4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1100, 1140, and 1143

[Docket No. FDA-2014-N-0189]

RIN 0910-AG38

Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to deem products meeting the statutory definition of "tobacco product," except accessories of a proposed deemed tobacco product, to be subject to the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). The Tobacco Control Act provides FDA authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, and any other tobacco products that the Agency by regulation deems to be subject to the law. Option 1 of the proposed rule would extend the Agency's "tobacco product" authorities in the FD&C Act to all other categories of products, except accessories of a proposed deemed tobacco product, that meet the statutory definition of "tobacco product" in the FD&C Act. Option 2 of the proposed rule would extend the Agency's "tobacco product" authorities to all other categories of products, except premium cigars and the accessories of a proposed deemed tobacco product, that meet the statutory definition of "tobacco

product" in the FD&C Act. FDA also is proposing to prohibit the sale of "covered tobacco products" to individuals under the age of 18 and to require the display of health warnings on cigarette tobacco, roll-your own tobacco, and covered tobacco product packages and in advertisements. FDA is taking this action to address the public health concerns associated with the use of tobacco products.

DATES: Submit either electronic or written comments on the proposed rule by [INSERT DATE 75 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 (the PRA) by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], (see the "Paperwork Reduction Act of 1995" section).

ADDRESSES: You may submit comments, identified by Docket No. FDA-2014-N-0189 and/or Regulatory Information Number (RIN) 0910-AG38, by any of the following methods, except that comments on information collection issues under the PRA must be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) (see the "Paperwork Reduction Act of 1995" section).

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name, Docket No. FDA-2014-N-0189, and RIN 0910-AG38 for this rulemaking. All comments received may be posted without change to http://www.regulations.gov, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the SUPPLEMENTARY INFORMATION section.

Docket: For access to the docket to read background documents or comments received, go to http://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Gerie Voss, Office of Regulations, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850-3229, 877-287-1373, CTPRegulations@fda.hhs.gov.

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Executive Summary

Purpose of the Proposed Rule

Cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco were immediately covered by FDA's tobacco product authorities in chapter IX of the FD&C Act (21 U.S.C. 387 through 387u) when the Tobacco Control Act went into effect. For other kinds of tobacco products, FDA has authority to issue regulations to bring them under the law by "deeming" them to be subject to such authorities. Consistent with the statute, once a tobacco

product is deemed, FDA may put in place "restrictions on the sale and distribution of a tobacco product," including age-related access restrictions and advertising and promotion restrictions, if FDA determines the restrictions are appropriate for the protection of the public health. The proposed rule has two purposes: (1) To deem products that meet the definition of "tobacco product" under the law except accessories of a proposed deemed tobacco product and subject them to the tobacco control authorities in the FD&C Act and (2) to apply specific provisions that are appropriate for the protection of the public health to deemed tobacco products. To satisfy these purposes, FDA is proposing two options (Option 1 and Option 2), which would provide two alternatives for the scope of the deeming provisions and, consequently, the application of the additional specific provisions.

Summary of the Major Provisions of the Regulatory Action

The proposed rule has two main sections: (1) Deeming provisions and (2) additional provisions to protect public health.

Deeming Provisions--Option 1 for the proposed rule would deem all products meeting the statutory definition of "tobacco product" except accessories of a proposed deemed tobacco product to be subject to FDA's tobacco product authorities under chapter IX of the FD&C Act. 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, and we expect that they will not have a significant impact on the public health. In addition, 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 this

proposed rule. Section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)), as amended by the Tobacco Control Act, defines the term "tobacco product" to mean "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product)."[1] Products that meet the statutory definition of "tobacco products" can include currently marketed products such as certain dissolvables, gels, hookah tobacco, electronic cigarettes, cigars, and pipe tobacco. Components and parts of tobacco products, but not their related accessories, would also be included in the scope of this proposed rule. 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. The proposed rule also deems any future tobacco products that meet the statutory definition of "tobacco product" except accessories of such product to be subject to FDA's authorities under chapter IX of the FD&C Act. For example, FDA envisions that there could be tobacco products developed in the future that provide nicotine delivery (e.g., via dermal or buccal absorption), similar to currently marketed medicinal nicotine products, but which are not marketed for therapeutic purposes. Such products would be "tobacco products" and subject to FDA's chapter IX authorities should the deeming rule be finalized.

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[1] FDA notes that products falling within the FD&C Act's definition of "tobacco product" may not be considered tobacco products for Federal excise tax purposes (see 26 U.S.C. 5702(c)).

FDA is also proposing a second option to deem only a subset of cigars (i.e., to exclude from the scope of this proposed rule certain cigars that we refer to as "premium cigars"). With respect to current products, while FDA recognizes that all cigars are harmful and potentially addictive, it has been suggested that different kinds of cigars may have the potential for varying effects on public health, based on possible differences in their effects on dual use, youth initiation and frequency of use by youth and young adults. Accordingly, FDA is seeking comment on these options to determine whether all cigars should be subject to deeming and what provisions of the proposed rule may be appropriate or not appropriate for different kinds of cigars.

In addition, FDA realizes that there are distinctions in the hazards presented by various nicotine-delivering products. Some have advanced views that certain new tobacco products that are noncombustible (such as e-cigarettes) may be less hazardous than combustible products given the carcinogens in smoke and the dangers of secondhand smoke from combustible products. Accordingly, FDA is seeking comment in this proposed rule as to how e-cigarettes should be regulated based on the continuum of nicotine-delivering products. We welcome comment on how to implement the provisions in the FD&C Act with respect to e-cigarettes. We also welcome any health and behavioral data about the effects of using e-cigarettes.

Once finalized, products deemed under this rule will be subject to the same FD&C Act provisions that cigarettes, roll-your-own tobacco, and smokeless tobacco are subject to, with respect to the following: (1) Enforcement action against products determined to be adulterated and misbranded; (2) required submission of ingredient listing and reporting of harmful and potentially harmful constituents (HPHCs) for all tobacco products; (3) required registration and product listing for all tobacco products; (4) prohibition against use of modified risk descriptors

(e.g., "light," "low," and "mild" descriptors) and claims unless FDA issues an order permitting their use; (5) prohibition on the distribution of free samples (same as for cigarettes); and (6) premarket review requirements. These actions would improve the public health by affording FDA critical information regarding the health risks of such products, preventing new products from entering the market if they are not appropriate for the protection of public health or found substantially equivalent to an identified predicate product, and reducing the use of misleading claims and descriptors about the relative risk of tobacco products, which may lead consumers to initiate tobacco product use or to continue using tobacco when they would otherwise quit.

Additional Provisions--In addition to the provisions in the FD&C Act that would apply automatically if the proposed products are deemed, FDA has the authority to invoke its other authorities under the Tobacco Control Act in regulating these products. At this time, under section 906(d) of the FD&C Act (21 U.S.C. 387f(d)), FDA proposes to apply three additional provisions to covered tobacco products: (1) Requirement for a minimum age of purchase; (2) health warnings for product packages and advertisements (which FDA is also proposing to apply to cigarette tobacco and roll-your-own tobacco); and (3) prohibition of vending machine sales, unless the vending machine is located in a facility where the retailer ensures that individuals under 18 years of age are prohibited from entering at any time. The term "covered tobacco products" would be defined as those products deemed to be subject to the FD&C Act under section 1100.2 of title 21 of the Code of Federal Regulations (CFR), other than a component or part that does not contain tobacco or nicotine.

Request for Public Comment--In addition to seeking comment on the overall proposed rule, FDA is specifically seeking comment on the application of the proposed rule to certain products or in certain circumstances, including the following:

1. As noted previously, given that different kinds of cigars may have the potential for varying effects on public health, FDA is proposing two options for the categories of cigars that would be covered by this rule. FDA is specifically seeking comment on whether all cigars should be subject to deeming and what provisions of the proposed rule may be appropriate or not appropriate for different kinds of cigars.

2. 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. 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 FD&C Act and, consequently, subject to the prohibition against characterizing flavors, despite being labelled as a little cigar or other non-cigarette tobacco product. 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.

3. Also as noted in this document, 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. FDA also notes the increase in e-cigarette use by youth and the availability of fruit and candy-flavored e-cigarette liquid. We do not currently have sufficient data about these products to determine what effects e-cigarettes have on the public health. Accordingly, FDA is seeking comment in this proposed rule as to how such products should be regulated. We particularly request comment 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.

4. FDA is proposing to deem those products meeting the definition of "tobacco product" in section 201(rr) of the FD&C Act, except the accessories of proposed deemed tobacco products to be subject to chapter IX of the FD&C Act. FDA is seeking comment on how its proposal to exclude accessories from the scope of the deeming rule would impact the public health. We also ask for comments, including supporting facts, research, and other evidence, as to whether FDA should define components and parts of tobacco products and how those items might be distinguished from accessories of tobacco products.

5. 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. 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, we do not believe that we have the authority to amend it with respect to e-cigarettes or other products. 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. FDA is also proposing a 24-month compliance period for the submission of premarket tobacco applications (PMTAs). In addition, we intend 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. FDA is specifically seeking comment on whether and, if so, how FDA should consider a different regulatory mechanism for newer proposed deemed tobacco products that cannot, as a practical matter, use the SE pathway.

6. 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. 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. FDA seeks comment on this issue.

7. FDA recognizes that some of the proposals in this document might impose significant costs on certain manufacturers, consistent with current practice under Federal Trade Commission (FTC) consent decrees with several large manufacturers, including the requirement to register and list products and the requirement for cigar manufacturers to randomly distribute and rotate warning statements on packages and advertisements, respectively. FDA seeks comment and data on alternative approaches for manufacturers to satisfy these requirements that would reduce costs for manufacturers yet would still be appropriate for the protection of the public health. We request comment on whether and how we should revise our existing guidance to provide for flexibility in this area, while still being appropriately protective of the public health.

8. 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 FDA is not currently aware of any tobacco products that do not contain nicotine. Thus, 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.

9. 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 Agency is not aware of studies specifically linking cigars to these reproductive effects. FDA requests comment on its proposal to require the use of only four of the five current FTC warnings for cigars.

10. 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, 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. FDA requests comment as to whether all cigars sold without product packaging, including those cigars we refer to as "premium cigars," should be exempt from the warning requirements.

11. As explained in the Initial Regulatory Flexibility Analysis, FDA finds that this rule would have a significant economic impact on a substantial number of small entities. FDA is seeking comments about any unique challenges faced by small manufacturers of proposed deemed tobacco products and how they should be addressed.

12. 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.

13. 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.

Effective Dates--The deeming provisions and age restrictions would be effective 30 days from the date of publication of the final rule. The proposed health warning requirements would be effective 24 months after the final rule is issued. In addition, manufacturers could continue to

introduce into domestic commerce existing inventory that may not contain the warning statements required under the final rule for an additional 30 days after the health warnings take effect.

Compliance Dates for PMTAs and SE Reports--As stated previously, we understand that, for some products, there may not be predicate products that were on the market as of February 15, 2007, to which to claim substantial equivalence. This may be particularly true for e-cigarettes and similar novel products. For this reason, we are proposing that these manufacturers who cannot use the SE pathway submit PMTAs to FDA no later than 24 months following the effective date of the final rule. We are also proposing a 24-month compliance period for the submission of SE reports. Therefore, FDA does not intend to initiate enforcement action against products on the market for failing to have made an appropriate submission until 24 months following the effective date of the final rule. If a manufacturer submits a PMTA or SE application for its affected products within the 24-month time frame, FDA does not intend to initiate action against those products for failing to have a marketing authorization unless and until such a time as we have responded to the application.

Costs and Benefits

The proposed rule consists of two coproposals, Option 1 and Option 2. The proposed Option 1 deems all products meeting the statutory definition of "tobacco product," except accessories of a proposed deemed tobacco product, to be subject to chapter IX of the FD&C Act. Option 1 also proposes additional provisions that would apply to proposed deemed products as well as to certain other tobacco products. The other coproposal, Option 2, is the same as Option 1 except that it exempts premium cigars. The proposed deeming action directly requires proposed deemed "tobacco products" to comply with the substantive requirements of chapter IX of the

FD&C Act and its implementing regulations. We expect that asserting our authority over these tobacco products will enable us to take further regulatory action in the future as appropriate; those actions will have their own costs and benefits and would, as is the case with all rulemaking, be subject to notice and comment.

