 months (current manufacturers) or 90 days prior to delivery for introduction into interstate commerce (new manufacturers).
905(b), (c), (d), and (h)	905(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	If the final rule publishes in the second half of the calendar year, FDA will designate a date for owners and operators to register that is no later than 6 months into the subsequent calendar year. (The registration date will be specified in a

FDCA citation	Provision	Compliance date
	<p>into the subsequent calendar year by which registration under this subsection shall occur 905(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 905(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</p>	<p>draft guidance for registration.).The timeframes for paragraphs (c) and (d) take effect after the date specified for (b) occurs.</p>
905(i)(1)	<p>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;</p>	<p>Must submit at the time of initial registration; see date specified for 905(b).</p>
	<p>(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</p>	
	<p>(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.</p>	
907(a)(1)(B)	<p>(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</p>	<p>Effective date of part 1100 PLUS 2 years.</p>

FDCA citation	Provision	Compliance date
	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(b)(2)(A)(i) and (ii)	911(a)—IN GENERAL.—No person may introduce or deliver for introduction into interstate commerce any modified risk tobacco product unless an order issued under subsection (g) is effective with respect to such product.911(b)(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.	Use of “light,” “low,” and “mild” descriptors: Effective date of part 1100 PLUS 1 year (stop manufacture); Effective date of part 1100 PLUS 13 months (stop distribution).
	(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 descriptors light, mild, or low or similar descriptors; or	
	***	
	(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)	
920(a)(1)	(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'	24 months after the issuance of the final regulation.