The proposed rule would generate some direct benefits by providing information to consumers about the risks and characteristics of tobacco products, which may result in consumers reducing their use of cigars and other tobacco products or engaging in compensatory health behaviors. Other potential benefits follow from premarket requirements, which could prevent more harmful products from appearing on the market and worsening the health effects of tobacco product use. The proposed rule would impose costs in the form of registration, submission, labeling, and other requirements; other likely costs are not quantifiable based on current data. The quantified costs of the proposed rule are shown in Table 1A.

Table 1A.--Summary of Quantified Costs Over 20 Years

	Lower Bound (3%)	Primary (3%)	Upper Bound (3%)	Lower Bound (7%)	Primary (7%)	Upper Bound (7%)
Present Value Option 1	365.2	592.0	1,010.1	281.4	467.6	810.2
Present Value Option 2	304.0	476.4	779.2	233.8	375.0	622.6
Annualized Value Option 1	23.8	38.6	65.9	24.8	41.2	71.5
Annualized Value Option 2	19.8	31.1	50.8	20.6	33.1	54.9

I. Legal Authority

The Tobacco Control Act was enacted on June 22, 2009, amending the FD&C Act and providing FDA with the authority to regulate tobacco products (Pub. L. 111-31). Specifically, section 101(b) of the Tobacco Control Act amends the FD&C Act by adding a new chapter that provides FDA with tools to regulate tobacco products. Section 901 of the FD&C Act (21 U.S.C. 387a), as amended by the Tobacco Control Act, states that the new chapter in the FD&C Act (Chapter IX--Tobacco Products) applies "to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Secretary [of Health

and Human Services] by regulation deems to be subject to this chapter." Under the statute, to extend FDA's "tobacco product" authorities to other tobacco products not specifically enumerated in the statute, FDA must issue a regulation deeming them to be subject to the FD&C Act. With Option 1 of this proposed rule, FDA is proposing to deem all products meeting the statutory definition of "tobacco product" except accessories of a proposed deemed tobacco product to be subject to the FD&C Act. Option 2 would propose to deem a certain subset of cigars, as well as other products meeting the definition of "tobacco product," but excluding the accessories of a proposed deemed tobacco product. Section 201(rr) of the FD&C Act, as amended by the Tobacco Control Act, defines the term "tobacco product" to mean "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product)" that is not a drug, device, or combination product under the FD&C Act. This proposed rule would extend FDA's "tobacco product" authorities to products that meet the statutory definition of "tobacco product" in section 201(rr) of the FD&C Act (including the components and parts of a tobacco product), except the accessories of a tobacco product.

Section 903 of the FD&C Act provides that a tobacco product is misbranded unless "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--… (B) a brief statement of--(i) the uses of the tobacco product and relevant warnings, precautions, side effects, and contraindications." Under section 906(d)(1) of the FD&C Act, FDA may require restrictions on the sale and distribution of a tobacco product, if the Agency determines that "such regulation would be appropriate for the protection of the

public health." The finding as to whether "such regulation would be appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account--(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and (B) the increased or decreased likelihood that those who do not use tobacco products will start using such products."

Based on the available data on the addictiveness of nicotine (as discussed in section V.A), the known adverse health effects of some of the products covered by this proposed rule, such as certain cigars and waterpipes, the likelihood that users of these products could co-use or migrate to other tobacco products like cigarettes, and the risk that failure to act will reinforce consumers' existing confusion and misinformation about these products' safety or lack of harmfulness, FDA believes that the sale and distribution restrictions the Agency is proposing--minimum age and identification requirements (including vending machine requirements) and health warning requirements--meet the public health standard set forth in section 906(d) of the FD&C Act. Specifically, FDA has concluded that the restrictions would be appropriate for the protection of the public health with respect to the risks and benefits to the population as a whole, including the increased likelihood that existing users will quit using tobacco products and the decreased likelihood that new users will initiate tobacco product use. This determination is made on the basis of several factors. First, the available data on the addictiveness of nicotine suggests the adolescent brain is more vulnerable to developing nicotine dependence than the adult brain, that exposure to substances such as nicotine can disrupt brain development and have long-term consequences on executive cognitive function and on the risk of developing a substance abuse disorder and various mental health problems as an adult (Ref. 1), and this exposure to nicotine

can also have long-term results on decreasing attention performance and increasing impulsivity which could promote the maintenance of nicotine use behavior (id.). Second, some of the products covered by this rule, such as combustible products like cigars, pipes, and waterpipes, are known causes of adverse health effects, including certain cancers and heart disease (see section V.B). Third, there is the potential for users of products covered by this rule to migrate to cigarettes or other currently regulated products, and evidence shows extensive co-use. For example, in 2012, 32 percent of high school tobacco users had smoked cigarettes and cigars in the past 30 days (Ref. 2). Current cigarette smokers are also more likely to have been waterpipe and e-cigarette users than non-smokers (Ref. 3). In 2012, 80.5 percent of current high school e-cigarette users reported current conventional cigarette smoking (Ref. 4). We believe that if this rulemaking is finalized, its provisions may lead to a decline in youth initiation for covered products, such as waterpipes and e-cigarettes. If use of those products tends to lead to use of traditional cigarettes, this rule should avert that cigarette usage. Finally, there is the risk that failure to act will reinforce consumers' existing confusion and misinformation about these products' safety or lack of harmfulness.

II. Background for Deeming All Tobacco Products To Be Subject to the FD&C Act

Adolescence is the peak time for tobacco product use initiation and experimentation (Ref. 5). In recent years, new types of tobacco products, sometimes referred to as "novel tobacco products," have become an increasing concern to public health due, in part, to their appeal to youth and young adults. Currently, non-regulated tobacco products come in many forms, including electronic cigarettes, nicotine gels, and certain dissolvable tobacco products (i.e., those dissolvable products that do not currently meet the definition of "smokeless tobacco" in section 900(18) of the FD&C Act (21 U.S.C. 387(18)) because they do not contain cut, ground,

powdered, or leaf tobacco and instead contain nicotine extracted from tobacco). These products are widely available. Electronic cigarettes (or e-cigarettes), for example, are widely available in retail outlets such as kiosks in shopping malls and on the Internet and their online popularity has surpassed that of snus and nicotine replacement therapies which have been on the market far longer than e-cigarettes (Refs. 6 and 7).

Additionally, young adults often mistakenly think non-cigarette tobacco products are safe alternatives to cigarettes (Ref. 8). Research has shown that youth are also particularly vulnerable to the appeal of novel tobacco products (Refs. 9, 10, 11, and 12). Because of their addictiveness and the marketing and sale of these products (and their subsequent use by youth), some non-cigarette tobacco products can introduce youth into a lifetime of addicted tobacco product use and related harms, including premature death (Refs. 13, 14, 15, and 16).

Further, many of the products proposed to be covered by this rule are offered in fruit and candy flavors, such as chocolate and grape flavors, making them especially attractive to children and young adults. For example, from 2010 to 2012, one cigar company introduced grape, white grape, and blueberry flavors to its line of little cigars and cigarillos (Ref. 17). In 2012, a manufacturer of nicotine solutions for e-cigarettes introduced Mint Mocha and Spiced Apple Cider flavors for their e-cigarette solutions (id.).

The first nationally representative study (derived from more than 4,000 young adults aged 18 to 34) to examine the prevalence of the use of flavored tobacco products following the 2009 FDA flavor ban in cigarettes found that 20 percent of tobacco users in the study currently use a flavored tobacco product (Ref.17). The most common flavored products include flavored pipe tobacco, little cigars, and hookah tobacco (id.). Research has shown that flavored product use is higher among 18-to-24-year-olds than 25-to-34-year-olds, and that sugar preference is

strongest among youth and young adults and declines with age (id.). Such findings indicate that flavored product use may influence tobacco-use patterns in young adulthood, a critical period when lifelong patterns of tobacco use are often established (Ref. 17 citing Ref. 18). See section V.A for further discussion regarding the impact of nicotine on youth and young adults. See also section V.B for a description of health risks associated with the proposed deemed tobacco products. Given this initial data regarding the increased prevalence of flavored tobacco products following the 2009 flavored cigarette ban, FDA seeks comments, data, and research regarding the following:

- Aside from this proposed rule, what additional actions, if any, should FDA take to address the sale of candy and/or fruit-flavored tobacco products to children and young adults? For example, what data should 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 SE reports, or are appropriate for the protection of public health in the case of premarket tobacco product applications?
- What is the likelihood that individuals who engage in flavored tobacco product use will initiate cigarette use and/or become dual users with cigarettes?
- 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 FDA's tobacco product authority, the statutory prohibition against characterizing flavors will not apply automatically to those products. However, once they are deemed, FDA may establish a product standard prohibiting flavors in those products. FDA requests information and data that would support establishing such a standard.

FDA is concerned that manufacturers may be labeling, packaging, or otherwise representing tobacco products that are, in fact, cigarettes to be little cigars, cigarillos, or similar products in order to evade the prohibition against characterizing flavors in cigarettes. 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 FD&C Act and, consequently, subject to the prohibition against characterizing flavors, despite being labelled as a little cigar or other non-cigarette tobacco product.

Moreover, efforts to improve public health by reducing the prevalence of cigarette smoking may be undermined by tobacco users switching to other tobacco products. The scientific evidence remains as yet unclear what the public health impact will be from products such as e-cigarettes. More youth who report they would never have used a tobacco product are experimenting with e-cigarettes (Ref. 4, 18); the number of cigarette smokers who actually quit tobacco product use with e-cigarettes is low (Ref. 19); current cigarette users experimenting with e-cigarettes have become dual users (id.)--with unknown health impacts. Although the health consequences of e-cigarettes are not well understood because of their relatively new entrance into the market, the health concerns and addictive properties of other tobacco products have been widely recognized in Surgeon General Reports and scientific literature.

When similar products are taxed or regulated differently, substitutions across products occur. For example, industry documents indicate that tobacco firms have been aware of disparities in the legal treatment of cigarettes and cigars and have made efforts to develop small cigars that cigarette smokers would smoke (Refs. 20 and 21). Sales of small cigars quadrupled in

the early 1970s, when cigars were taxed at a much lower rate than cigarettes and cigarette (but not small cigar) advertisements were banned from television and radio (Ref. 21).[2]

This substitution is evidenced in the recent trends regarding cigarette consumption compared to the use of other combustible tobacco products (e.g., small and large cigars, pipe tobacco, and roll-your-own tobacco). For example, the Centers for Disease Control and Prevention (CDC) reported a 32.8 percent decrease in cigarette consumption between 2000 and 2011, while the consumption of non-cigarette combustible products increased from 15.2 billion "cigarette equivalents" (i.e., small cigars and large cigars, and per-cigarette equivalents for pipe tobacco and roll-your-own tobacco) to 33.8 billion--a 123.1 percent increase over the same time period (Ref. 22). Pipe tobacco consumption during this period increased 482.1 percent, and consumption of large cigars increased 233.1 percent (id.). This research suggests that recent changes in consumption of non-cigarette combustible products, particularly increases in large cigar and pipe tobacco use, are associated with a decline in cigarette consumption, and indicate that certain cigarette smokers may switch to non-cigarette combustible products (id. at 567). While researchers posited that this change in prevalence rates is likely due to the lower taxes (and ultimately lower cost to the consumer) (id. at 566), the lack of regulation over certain tobacco products may be a contributing factor. Without a common regulatory framework, tobacco firms can exploit differences in regulatory requirements to drive consumers to different product markets.

[2] FDA notes that taxation falls under the jurisdiction of the U.S. Department of Treasury/Alcohol and Tobacco Tax and Trade Bureau (TTB) and that neither FDA's act of "deeming" nor any other FDA regulations directly affect the taxation of any tobacco product.

III. Continuum of Nicotine-Delivering Products

There are public health questions and concerns about currently unregulated tobacco products. Nevertheless, there are distinctions in the hazards presented by various nicotine-delivering products. Some have advanced views that certain new non-combustible tobacco products (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. To the extent that certain products are shown to be less harmful, they could help reduce the overall death and disease toll from tobacco product use at a population level in the United States. This is a function of the existence of a continuum of nicotine-delivering products that pose differing levels of risk to the individual.

Cigarette smoking is the major contributor to the death and disease attributable to tobacco use. The challenge for FDA, in considering currently regulated products and any additional products that would be deemed to be subject to the FD&C Act, is that regulatory policy under the Tobacco Control Act must account for the net public health impacts at the population level. This includes impacts on initiation, cessation, and an evaluation of product harm.

Emerging technologies such as the e-cigarette may have the potential to reduce the death and disease toll from overall tobacco product use depending on who uses the products and how they are used. If such products result in minimal initiation by children and adolescents while significant numbers of smokers quit, then there is a potential for the net impact at the population level to be positive. If, on the other hand, there is significant initiation by young people, minimal quitting, or significant dual use of combustible and non-combustible products, then the public health impact could be negative.

FDA is aware that some e-cigarettes (as well as other products that would be deemed under this proposed rule) are being marketed with flavors that may be attractive to young people. FDA asks for comments, data, and research to determine whether the Agency's evaluation of the relative risk or potential for harm reduction of such a product should be different in the presence of flavors in these products, especially if there is evidence that these flavors make the products more attractive to children. Because e-cigarettes are not currently subject to FDA jurisdiction (unless they are marketed for therapeutic purposes), FDA currently lacks the authority to collect vital information about these products. Deeming these products would permit us to collect information about their ingredients to ensure that other potentially harmful constituents are not present. Deeming would also allow us to collect information regarding health and behavioral effects of these products.

IV. Deeming Tobacco Products To Be Subject to the FD&C Act

At this time, based on the statute, cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco are subject to the self-executing provisions in the Tobacco Control Act, including: (1) General controls (e.g., registration, product listing, ingredient listing, user fees for certain products, and adulteration and misbranding provisions) and (2) premarket review requirements for certain products. See, e.g., sections 902 (adulteration provisions), 903 (misbranding provisions), 904 (ingredient listing), 905 (registration and product listing), 910 (premarket review for "new" "tobacco products"), 911 (premarket review for "modified risk tobacco products"), and 919 (user fees) of the FD&C Act (21 U.S.C. 387b, 387c, 387d, 387e, 387j, 387k, and 387s). This proposed rule would apply these FD&C Act provisions that are currently applicable to cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco to other tobacco products meeting the statutory definition of tobacco product. Option 1

would apply this proposed rule to all products meeting the statutory definition of "tobacco product," except accessories of a proposed deemed tobacco product, to be subject to the FD&C Act. Option 2 would propose to deem a certain subset of cigars (not including premium cigars), as well as other products meeting the definition of "tobacco product," but excluding the accessories of a proposed deemed tobacco product. These two options, as well as FDA's definition of a "covered cigar," are further discussed in section IV.C. FDA requests comments, data, and research as to which option should be utilized for the scope of this rule and, if Option 2 is selected as the scope of the final rule, the appropriateness of the definition of "covered cigar."

A. Public Health Benefits of Deeming

Deeming "tobacco products" (except accessories) to be subject to the FD&C Act would result in significant benefits for the public health. Once deemed, tobacco products become subject to the FD&C Act and its implementing regulations, affording FDA additional tools to use to reduce the number of illnesses and premature deaths associated with the use of tobacco products. For example, it would provide FDA with critical information regarding the health risks of the proposed deemed tobacco products including information derived from ingredient listing submissions and reporting of hazardous and potentially hazardous constituents required under the FD&C Act. Deeming would provide FDA with information on the location and number of regulated entities and allow the Agency to establish effective compliance programs. Deeming also would help to correct consumer misperceptions, due to variations in the regulatory status of tobacco products, that tobacco products not currently regulated by FDA are safe alternatives to currently regulated tobacco products (see section V.C). In addition, it would reduce the use of misleading claims on the products to allow for better-informed decision-making by consumers and would prohibit these products from being targeted to youth populations. It would prevent

new products from entering the market that are not appropriate for the protection of public health or are not substantially equivalent to a predicate product already on the market. Newly deemed tobacco products also may be subject to future regulations if FDA determines that such regulation would be appropriate for the protection of the public health (section 906(d) of the FD&C Act).

The following public health benefits would result directly from the deeming provisions of this proposed rule:

- Adulteration and misbranding prohibited for all tobacco products (section 902 and 903 of the FD&C Act): Applying sections 902 and 903 of the FD&C Act would ensure that every tobacco product meets the same basic requirements and ensure that the labeling of such products is not false or misleading. FDA would be able to take enforcement action against any tobacco products that did not meet these basic standards. For example, if a product was produced in insanitary conditions or was contaminated, or if its labeling contained a misleading claim, it would be subject to FDA enforcement action, including seizure or injunction.

- Requirement for ingredient listing and reporting of HPHCs for all tobacco products (section 904 of the FD&C Act): Under this requirement, manufacturers and importers of all tobacco products would provide ingredient listings and reporting of HPHCs to FDA. FDA would be able to take enforcement action with respect to those tobacco products for which an ingredient listing or report of HPHCs was not provided. Ingredient listings and reports of HPHCs would assist FDA in better understanding the contents of regulated products and their health consequences. That information would assist FDA in assessing potential health risks and determining if future regulations to address the health risks posed by particular products are warranted. However, FDA recognizes that it could be difficult for manufacturers of certain

proposed deemed products (e.g., small businesses) to fulfill these requirements. Accordingly, FDA requests comments as to whether smaller manufacturers may be unable to satisfy these requirements and how FDA might be able to address those manufacturers' concerns.

- Requirement for registration and product listing (section 905 of the FD&C Act): With application of this requirement, FDA would require registration of all tobacco product manufacturing establishments and product listings for all tobacco products. FDA would be able to conduct more efficient inspections and bring enforcement action, if necessary, against a tobacco firm not in compliance with the requirements of the Tobacco Control Act. While this requirement would provide FDA with critical information, the Agency also recognizes that it could be costly for certain manufacturers of proposed deemed products. Therefore, FDA requests comment and data on possible ways to implement this requirement (e.g., delaying compliance with this provision) that would reduce costs for manufacturers yet still be appropriate for the protection of public health.

- Review of premarket applications and SE reports (section 905 and 910 of the FD&C Act): With the SE pathway, FDA can evaluate whether a new product raises different questions of public health compared to its predicate product. Through the premarket application pathway, FDA could authorize the introduction of products into the market where appropriate for the protection of public health and prevent introduction of products that are detrimental to the public health.

Implementation of these proposed provisions would allow FDA to monitor product development and changes and to prevent more harmful or addictive products from reaching the market. The proposed provisions would also provide a mechanism through which those products that are less harmful or addictive could enter the market. The greater regulatory certainty created

by premarket authorizations should help companies to invest in creating novel products, with greater confidence that improved products will enter the market without having to compete against equally novel, but more dangerous products. For example, a company wishing to invest the additional resources needed to ensure that its e-cigarette is designed and manufactured with appropriate methods and controls will be more likely to do so if the product is not competing against products that are more cheaply and crudely made, yet appear to be identical to the consumer. FDA, through its authorities to authorize and deny the introduction of new products, can help reduce tobacco-related morbidity and mortality. Over time, the employment of the premarket authorities can spur innovation and help to create a market where available products are less dangerous when consumed, less likely to lead to initiation of tobacco use, and/or easier to quit.

Further, FDA's premarket review of the proposed deemed products will increase product consistency. For example, FDA's oversight of the constituents of e-cigarettes cartridges would help to ensure quality control relative to the chemicals and their quantities being aerosolized and inhaled. At present, there is significant variability in the concentration of chemicals amongst products--including variability between labeled content and concentration and actual content and concentration. The health consequences of these products are still largely unknown and the popularity of these products is growing exponentially (Refs. 23, 24, and 25). Without a regulatory framework, users who expect consistency in these products may instead be subject to significant variability in nicotine content among products, raising potential public health and safety issues.

- Elimination of "light," "low," and "mild" descriptors and other unproven modified risk claims (section 911 of the FD&C Act): Applying this requirement to proposed deemed

products would help reduce consumer confusion and misconceptions about such products. Congress has concluded that the health dangers of tobacco products marketed as modified risk tobacco products that "do not in fact reduce risk" are "so high" that FDA's premarket review is necessary to protect public health and ensure that such products will reduce health risks (section 2(39), (40), and (43) of the Tobacco Control Act). Given that certain users have initiated and continued using certain tobacco products rather than others (or quitting entirely) based on unproven modified risk claims and consumers' unsubstantiated beliefs that some tobacco products are less hazardous than others, this requirement could lead to increased cessation and reduced initiation.

- Prohibition of free samples of the proposed deemed products (section 102 of the Tobacco Control Act): This prohibition would eliminate a pathway for youth to access tobacco products, reducing youth initiation and therefore short-term and long-term morbidity and mortality resulting from these products. The Institute of Medicine (IOM) has stated that free samples of cigarettes "encourage experimentation by minors with a risk free and cost-free way to satisfy their curiosity" (Ref. 26). While the IOM was speaking in the context of cigarettes, the same rationale would apply to the proposed deemed products. In addition, the United States Court of Appeals for the Sixth Circuit previously recognized that FDA has provided "extensive" evidence that free tobacco samples constitute an "easily accessible source" for youth (Discount Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509, 541 (6th Cir. 2012) (citing 61 FR 44396 at 44460, August 28, 1996), cert. denied, 133 S. Ct. 1966 (2013)). FDA requests comments and data showing the extent to which this restriction would reduce youth use of the proposed deemed products.

- Authority to propose product standards for proposed deemed tobacco products (section 907 of the FD&C Act (21 U.S.C. 387g)): If products meeting the definition of tobacco products are deemed to be subject to the tobacco authorities in the FD&C Act, FDA would have the authority to propose product standards that would apply to proposed deemed tobacco products, if such standards were appropriate for the protection of public health. For example, FDA could issue a standard regarding additives, constituents, or other components of a proposed deemed tobacco product under section 907 of the FD&C Act. This would help to ensure that tobacco products meet standards that are appropriate for the protection of the public health.

B. The Sottera Decision

In 2008 and early 2009, FDA detained several shipments of electronic cigarettes and their accessories offered for import by Smoking Everywhere and Sottera, Inc. (doing business as NJOY) and eventually refused admission into the United States to two of Smoking Everywhere's shipments on the ground that the products appeared to be unapproved drug/device combination products. Smoking Everywhere--subsequently joined by Sottera, Inc.--sued the Agency and argued, among other things, that the Supreme Court's decision in Food & Drug Administration v. Brown & Williamson Tobacco Corp., 529 U.S. 120 (2000) foreclosed regulation of electronic cigarettes under the drug and device provisions of the FD&C Act unless the products were intended for therapeutic use. The district court agreed and issued a preliminary injunction. (See Smoking Everywhere, Inc. v. FDA, 680 F. Supp. 2d 62 (D.D.C. 2010).) The government appealed this decision to the United States Court of Appeals for the D.C. Circuit.

On December 7, 2010, the D.C. Circuit affirmed the preliminary injunction, holding that products meeting the FD&C Act's definition of "tobacco product," including electronic cigarettes, are "drugs" and/or "devices" under the FD&C Act if they are "marketed for

therapeutic purposes," whereas "customarily marketed tobacco products" are "tobacco products" under the Tobacco Control Act. (See Sottera, Inc. v. Food & Drug Administration, 627 F.3d 891 (D.C. Cir. 2010).) On January 24, 2011, the D.C. Circuit denied the government's petitions for rehearing and rehearing en banc (by the full court). (See Sottera, Inc. v. FDA, No. 10-5032 (D.C. Cir. Jan. 24, 2011) (per curiam).) This case affirms that FDA cannot regulate "customarily marketed" tobacco products, including pipe tobacco, small and large cigars, e-cigarettes, and hookah tobacco, until a regulation that deems them to be subject to the FD&C Act is finalized.

On April 25, 2011, FDA issued a letter to stakeholders announcing that the government had decided not to seek further review of the Sottera decision and that it would comply with the jurisdictional lines established by Sottera (see Ref. 27). The Agency noted that the Tobacco Control Act places certain "tobacco products" (i.e., cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco) immediately under the general controls and premarket review requirements of the FD&C Act (see section 901(b) of the FD&C Act). The Tobacco Control Act also permits FDA, by regulation, to extend those controls to other categories of "tobacco products" (id.). Further, the stakeholder letter announced FDA's intention to propose a regulation that would extend the Agency's "tobacco product" authorities in the FD&C Act to other categories of tobacco products that meet the statutory definition of "tobacco product" in section 201(rr) of the FD&C Act.

C. Options for Premium Cigars and Request for Comments Regarding Scope

As discussed in sections V and VI, although all cigars are harmful and potentially addictive, it has been suggested that different kinds of cigars (e.g., small cigars, cigarillos, large cigars, premium cigars) may have the potential for varying effects on public health, if there are differences in their effects on youth initiation, the frequency of their use by youth and young

adults, and other factors. In addition, the proportion of cigar smokers showing clear signs of dependence remains unknown, and usage patterns indicate that cigar only use beginning in adulthood is less likely to produce addiction than the use of cigarettes. Thus, by proposing two options for the scope of this rule, FDA is seeking comment on whether all cigars should be subject to deeming and what additional restriction(s) may or may not be appropriate for different kinds of cigars. In particular, FDA is seeking comment on the relative merits of Option 1 versus Option 2, taking into account what is appropriate to protect the public health, including possible benefits to the public health or possible negative public health consequences of adopting one Option or the other.

Under Option 1, the proposed rule would extend FDA's authority to all products meeting the definition of "tobacco product," except the accessories of such products. (See section IV.E for more information regarding FDA's proposal not to include accessories in the scope of this rule). This scope would include all cigars, including small, large, and premium cigars. FDA considers a cigar to be a tobacco product that: (1) Is not a cigarette and (2) is a roll of tobacco wrapped in leaf tobacco or any substance containing tobacco. (See 26 U.S.C. 5702(a)).

Under Option 2, the proposed rule would extend FDA's authority to a subset of cigars (defined as "covered cigars") and to other products meeting the definition of "tobacco product," except the accessories of such products. In order to define the products that would be subject to this approach, FDA would propose to define a covered cigar to mean: any cigar as defined in this part, except a cigar 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.

While FDA is proposing this second option to possibly define a subset of cigars and provide a separate regulatory regime for them, FDA may determine that it is most appropriate to include elements of both options in any final rule. For example, FDA may decide to deem all cigars subject to the tobacco product authorities in Chapter IX of the FD&C Act but may impose different additional restrictions for a certain subset of those cigars. We ask for comments, including supporting facts, research, and other evidence, on the following questions regarding this issue:

- 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?
- 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"?
- 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.
- 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 we were to include this restriction, what should the rate be? How would FDA determine compliance with such a restriction?

- Is it appropriate to include the proposed weight restriction (6 pounds per 1000 units) in differentiating "premium" cigars from other cigars?
- 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)?
- How should the fact that studies indicate that young adults likely prefer cigarillos, as opposed to traditional large cigars, affect FDA's decision about whether to regulate "premium" cigars?

Although the Agency is proposing a definition with respect to Option 2, FDA remains concerned that any attempts to create a subset of premium cigars that are excluded from regulatory authority might sweep other cigar products under its umbrella. Therefore, we ask for any comment as to how FDA could further refine this definition, 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.

1. Option 1: Do Not Restrict Categories of Cigars

Under Option 1, FDA would not restrict the categories of cigars that fall under the umbrella of deeming and the additional provisions proposed here (i.e., minimum age and identification; vending machine restrictions; and health warning requirements). Therefore, small,

large, and premium cigars would all be subject to FDA's tobacco product authorities under this option.

As FDA has explained throughout the rule, all cigars are harmful and potentially addictive (including small cigars, cigarillos, large cigars, and premium cigars). Cigar smoking is strongly related to certain cancers (including oral, esophageal, laryngeal, and lung cancers), heart disease, and premature death (Refs. 28 and 30). Cigar smoking can cause cancers of the mouth and throat even for smokers who do not inhale (Ref. 28 at 120-130). As a result, cigar smokers who do not inhale have disease risks higher than those who have never smoked, including a 7 to 10 times higher overall risk of mouth and throat cancer (Ref. 28 at ii, 125). This similarity in risk is likely due to the similar doses of tobacco delivered directly to the oral cavity and esophagus by cigars and cigarettes (Ref. 30 at 738). In addition, cigar smokers, regardless of whether they inhale, receive a high smoke exposure to the mouth and tongue. The esophagus is exposed to the carcinogens of tobacco smoke, which collect on the mouth's surface and are swallowed with saliva, rendering cigar smoking a cause of esophageal cancer (Ref. 28 at 130). See section VII.E for further discussion of the dangerous health risks associated with cigar smoking, including data regarding risks of additional cancers and disease.

Cigar tobacco contains nicotine in concentrations similar to those observed in cigarettes; however, given that most cigars contain more tobacco, many typically contain greater quantities of nicotine than cigarettes (Ref. 28 at 81). A large cigar may contain as much tobacco as a whole pack of cigarettes (Refs. 30 and 31). Nicotine levels in cigar smoke can be up to 8 times higher than levels in cigarette smoke--1.7 mg in nonfiltered cigarettes, 1.1 mg in filtered cigarettes, 3.8 mg in little cigars, 9.8 mg in cigars, and 13.3 mg in premium cigars (Ref. 28 at 67). Even cigar

smokers who do not inhale can become addicted to the product given the absorption of nicotine through the buccal mucosa (Ref. 28 at 183-184).

Regardless of whether large cigar and pipe smokers inhale, smoke particles are deposited into the lungs and stomach area (Ref. 32). All cigars, regardless of size, produce higher levels of carcinogenic tobacco-specific nitrosamines per gram in mainstream cigar smoke than cigarettes produce in mainstream cigarette smoke (Ref. 28 at 75-76). A large cigar may contain as much tobacco as a whole pack of cigarettes (Refs. 30 and 31). Cigar smoke also produces measurable amounts of lead and cadmium (Ref. 28 at 75-76), and the concentrations of some toxic and carcinogenic compounds are higher in cigar smoke than in cigarettes (Ref. 33). The National Cancer Institute (NCI) found that "cigar smoke is as, or more, toxic and carcinogenic than cigarette smoke; and differences in disease risks produced by using cigarettes and cigars relate more to differences in patterns of use, and differences in inhalation, deposition and retention of cigar smoke than to differences in smoke composition" (Ref. 28 at 3).

Furthermore, a recent analysis of cigar use by young adults (aged 18 to 29) was presented at the meeting of the Society for Research on Nicotine and Tobacco providing preliminary confirmation that young adults do use premium cigars. This analysis was derived from data from the National Adult Tobacco Survey, a nationally representative survey conducted by the Centers for Disease Control and Prevention (CDC). The analysis shows that the percentage of young adults reporting current premium cigar use (15.1 percent) was just as high as the percent reporting current use of little filtered cigars (11.9 percent) (Ref. 34). Although the patterns of use may be quite different, this analysis shows that current premium cigar use is being reported by young adults and that such use is not restricted to older adults. In addition, among all young adults aged 18 to 29, 2.5 percent reported current use of premium cigars, compared with 1.7

percent among those aged 30 to 44, 1.2 percent among those aged 45 to 64, and 0.4 percent among those aged 65 and over (id.). Given that this analysis has not yet been included in a peer reviewed journal, FDA is including this analysis in the docket and specifically requests comment on it.

Under this option, FDA is proposing that all cigars be treated in a similar manner and that they all be deemed to be subject to FDA's authorities in the FD&C Act as well as the additional provisions proposed under this rule.

2. Option 2: Restrict Rule to Covered Cigars

FDA has heard from numerous interested parties, including manufacturers and retailers of premium cigars, on issues related to how premium cigars should be regulated. Some have contended that usage patterns of certain types of cigars (typically known as premium cigars) can vary dramatically from usage patterns of other cigars. They claim that the premium cigars category includes cigars that are used on celebratory occasions only a few times per year. In order to evaluate this contention and determine the proper scope for this rule, FDA has attempted to define the category of premium cigars by defining "covered cigar" and excluding what might be considered "premium cigars" from that definition. As stated throughout this section, FDA requests comment on its proposed definition of a "covered cigar."

Although FDA recognizes that all cigars are potentially addictive, the ability of cigars to deliver nicotine at a level capable of producing dependence is based on the degree of cigar smoke inhalation, the rate of oral nicotine absorption, the development of tolerance to nicotine, the age of initiation, and the duration of exposure (Ref. 28 at 183). The proportion of cigar smokers showing clear signs of dependence also remains unknown (Ref. 28 at 189). Some

members of industry have noted that these factors suggest that those who smoke certain types of cigars are not addicted to them.

In addition, as explained in section VII.D, young adults appear to be particularly interested in cigarillos, rather than large cigars. It has been suggested that adolescents are not attracted to large and premium cigars, because they are offered for sale at a much higher cost relative to other types of tobacco products and are more difficult to access (e.g., large and premium cigars are typically sold at tobacconists' shops versus convenience stores). This is supported by the study of youth use of cigars by the Office of Inspector General for the Department of Health and Human Services which states that "[m]anufactured cigars, rather than premium cigars, are most commonly used by teens due to their ease of purchase, low cost …." (Ref. 35). Some industry representatives have stated that there is "no evidence to suggest that premium cigar use is increasing among youths" (FDA-2011-P-0623). They also question whether adolescents use cigars, citing to the NCI Monograph No. 9, which states that "[f]ew surveys have questioned cigar smokers about the quantity and type of cigars typically consumed" (Ref. 28).

The International Premium Cigar and Pipe Retailers Association (IPCPRA), in its citizen petition seeking to exempt large and premium cigars from FDA regulation, acknowledged that a premium, hand-rolled cigar may be a "tobacco product" under the Act, but "there is no evidence to suggest that it carries anywhere near the public health risks of a cigarette." (FDA-2011-P-0623). Therefore, they claim that premium cigars are not a public health problem requiring FDA regulation.

To support this argument, the IPCPRA notes that NCI has remarked about the dose-response relationship between the numbers of cigars smoked and the risk of disease, stating that

"as many as three-quarters of cigar smokers smoke only occasionally … [and t]his difference in frequency of exposure translates into lower disease]." (id.). In addition, they note that the health risk tables in NCI's Monograph No. 9 refer to those who smoke 1-2 cigars per day and, therefore, the NCI Monograph does not even provide health risk data for the 75 percent majority of smokers who NCI identifies as "occasional" cigar smokers. They also state that "smokers of 1-2 cigars per day are at no greater risk statistically … for risk of numerous cancers, coronary heart disease, chronic obstructive pulmonary disease (COPD), and cerebrovascular disease." (FDA-2011-P-0623). Moreover, given the difference in inhalation patterns between cigarettes and cigars smokers noted by NCI, the IPCPRA claimed that the vast majority of premium cigar smokers are occasional users who do not inhale and, therefore, there would be little public health benefit if FDA were to regulate premium cigars. FDA requests any comments, data, and information regarding IPCPRA's analysis of this NCI data or other data related to disease risk, nicotine addiction, and how premium cigars are used.

D. Request for Comments Regarding Regulation of E-Cigarettes

FDA realizes that while all tobacco products are potentially harmful and potentially addictive, different categories of tobacco products may have the potential for varying effects on public health. For example, some have advanced views that certain new non-combustible tobacco products (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.

FDA is aware of the recent significant increase in the prevalence of e-cigarette use and continues to research how e-cigarette use is impacting the public health. In a computer-based mail-in survey of more than 10,000 U.S. adults, the prevalence of those who had ever used e-cigarettes (referred to as "ever use") quadrupled from 2009 to 2010 (Ref. 25). In 2011, 6.2

percent of all adults and 21.2 percent of current smokers had ever used e-cigarettes, representing an almost two-fold increase from 2010 estimates (Ref. 24). Data from Wave 8 of the International Tobacco Control (ITC) Four-Country Survey (collected from July 2010 to July 2011) indicated that 20.4 percent of those aware of e-cigarettes had reported trying the product (Ref. 36).

The numbers of individuals that have tried e-cigarettes in the previous 30 days also are indicative of the recent popularity of these products. An analysis of data from a nationally representative online study found that 3.4 percent of the general population had ever used e-cigarettes and 35.9 percent of the group that had used the products had used them within the previous 30-day period (Ref. 23). In addition, according to the 2011 and 2012 National Youth Tobacco Survey given to middle and high school students, e-cigarette use more than doubled, rising from 3.3 percent to 6.8 percent over these 2 years, including an increase of concurrent cigarette and e-cigarette use from 0.8 percent to 1.6 percent--a statistically significant increase (Refs. 4, 37). A study of 4,444 students from 8 colleges also found that 4.9 percent of students had ever used e-cigarettes, and 1.5 percent reported use in the past 30 days (Ref. 38).

We do not currently have sufficient data about e-cigarettes and similar products to determine what effects they have on the public health. Nevertheless, several recent studies of limited numbers of users suggest that e-cigarettes may have the potential to help smokers, particularly those who have had limited success with currently approved cessation programs (Refs. 39, 40, 41, 42, and 43). There is no evidence to date that e-cigarettes are effective cessation devices. For example, one trial examining cessation success between e-cigarettes, nicotine replacement patches, and placebos found that “[a]chievement of abstinence was substantially lower than we anticipated.” (Ref. 19). This study demonstrated cessation in 21 of

289 smokers (7.3 percent) versus 17 of 295 (5.8 percent) with nicotine patches. However, none of these results reached statistical significance (Ref. 19).[3] In addition, several large studies appear to raise questions as to whether e-cigarettes are effective cessation aids in real-world use. In a nationally representative survey of 1,836 current or recently former adult smokers, researchers found that, compared with smokers who had never tried to quit, ever-use of e-cigarettes was not associated with successful quit attempts, but was associated with unsuccessful quit attempts (Ref. 44). In another study that analyzed data from 2,758 callers to 6 state tobacco quitlines, e-cigarette users were significantly less likely to be tobacco abstinent at 7 months than participants who had never tried e-cigarettes (Ref. 45).

Some studies on very small numbers of subjects have found that e-cigarettes may have the potential to help with cessation by delivering a sufficient nicotine dose, particularly for experienced e-cigarette users (Refs. 39, 40, 41, 42, 43, and 46). Other studies have suggested that the sensory aspects associated with e-cigarettes may also have the potential to provide some short-term smoking reduction benefits. For example, in the study of 25 smokers utilizing e-cigarettes to address the short-term potential for smoking reduction, researchers found promising results but indicated that such "results are not predictive of long-term reduction or quitting" (Ref. 39). This study found that in smokers who had utilized e-cigarettes for 1 week, 10 puffs from the e-cigarette over a 4.5-minute period resulted in acute increases in plasma nicotine and heart rate and a median 55 percent reduction in craving (id.). In addition, the study noted a considerable individual variation in smoking topography and found that whether a user can obtain a sufficient nicotine dose depends on whether he or she is an experienced user (id.). Even though there is no evidence to date of a long-term cessation benefit, some researchers believe that e-cigarettes are at

[3] The observed p-value for cessation with e-cigarettes versus nicotine patches was p=0.46, and the observed p-value for cessation with e-cigarettes versus placebo was p=0.44 (Ref. 19).

least capable of suppressing the urge to smoke (Ref. 41). Separately, although this is unrelated to smoking reduction, some researchers have stated that substituting e-cigarettes for tobacco cigarettes "may substantially reduce exposure to tobacco-specific toxicants" (Ref. 47).

Although e-cigarettes may have short-term smoking reduction benefits, FDA cautions that long-term studies are not available to conclude that e-cigarettes are a proven cessation product nor to establish what effects e-cigarettes have in users who might have otherwise quit, but instead engage in dual use of e-cigarettes and another tobacco product. There also is very limited information currently available on the positive and negative subjective effects, including craving and withdrawal, and the topography of e-cigarettes. FDA believes it is important to evaluate e-cigarettes based on their individual characteristics and their influence on behaviors in order to learn more about the potential benefits and drawbacks of the products. FDA will continue to analyze the potential benefits and harms of e-cigarettes, as well as their impact on nonusers and the population level as a whole, if the deeming rule is finalized. Thus, 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. Without more data, it is not possible to know the impact of these products either on reducing usage of cigarettes or in possibly prolonging usage of cigarettes while continuing to expose users to the harmful carcinogens in combustible tobacco products (Ref. 23).

E. Request for Comments Regarding Components, Parts, and Accessories

FDA asks for comments, including supporting facts, research, and other evidence, as to whether FDA should define components and parts of tobacco products and how those items might be distinguished from accessories of tobacco products. As stated throughout this

document, the FD&C Act defines "tobacco product" to include the components, parts, and accessories of such tobacco products (section 201(rr) of the FD&C Act). At this time, FDA is proposing to deem those products meeting the definition of tobacco product, except the accessories of proposed deemed products, to be subject to its tobacco control authorities. Therefore, components and parts of the proposed deemed tobacco products would fall under the scope of this rule, but accessories would not. We are proposing to include components and parts within the scope of this proposed rule, because they are included as part of a finished tobacco product or intended for consumer use in the consumption of a tobacco product. However, because accessories are not expected to be used in the consumption of a tobacco product, we expect that accessories will have little impact on the public health. FDA is seeking comment on its proposal to exclude accessories from the scope of the deeming rule.

FDA believes that components and parts of tobacco products are those items that are included as part of a finished tobacco product or intended or expected to be used by consumers 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. In addition, FDA considers accessories 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, but may be used, for example, in the storage or personal possession of a proposed deemed product. Therefore, items such as hookah tongs, hookah bags and cases, hookah charcoal burners and holders, cigar foil cutters,

humidors, or cigar carriers would be considered accessories and would not fall within the scope of this proposed rule.

At this time, FDA is not proposing definitions for components, parts, or accessories. If FDA were to develop definitions of these categories of products, the definitions likely would include factors such as whether these items are directly involved in the consumption, storage, or personal possession of tobacco products. These definitions also likely would take into account the foreseeable effect on public health of these items and whether a tobacco product can effectively be consumed without such items. If you believe FDA should define these terms, we seek comment on how to define the categories of "components," "parts," and "accessories." We also ask for comments on whether and how the use of certain components, parts, or accessories might be used to alter the effects of the tobacco product on public health, the constituents delivered by the product, or the potential initiation of new tobacco users.

V. Basis for Additional Provisions

Substantial research informs the Agency's view that the access provisions proposed as part of this rule (e.g., age restrictions under 18; prohibition on vending machines) are effective in reducing initiation of cigarette and smokeless tobacco use, increasing cessation of cigarette and smokeless tobacco use, and otherwise reducing cigarette and smokeless tobacco product use among youth and adults. The research also reflects that health warnings on packages and advertisements effectively help consumers to understand and appreciate the health risks of tobacco use. Because historically most tobacco users in the United States have smoked cigarettes or used smokeless tobacco (Ref. 28), tobacco product use research and tobacco control efforts thus far have focused primarily on these products (Ref. 29) and not on many of the tobacco products, particularly novel products like certain dissolvables and gels, covered by this proposed

rule (Ref. 48). Research findings regarding the use of cigarettes and smokeless tobacco products, including research regarding restrictions on those products that are identical to the restrictions proposed on products subject to deeming in this rule, also support FDA's proposed action here. FDA's reliance on these data is appropriate because of the addictive nature of tobacco products in general and the similar well-documented risks of several other tobacco products subject to this rule. In addition, consumer confusion and misinformation, reflected in mistaken beliefs that non-cigarette tobacco products are safe alternatives to cigarettes, also support the Agency's determination that the proposed restrictions are appropriate for the protection of the public health.

A. Addictive Nature of Products

The Surgeon General has long recognized the addictive nature of tobacco products due to the presence of highly addictive nicotine that can be absorbed into the bloodstream (see, e.g., Ref. 49 at 6-9). While the amount of nicotine delivered and the means through which it is delivered can either reduce or enhance the nicotine's potential for abuse and physiological effects (Ref. 50 at 113), nicotine is addictive (as discussed in section V.A), and FDA believes that all tobacco products currently available contain nicotine (Ref. 49). The quicker the delivery, rate of absorption, and attainment of high concentrations of nicotine, the greater the potential for addiction (Ref. 50 at 113). At the same time, the ultimate levels of nicotine absorbed into the blood from tobacco products currently on the market can be similar in magnitude regardless of the product forms used to deliver nicotine (Ref. 49). For example, research has shown that oral use of smokeless tobacco products that do not emit smoke results in "high venous concentrations of nicotine equal to those for use of cigarettes" (Ref. 50 at 113).

1. Impact of Nicotine on Youth and Young Adults

Adolescence is when most tobacco users begin to develop their behavior (Ref. 51 at 5, 58, 65-67). If individuals do not start using cigarettes during childhood or adolescence, they are unlikely ever to smoke (id.). Research shows that more than 80 percent of established adult smokers began smoking before the age of 18 (Ref. 52). An analysis by the World Health Organization (WHO) of studies performed among final-year high school students in the United States suggests that fewer than two out of five smokers who believe that they will quit within 5 years actually do quit. In high-income countries, about 7 out of 10 adult smokers say they regret initiating smoking and would like to stop (Ref. 53 at 2). When tobacco product use persists into adulthood, the risk of long-term, severe health consequences (such as cancer, heart disease, lung disease, and other serious medical conditions) increases as duration of use increases (Ref. 50).

In addition, there are data suggesting that the adolescent brain is more vulnerable to developing nicotine dependence than the adult brain. There is also evidence to suggest that these brain changes are permanent (Refs. 54 and 55). The Surgeon General reported that "most people begin to smoke in adolescence and develop characteristic patterns of nicotine dependence before adulthood" (Ref. 51 at 29). These youth develop physical dependence and experience withdrawal symptoms when they try to quit smoking (id.). As a result, addiction to nicotine is often lifelong (Ref. 56). Youth and young adults generally "underestimate the tenacity of nicotine addiction and overestimate their ability to stop smoking when they choose" (Ref. 57). For example, one survey revealed that "nearly 60 percent of adolescents believe that they could smoke for a few years and then quit" (Ref. 58).

Moreover, exposure to substances such as nicotine can disrupt brain development and have long-term consequences on executive cognitive function (such as task-switching and

planning) and on the risk of developing a substance abuse disorder and various mental health problems (particularly affective disorders such as anxiety and depression) as an adult (Ref. 1). This exposure to nicotine can also have long-term effects including decreased attention performance and increased impulsivity, which could promote the maintenance of nicotine use behavior (id.). Further, the 2010 Surgeon General's report noted that symptoms of dependence could result from even a limited exposure to nicotine during adolescence (Ref. 50). Thus, FDA seeks to limit youth exposure to nicotine and other addictive constituents in tobacco by proposing restrictions on the age at which individuals can purchase covered tobacco products. FDA is proposing to prohibit sales of proposed deemed products to individuals under 18 years of age, consistent with the current regulatory prohibition on sales of cigarettes and smokeless tobacco products to individuals under 18 years of age.

Nicotine addiction research studies suggest that nicotine increases sensitivity to rewarding stimuli in the environment, which may reinforce smoking behavior in vulnerable individuals and contribute to nicotine addiction (Ref. 59). Researchers have found that adolescent brains are particularly vulnerable to the rewarding effects of nicotine, and nicotine exposure during adolescence diminished the negative effects of high nicotine exposure as an adult (Ref. 60 at 658). Nicotine also may play a role in neurodevelopment in adolescence, alter future responsiveness to nicotine, and increase brain activation related to smoking cues (Ref. 61 at 1968, Ref. 62 at 152, and Ref. 63 at 7). Ingredients in tobacco or tobacco smoke other than nicotine may have reinforcing or synergistic effects of their own (Ref. 50 at 111). See section VII.C for additional discussion regarding the addictiveness of nicotine.

2. Nicotine Levels

Tobacco product users absorb nicotine readily from tobacco smoke through the lungs and through the mouth or nose for noncombustible forms of tobacco (Ref. 49 at iii). Nicotine can also be absorbed through the skin, as evidenced by the use of the nicotine patch for relieving nicotine withdrawal symptoms. With regular use, nicotine levels accumulate in the body during the day from the tobacco product use and then decrease overnight as the body clears the drug (id).

Nicotine introduced through the lungs is rapidly distributed to the brain (Ref. 49 at 12). Although somewhat slower, absorption of nicotine through the oral mucosa and skin is substantial and can produce blood levels comparable to those achieved through lung absorption. The effects of nicotine on the central nervous system occur rapidly after absorption of nicotine from tobacco products (id.). Mild nicotine intoxication even occurs in first-time smokers (Ref. 49 at 15-16). Tolerance to the effects of nicotine develops rapidly. The nicotine level in proposed covered tobacco products varies, both across product types and brands of the same product type.

Given the ease with which nicotine can be absorbed into the body, and the impacts on tobacco users (particularly youth) as described in section V.A, the nicotine consumption associated with the proposed deemed products is a primary reason why FDA believes that deeming these products to be subject to FDA's tobacco product authorities is necessary and the proposed additional restrictions are appropriate for the protection of public health. Each of the products described in this document contains nicotine and, therefore, has the potential to addict consumers.

a. Nicotine in, and absorption of nicotine from, cigars.

Cigar tobacco contains nicotine in concentrations similar to those observed in cigarettes; however, given that most cigars contain more tobacco, many typically contain greater quantities

of nicotine than cigarettes (Ref. 28 at 81). The amount of nicotine in a cigar can range from the equivalent of a single cigarette to the equivalent of an entire package of cigarettes, depending on cigar size and the amount of tobacco incorporated into its components (Refs. 28 at 182 and 30 at 736). A study of 10 cigars selected at random from a cigar retailer found that the cigars ranged in nicotine concentration from 4.70 milligrams per gram (mg/g) to 22.00 mg/g (Ref. 28 at 183).

In fact, nicotine levels in cigar smoke can be up to 8 times higher than levels in cigarette smoke--1.7 mg in nonfiltered cigarettes, 1.1 mg in filtered cigarettes, 3.8 mg in little cigars, 9.8 mg in cigars, and 13.3 mg in premium cigars (Ref. 28 at 67). Whether cigars deliver nicotine at a level capable of producing dependence is based on the degree of cigar smoke inhalation, the rate of oral nicotine absorption, the development of tolerance to nicotine, the age of initiation, and the duration of exposure (Ref. 28 at 183). Even cigar smokers who do not inhale can become addicted to the product given the absorption of nicotine through the buccal mucosa. The nicotine exposure from inhaling the smoke from a single cigarillo is similar to exposures from inhaling smoke from single cigarettes (Ref. 64). The proportion of cigar smokers showing clear signs of dependence remains unknown (Ref. 28 at 189).

Nicotine can exist in protonated and free base (or unprotonated) form; and when in free base form, it is the most addictive and readily absorbed via respiratory tissues, skin, and the gastrointestinal tract, which results in the cigar being more addictive and even more difficult for the user to cease using than the cigar would be if it only delivered nicotine in the protonated form (Refs. 49 at 593 and 50 at 16). "The amount of nicotine available as free, unprotonated nicotine is generally higher in cigars than in cigarettes due to the higher pH of cigar smoke" (Ref. 28 at 97). Nicotine absorbed across the buccal mucosa can provide sustained amounts of "free base" nicotine to the user, which may explain why cigar smokers are less likely to inhale than cigarette

smokers (id.). Thus, a cigar also can deliver nicotine much like chewing tobacco or oral snuff with nicotine extraction from the unburned tobacco absorbed directly through the buccal mucosa and lips (Ref. 28 at 183-184). Researchers have found that some cigar smokers, particularly those who formerly smoked or currently smoke cigarettes, were likely to obtain the nicotine by inhaling smoke directly into the lungs, where it was absorbed as rapidly as cigarette smoke (Ref. 28 at 186).

Usage patterns suggest that cigar-only use that begins in adulthood may be less likely to produce dependence than cigarette smoking, and it is not likely "that substantial levels of physical dependence would be observed in people who rarely smoked on 2 or more consecutive days" (Ref. 28 at 189-190) (emphasis added). However, studies suggest that cigar use is underreported by adolescents in part due to misunderstanding of the definition of "cigar" in national surveys (Ref. 65 at 845 and Ref. 66 at 2, 4). For example, when a group of students were re-administered a national survey but asked whether they had used cigars with the brand name "Black and Mild" in the past 30 days rather than just "cigars, little cigars, or cigarillos," the percentage of students reporting cigar use nearly doubled--from 12.9 percent to 20.7 percent. (Ref. 65 at 842). Therefore, adolescents need to be aware that small and large cigars, like cigarettes, contain nicotine that can cause addiction (see section V.A for further discussion regarding the effects of nicotine on adolescent brains).

b. Nicotine in, and absorption of nicotine from, e-cigarettes.

The amount of nicotine in e-cigarettes varies among brands. In a 2012 study, researchers tested the products under conditions in which e-cigarette users use their products (Ref. 6). They found that "high nicotine" cartridges delivered between 0.5 mg and 15.4 mg of nicotine, and cartridges labeled "low" or "medium" delivered between 0.5 mg and 3.1 mg of nicotine (id.). The

efficacy of the nicotine aerosolization also varied widely--with some e-cigarettes aerosolizing within a range of 21 to 85 percent of the relative amounts of nicotine present in the cartridges (id.). As a result, nicotine levels of a single puff of 70 milliliters may be estimated between 1.7 micrograms (mcg) and 51.3 mcg (id.). We are also aware that some e-cigarettes currently being marketed claim to permit users to adjust the level of nicotine delivery and that some users may attempt to employ this claimed feature to reduce their nicotine use over time.

c. Nicotine in hookah tobacco.

Researchers have found that the nicotine level to which users are exposed while smoking hookah tobacco is greater than the level from cigarette smoking and, therefore, that hookah smoking also carries the potential for addiction (Ref. 67). In a study of frequent hookah tobacco users, half of the men and a third of the women reported trying, but failing, to quit smoking hookah tobacco in the past (id.). The researchers note that "[h]ookah smoking exposes users to smoke and may be a gateway to nicotine addiction" (id.).

d. Nicotine in dissolvables.

To date, little evidence is available to ascertain the pharmacological properties and harmful effects of dissolvable tobacco products or compare them with FDA-approved nicotine replacement products or other tobacco products (Ref. 68). The dose of unprotonated nicotine in dissolvable tobacco products can vary widely across product formulations and brands, as well as the manufacture date, lot, and batch (id.) Researchers at Indiana University-Purdue University Indianapolis published the first chemical analysis of dissolvable tobacco and found that "dissolvables contain nicotine levels comparable to those in a single cigarette" (Ref. 69, citing Ref. 70). Rapid intake of nicotine leads to the highest blood and brain concentrations at the

lowest doses of nicotine, but oral administration requires higher doses of nicotine to produce the same toxic effects (Ref. 70).

B. Health Risks of Products

The health effects of cigarettes have been well documented (see, e.g., Refs. 49, 50, and 51). Like cigarettes, many of the tobacco products proposed to be deemed through this rule have well-documented adverse health effects. The health risks of some of these proposed deemed products are discussed in this section. See section VII for additional rationales for specific proposed health warnings.

In the "Findings" section of the Tobacco Control Act (section 2), Congress notes that 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" and that 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." In enacting the Tobacco Control Act, Congress found that providing FDA with authority to regulate tobacco products, including the advertising and promotion of such products, would result in significant benefits to the American public in human and economic terms (section 2(12) of the Tobacco Control Act). The U.S. Government has a substantial interest in reducing the number of Americans, particularly youth and young adults, who use cigarettes and other tobacco products, to prevent the life-threatening health consequences associated with tobacco product use (section 2(31) of the Tobacco Control Act). Virtually all new users of most tobacco products are youth, and a reduction in tobacco product use by this population alone could significantly reduce tobacco-related death and disease in the United States (Ref. 51).

Congress also expressed concern about the addictiveness of these "inherently dangerous products" (section 2(2) of the Tobacco Control Act). In 1988 the Surgeon General found that "all tobacco products contain substantial amounts of nicotine" (Ref. 49). Addictiveness means "[t]he state or quality of being addictive; addictedness, addiction; an instance of this." (Ref. 71). Because the covered tobacco products (i.e., those products deemed to be subject to the FD&C Act under § 1100.2, other than a component or part that does not contain tobacco or nicotine) are made or derived from tobacco and contain nicotine, they are addictive (Refs. 72, 73, 74, 75, and 76). There are several symptoms that are indicative of addiction to drugs including nicotine. The primary criteria are highly controlled or compulsive use, psychoactive effects, and drug-reinforced behavior (Ref. 50 at 105-106). Additional criteria are stereotypic patterns of use, despite harmful effects, relapse following abstinence, and recurrent drug cravings (id.). Dependence-producing drugs often produce tolerance and physical dependence (id.).

"Tobacco use is the leading preventable cause of disease, disability, and death in the United States" (Ref. 77). When people do not use tobacco products, the positive impact on public health is great. For example, smoking declines in the last half century are responsible for nearly 40 percent of the reduction in male lung cancer deaths between 1991 and 2003 (Ref. 78). By extending FDA's "tobacco product" authorities to tobacco products meeting the statutory definition, FDA would be better able to ensure that the health risks of these products are effectively communicated to consumers and that youth do not have access to these products. These steps would increase the likelihood that existing users will quit using tobacco products, and decrease the likelihood that new individuals, including youth, will initiate tobacco product use.

1. Dissolvable Products

As stated previously, dissolvable products that do not currently meet the definition of smokeless tobacco under 21 U.S.C. 387(18), because they do not contain cut, ground, powdered, or leaf tobacco and instead contain nicotine extracted from tobacco, are not currently regulated by FDA. This proposed rule would ensure that all dissolvable products are subject to FDA regulation.

The "Monitoring the Future" study found that the use of noncombustible tobacco products (including pouches and dissolvables, which contain nicotine, tobacco carcinogens, and toxicants) has increased amongst youth in grades 8, 10, and 12 over the past several years (Ref. 83). Compared to cigarettes, scientists have found that dissolvables have a higher proportion of unprotonated nicotine but that dose can vary widely (Ref. 68). The potential for acquiring nicotine dependence exists for individuals who initiate tobacco product use with dissolvable products, but the information about hazardous or potential hazardous constituents in such products is sparse (id.).

Certain dissolvable smokeless tobacco products also have the potential for unintended poisonings given the candy-like appearance of certain dissolvable tobacco products. Data from 2010 indicates that 13,705 tobacco product ingestion cases were reported and more than 70 percent of those cases involved infants under a year old (Ref. 79). While it is unclear exactly how many of these cases involved dissolvables, smokeless tobacco products (in all forms, including dissolvables) were the second most common tobacco product ingested by children, after cigarettes (id.).

2. Cigars

Regardless of whether large cigar and pipe smokers inhale, smoke particles are deposited into the lung (Ref. 32). A large cigar may contain as much tobacco as a whole pack of cigarettes (Refs. 30 and 31). In addition, the concentrations of some toxic and carcinogenic compounds are higher in cigar smoke than in cigarettes, and tobacco smoke is a major source of fine-particle and carbon monoxide indoor air pollution (Ref. 33). A smoker's risk of cardiovascular disease is particularly high for former cigarette smokers who switch to cigars, because they are more likely to be regular users and to inhale the smoke (Ref. 28 at 155).

As discussed further in section VII.E, cigar smoking also is strongly related to certain cancers (including oral, esophageal, laryngeal, and lung cancers), heart disease, and premature death (Refs. 28 and 62). Cigar smokers who inhale have a similar risk of death and disease as cigarette smokers (see, e.g., Ref. 28). Research suggests that smoking small cigars, in particular, is associated with smoke inhalation that leads to significant exposure to carbon monoxide and presumably other toxic components of tobacco smoke, which can lead to respiratory diseases usually associated with cigarette smoking (Ref. 64).

Moreover, age of initiation data illustrates the increasing popularity of cigars, in particular small cigars, and the potential risks for youth and young adults. According to the 2010 and 2011 data from the National Survey on Drug Use and Health (NSDUH), 2.95 million people aged 12 or older initiated cigar use in 2010--1.087 million of whom where between the ages of 12 and 18. In 2011, 2.8 million initiated cigar use, of which 1.113 million were between the ages of 12 and 18 (Refs. 6, 80, 81, and 82). The 2010 "Monitoring the Future" study showed that 23 percent of 12th graders reported smoking small cigars in the past year (Ref. 83). While there was a dip in the number of high school seniors smoking small cigars, that number remained high at

19.5 percent in 2011 (Ref. 84). Additional discussion of the health risks associated with cigars is included in section VII.E.

3. Pipe Tobacco

Studies of pipe smokers illustrate a risk of tobacco-related disease similar to the risk in those who inhale cigar smoke or smoke cigarettes (Ref. 85). The Surgeon General previously found that pipe and cigar smokers experience oral and laryngeal cancer risks similar to that of a cigarette smoker (Ref. 86). Moreover, when compared with never having used tobacco, researchers found that pipe smokers have an increased risk of death from cancers of the lung, oropharynx, esophagus, colorectum, pancreas, larynx, and from coronary heart disease, cerebrovascular disease, and COPD (Refs. 32 and 85). Further, in a Norwegian study involving 16,932 participants, researchers found that pipe smokers have an elevated risk of premature mortality similar to that of cigarette smokers who smoke at comparable consumption levels (Ref. 87). This finding applies to total mortality and mortality for smoking-related diseases (i.e., ischaemic heart disease, stroke, cardiovascular disease, and other smoking related cancers), except for lung cancer where smokers of only cigarettes have the highest mortality (id.). Notably, even men with the lowest daily consumption of pipe tobacco (less than three pipefuls per day) were found to have significantly higher health risks than never users (id.).

4. Waterpipe Smoking

Waterpipe smoking (also known as hookah, shisha, and narghile) uses specially made tobacco that comes in different flavors, such as apple, mint, cherry, chocolate, and licorice (Ref. 88). This type of tobacco use carries similar health risks as smoking cigarettes with respect to the large amounts of ultrafine particles emitted during a waterpipe smoking session (Ref. 89). Waterpipe smoke contains many of the same carcinogens and heavy metals as cigarette smoke,

and because waterpipe smoking sessions last longer than smoking a cigarette and there is increased smoke volume, a single session of waterpipe smoking (which typically lasts 20 to 80 minutes) could potentially be more dangerous than smoking a cigarette (which typically takes 5 to 7 minutes) (Refs. 90 and 91). When compared to smoking a single cigarette, a meta-analysis of studies regarding waterpipe use showed that a single episode of waterpipe use is associated with exposure to 1.7 times the nicotine, 6.5 times the carbon monoxide, and 46.4 times the tar (Ref. 9). In one study of participants aged 18 to 50 years old, researchers found that a single waterpipe session leads to measurable transient dysfunction in cardiac autonomic regulation and suggests an increased risk of adverse cardiovascular events for hookah users (Ref. 92). When compared to individuals who do not use waterpipes, researchers also have found that waterpipe users (as ascertained by analyses in multiple studies of participants ages 10 to 80) more than double their risk of lung cancer, respiratory illness, and low birth weight when users are expectant mothers (Refs. 10, 93, and 94).

Studies also have demonstrated the presence of high levels of tobacco-related carcinogens such as certain polycyclic aromatic hydrocarbons (PAHs) and tobacco-specific nitrosamines (TSNAs) in waterpipe users, which increase cancer risk in users (Ref. 95 citing Refs. 96 and 97; and Ref. 98). For example, a study of exposure to nicotine, carbon monoxide, and carcinogens in subjects who used waterpipes under controlled conditions found that users had significantly higher carbon monoxide levels than even cigarette smokers, which can pose potential health risks especially for people with cardiovascular and pulmonary diseases (Ref. 98). This study also found increased urinary levels of TSNAs and PAHs following waterpipe smoking (id.). In fact, the excretion of all PAH metabolites increased 50 percent following waterpipe smoking, indicating that it is a significant source of exposure to this class of

carcinogens (id.). Waterpipe use also poses additional public health risks due to shared mouthpieces and the heated, moist smoke that waterpipes produce. As a result, users are at increased risk of contracting communicable diseases and viruses (Ref. 99).

Moreover, waterpipe use appears to be increasing among youth in the United States, further illustrating the potential risks for youth and young adults (Ref. 90). In 2010, results of the "Monitoring the Future" study showed that 17 percent of 12th graders reported smoking tobacco in a waterpipe (Ref. 83). The following year, 18.5 percent of high school seniors reported smoking tobacco in a waterpipe (Ref. 84). Researchers also studied waterpipe use among 689 students from 3 high schools in San Diego County. Of the study participants, 26.1 percent had used hookah and the mean age of initiation was 15.8 years (Ref. 90). Waterpipe users are exposed to tobacco toxicants and thus are at risk for the same types of harms caused by cigarette smoking and, in addition, may become cigarette smokers or dual tobacco users (Ref. 88).

5. E-Cigarettes

We do not currently have sufficient data about e-cigarettes to determine what effects they have on the public health. Some studies have revealed the existence of toxicants in both the e-cigarette liquid and the exhaled aerosol of some e-cigarettes. For example, FDA previously noted the presence in a certain e-cigarette cartridge of contaminants such as diethylene glycol (DEG)--a chemical that has caused poisonings in other consumer products such as acetaminophen and cough syrup and which FDA has stated "is toxic to humans" (Ref. 100, Ref. 101 citing Refs. 102, 103, and 104). While the presence of DEG in any product is of great concern, we note that it was found in only 1 of 18 cartridges studied and it was not found at all in another 16 studies (Ref. 41).

Further, one study found that toxic chemicals such as formaldehyde and acetaldehyde were detected in the cartridges as well as the aerosol from certain e-cigarette nicotine solutions (Ref. 47). Acrolein, which can cause irritation to the nasal cavity and damage to the lining of the lungs and may contribute to cardiovascular disease in cigarette smokers, was also found in the aerosol (id.). While the level of carcinogenic formaldehyde from the e-cigarette aerosol was somewhat comparable to the amount received from cigarette smoking, the overall levels of the toxicants tested in this study were 9 to 450 times lower than those in cigarette smoke (id.). In another study, a total of 22 chemical elements, some of which can cause adverse health effects in the respiratory and nervous systems, were identified in e-cigarette aerosol (Ref. 105). Among those elements were lead, nickel, and chromium, which are included on the Agency's harmful and potentially harmful constituents list (id., citing 77 FR 20034, April 3, 2012). Research published in 2013 reported that under near real-use conditions, e-cigarettes increased indoor air levels of polycyclic aromatic hydrocarbons, 1,2-propanediol, 1,2,3-propanetriol, glycerine, nicotine, fine particles, ultrafine particles, particle number concentrations, and aluminum. (Refs. 106 and 107).

Despite the existence of certain toxicants in e-cigarette devices and the exhaled aerosol, several studies support the notion that the quantity of toxicants is significantly less than those in tobacco cigarettes and tobacco smoke and similar to those contained in recognized nicotine-replacement therapies. For example, researchers reviewing the result of 16 laboratory analyses of e-cigarettes only found trace levels of TSNAs, and these were at levels similar to those in the nicotine patch (Ref. 41). Testing on some devices also has revealed the existence of TSNAs in cartridge fluid, but generally at low levels similar to those in nicotine replacement therapies (Refs.108). Another study, published in 2013, also found cadmium, lead, and nickel in the e-

cigarette aerosol but only in trace levels and comparable to those levels found in the Nicorette inhaler (Ref. 47). Two researchers stated in 2011 that the "preponderance of the available evidence shows [e-cigarettes] to be much safer than tobacco cigarettes and comparable in toxicity to conventional nicotine replacement products" (Ref. 41). Even if such findings are applicable to many products, e-cigarette manufacturers may vary in the quality of production, as discussed in section V.B.5. with respect to contamination with DEG, and as discussed further with respect to significant variability in nicotine content, and such variation may be dangerous. As such, given the existence of toxic chemicals in at least some e-cigarettes and the fact that most contain nicotine, FDA believes that its oversight of these products (which would occur if this deeming ruling becomes final) is appropriate for the protection of the public health.

Researchers have identified instances of poor quality control and significant variability in nicotine content when testing certain e-cigarette cartridges (Refs. 6, 102, 109, and 110). For example, in one study, researchers found that actual nicotine amounts differed from label amounts by more than 20 percent in 9 out of 20 original e-cigarette cartridges tested, and in 3 out of 15 refill cartridges tested (Ref. 6). Yet, in another study, researchers theorized that manufacturing processes may have improved over time, because the nicotine content in both the original and-refill bottles was close to what was on the label and the difference between the content and labels was smaller than was previously reported (Ref. 111). However, it is unclear whether manufacturing processes have actually improved over time, because this study was conducted before or at the same time as studies finding significant variability in nicotine content. This potential variability in nicotine content could be misleading to consumers who believe that they are consuming one level of nicotine but instead may be consuming higher levels in certain instances.

More recently, some have noted the availability of flavored e-cigarette liquids and expressed concern about the possibility that these candy flavors could appeal to youth. E-cigarettes are available in numerous flavors including vanilla, chocolate, peach schnapps, bubblegum, and cola (Refs. 112 and 113). Following the release of a 2013 report by CDC noting the increased prevalence of e-cigarette use in middle school and high school students, students have been quoted in newspaper articles noting that classmates use e-cigarettes and that they prefer flavors like gummy bears "because it tastes really good" (Ref. 114). If this deeming rule becomes final, FDA would have the authority to issue regulations to prevent youth access to e-cigarettes (such as the minimum age and identification provision, which is being proposed with this rule). FDA asks for comments, data, and research regarding the following:

- 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 Agency consider taking with respect to e-cigarettes?
- 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 FDA's regulatory decisions regarding e-cigarettes?

Another area for concern regarding e-cigarettes is their potential for acute toxicity. In February 2014, 41.7 percent of the combined calls to poison control centers for conventional cigarettes and e-cigarettes were for e-cigarette exposures (Ref. 115). In addition, 51.1 percent of those exposures were for children aged 0 to 5 years (id.).

Although the public health impact of e-cigarettes is unknown, FDA believes e-cigarettes that contain nicotine derived from tobacco should be deemed to be tobacco products in order to

obtain product and ingredient listing information and levels of harmful and potentially harmful constituents to ensure that users are not exposed to inhaled chemicals known to be harmful. We also believe that more information is needed to determine the public health impact of these products.

Notably, in light of the impact of nicotine on youth (see section V.A), and given the data on co-use and poly-use of tobacco products by youth and others (see section V.D), FDA is proposing that tobacco products in all forms, as defined by statute, not just cigarettes and smokeless tobacco, be similarly regulated.

C. Consumer Confusion and Misinformation About Certain Covered Tobacco Products

1. Misinformation About the Harmfulness of Various Tobacco Products

Despite the addictiveness of nicotine and the documented adverse health effects of cigarettes, smokeless tobacco, cigars, and hookah tobacco, studies show that many consumers wrongly view certain tobacco products, including novel tobacco products, as safe alternatives to cigarettes and smokeless tobacco. Variations in the regulatory status of tobacco products may reinforce that mistaken perception.

Research reflects that many people inaccurately think cigars, as well as waterpipes and other tobacco products covered by this proposed rule, are safe alternatives to cigarettes. Indeed, research suggests that youth perceive cigars in a more positive light than cigarettes and believe cigars are more natural and less harmful (Refs. 35 and 116); and some do not realize that cigars contain nicotine (id.). In addition, in a focus group of African-American youth aged 14 to 18, researchers found that the participants were not well versed in the harms caused by smoking cigars (Ref. 116). In fact, the study found that youth had received very little cigar-specific health education, reinforcing the importance of alerting consumers about the dangers of smoking cigars

(id.). Likely referring to small cigars, the youth noted that cigars were easy to obtain, that new brands were targeting youth, and that the products were prominent in rap videos (id.). Use of cigar products by youth and young adults is no longer an "alternative" to cigarette use, but rather is now the primary tobacco product of choice in certain urban and suburban areas (Ref. 117). One study also showed that adult cigar smokers (including cigarillo smokers) were three times as likely as non-cigar smokers to believe, mistakenly, that switching from cigarettes to cigars reduces a smoker's chance of illness (32.3 percent versus 11.2 percent), with former cigarette smokers the most likely among cigar smokers to believe that cigars are a safer alternative (47.9 percent) (Ref. 117). See section VII.C.1 for additional discussion of consumers' confusion and misinformation about the addictiveness of cigars.

Such confusion and misinformation about the harmfulness and addictiveness of cigars are particularly troubling given the increasing popularity of cigars (in particular, small cigars) among youth, especially young adult males and teenagers (Ref. 54). The 2010 National Survey on Drug Use and Health found that over 1 in 10 young adults (ages 18-25 years old) smokes cigars (Ref. 54 at 146, Table 3.5b). In 2011, 19.5 percent of high school seniors reported using small cigars in the past year (Ref. 84). The CDC also issued a study in 2012, which found that total cigarette consumption decreased 32.8 percent from 2000 to 2011, while consumption of loose tobacco and small and large cigars increased 123.1 percent over the same period (Ref. 22). These data suggest that certain smokers have switched from cigarettes to other combustible tobacco products (id.)

Whereas studies have shown that cigarette and waterpipe smoking deliver similar nicotine levels, one study showed that 46 percent of students wrongly believed that hookah is less addictive or safer than cigarettes, one third of which wrongly believed that hookah had less nicotine, no nicotine, or was generally less addictive than cigarettes (Ref. 90). Moreover,

findings suggest that mistaken beliefs that waterpipe smoking is "safer or less addictive than cigarettes" are more prevalent among those who have ever used hookah (78.2 percent) compared to hookah nonusers (31.6 percent) (id.). Similarly, another study found that "[freshmen college] students who used waterpipes and cigars perceived them as less harmful than regular cigarettes" (Ref. 119). These findings are consistent with the finding that perceiving less product harm is associated with product use (id.). Moreover, research has shown that such false beliefs about product risks can be a significant predictor of subsequent use behavior (Refs. 120 and 121). For instance, adolescents with the lowest perceptions of short-term risks related to smoking were 2.68 times more likely to initiate smoking (Ref. 121).

In addition, some dissolvable tobacco products have a candy-like appearance, frequently are sold next to candy, and are packaged to make them more attractive to children, which can mislead consumers to think that they are, in fact, candy or somehow safer than other tobacco products (Refs. 17 and 79). This rule, if finalized, would apply the same requirements to all dissolvable tobacco products, including those that do not consist of cut, ground, powdered, or leaf tobacco.

Many consumers believe that e-cigarettes are "safe" tobacco products or are "safer" than cigarettes. FDA has not made such a determination and conclusive research is not available. Several studies have evaluated consumers' awareness of e-cigarettes and their perceptions of risk. For example, researchers involved in Wave 8 of the ITC Four-Country Survey (involving data from the United States, Canada, Australia, and the United Kingdom) asked all those respondents who were aware of e-cigarettes to relay their perceptions of the product (Ref. 36). The vast majority of the respondents who were aware of these products indicated that they believed e-cigarettes were less harmful than traditional cigarettes, including 65.9 percent of U.S.

respondents--despite, as noted, the absence of a firm body of evidence to support such beliefs (id.). Two other surveys revealed similar results: (1) An online survey in which 70.6 percent of individuals aware of e-cigarettes believed that e-cigarettes were less harmful than regular cigarettes and (2) a telephone survey in which 84.7 percent of individuals aware of these products believed they were less harmful than regular cigarettes (Ref. 23). However, while the use of e-cigarettes may have prompted some smokers in the ITC Four-Country Survey to reduce their overall cigarette smoking and to adopt non-daily cigarette use, users of e-cigarettes were not more likely to quit than nonusers of e-cigarettes (Ref. 36). Once again, there is not adequate evidence that e-cigarette use is a safe alternative to conventional cigarette smoking. See section VII.C.1 regarding the current mixed evidence about potential short-term reduced smoking benefits from e-cigarettes. Notably, as discussed in that section, many consumers have strong, but to date unsubstantiated, beliefs that e-cigarettes are a safe and effective way for quitting cigarette use, and many consumers start consuming e-cigarettes because of those unsubstantiated beliefs. Researchers also have expressed concerns that e-cigarettes that deliver very low levels of nicotine may be effective starter products for non-tobacco product users (Ref. 101). Such risks could be mitigated by the establishment of an FDA regulatory approach for these products that focuses on limiting youth initiation (id.).

2. Mistaken Perception by Adolescents

Nonclinical information, which includes cellular, tissue, and whole animal-based laboratory studies, both informs and supports clinical information. Most tobacco-related adverse health effects are long-term effects, such as COPD and cancer. What can take years or decades to develop in a human can be studied in nonclinical assays in mere days or months. In addition, nonclinical studies allow for histopathology, which yields strong scientific evidence of a

biologically based cause for a clinically detectable symptomology. Through nonclinical studies, science is able to better control for exposure level of the product being tested, as well as control for exposure time and to include a recovery period, during which no exposure to the product can be controlled. All of these aspects of nonclinical testing enable science to better make the connection between an outcome, such as a toxicity endpoint, and the experimental treatment, such as a specific tobacco product or tobacco constituent. (See, e.g., Ref. 121.)

Non-clinical research has shown that: (1) Alterations to the brain caused by nicotine may have a lasting effect on the developing brain (Ref. 55 at 668-676); (2) the rewarding effects of low and moderate doses of nicotine were enhanced in adolescent animals as compared to adult animals, while the aversion to high doses of nicotine normally seen in adult animals were reduced (Ref. 60 at 658-663); (3) these affects are long lasting, as exposure to nicotine during adolescence reduced aversion to high doses of nicotine when the animals were tested as adults; (4) the adolescent brain is differentially sensitive to both the acute and repeated effects of nicotine relative to the adult brain (Ref. 76 at 2295); and (5) there are significant differences in nicotine sensitivity between early and late phases of adolescence (Ref. 60 and 76).

Brain processes that lead to rational decision making continue to mature through adolescence (Ref. 122 at 69-70). Acquisition of a fully coordinated and controlled set of executive functions occurs relatively later in development. As a result, several researchers have found that young people may not have the ability to rationally consider the risks and benefits involved with smoking and its long-term effects (Ref. 123 at 259-266). Young people also wrongly perceive that they are personally at less risk than others who smoke, and youth underestimate antismoking attitudes of their peers (id.). "The belief pattern that emerges from this study and other research is one in which many young smokers perceive themselves to be at

little or no risk from each cigarette smoked because they expect to stop smoking before any damage to their health occurs. In reality, a high percentage of young smokers continue to smoke over a long period of time and are certainly placed at risk by their habit" (id.). Because they lack fully capable executive function, youth seriously underestimate the future costs associated with an addiction to nicotine (Ref. 55 at 4). Researchers believe that youth underestimate the risks of smoking because they are unable to appreciate the nature, severity, and probabilities of consequences associated with smoking. Youth also fail to understand the cumulative nature of the risk (Ref. 123 at 259-266). The proportion of students seeing a great risk associated with being a smoker leveled off during the past several years, according to recent research results, as has the proportion of teens saying that they disapprove of smoking or attach negative connotations to it (Ref. 83). Similarly, the "Monitoring the Future" survey identified a "rebound" in the rate of smokeless tobacco product use by high school students, which previously had declined from the mid-1990s to the early 2000s (id.). Researchers attributed the "rebound" to leveling off perceptions of harm caused by smokeless tobacco products, increased advertising of these products, and a proliferation of new types of smoke-free tobacco products (id.). In addition to systematically misunderstanding their risks of harm from various tobacco products, youth and young people also systematically underestimate their vulnerability to becoming addicted to nicotine and the use of tobacco products, and overestimate their ability to stop using tobacco products when they choose. See section VII.C.

D. Use as Starter Products or Dual Use With Other Tobacco Products

A non-cigarette "tobacco product" can be a starter product for new tobacco users before they migrate to cigarettes or other tobacco products, or for existing users to become dual users. In a 2008 study, researchers estimated that there were 7.3 million adolescent cigarette smokers in

the United States in 2002 and 2004, and almost half of them were polytobacco users (users of more than one type of tobacco product) (Ref. 124). Of the estimated 3.3 million polytobacco users, 1.9 million used one other tobacco product and 1.4 million used two or more other products (id.). The 2012 Surgeon General's Report found that "among adolescent and young adult tobacco users, concurrent use of cigarettes, smokeless tobacco, and/or cigars is common" (Ref. 54 at 209). According to the 2009 Youth Risk Behavior Surveillance, among high school males who use tobacco, 13.2 percent smoke cigars (i.e., cigars, cigarillos, or little cigars) only, 21.2 percent smoke cigars and cigarettes, and 19.2 percent smoke cigarettes and cigars and also use smokeless tobacco (Ref. 54 at 155, Figure 3.13).

Significantly, studies of a variety of tobacco products suggest that some non-cigarette tobacco users may go on to become addicted cigarette smokers. For example, in one study of male smokeless tobacco users who were nonsmokers at baseline, 44.8 percent were still exclusively using smokeless tobacco at the 4-year followup, 25.5 percent had switched to smoking, 14.3 percent continued using smokeless tobacco but also became smokers, and 15.2 percent were no longer using any form of tobacco (Ref. 125). Thus, almost 40 percent of the original smokeless tobacco users had either switched to cigarettes or become dual users. In contrast, 78.7 percent of males who smoked at baseline but did not use smokeless tobacco were still smokers 4 years later, with only 0.8 percent switching to smokeless tobacco, 3.6 percent continuing to smoke but becoming smokeless tobacco users as well, and 16.9 percent quitting tobacco product use altogether (id.). Similarly, in a study of smokeless tobacco product use in young adult males, current smokeless tobacco users were 233 percent more likely to have initiated smoking at the 1-year followup than nonusers (Ref. 126). Subjects who reported past smokeless tobacco product use were 227 percent more likely to begin smoking than participants

who had never used smokeless tobacco (id.). It is not yet clear whether users of the proposed deemed products go on to become addicted to cigarettes, but experts have expressed concern that e-cigarettes may draw more consumers to nicotine-containing products (Refs. 101).

Research involving tobacco products that would be covered by this rule reveals similar conclusions. The prevalence of hookah use appears to be high among youth who have already tried cigarette smoking and is associated with other tobacco product use behaviors. For example, in one study involving 951 adolescents, researchers found that those who had used hookah tobacco in the last 30 days concurrently used multiple tobacco products including cigarettes (74.7 percent) and cigars, cigarillos, and/or little cigars (48.1 percent) (Ref. 127). Given that waterpipe smoking has been found to increase one's risk of nicotine dependence, this tendency towards dual use is particularly concerning (Ref. 93). Regular waterpipe smokers evidence similar withdrawal and craving symptoms as cigarette smokers (Ref. 128). Engagement in waterpipe tobacco product use among individuals that would otherwise remain tobacco naïve is of great concern, as about half of waterpipe users are non-current cigarette smokers (Ref. 129). Waterpipe smoking frequency predicts regular cigarette use 8 months later among adolescent males (Ref. 130). Among high school non-smokers and experimental smokers, there was a strong association between age 20/21 smoking and waterpipe use: Previous non-smokers were more likely to smoke cigarettes if they use waterpipes, suggesting that waterpipe use may have preceded cigarette use (Ref. 131). College students with waterpipe experience, but no cigarette use, were more likely to express intent to try a cigarette soon (Ref. 26).

A cross-sectional health risk survey of approximately 4,500 high school students revealed that high school-aged cigar smokers are more susceptible to future cigarette smoking than nonusers. Specifically, in students who tried cigars (defined as cigars, little cigars, and cigarillos)

first, 14.6 percent used cigarettes only, 12.2 percent used cigars only, and 43.6 percent used both cigarettes and cigars (Ref. 117).

VI. Proposed Minimum Age and Identification Restrictions

Currently, there are Federal minimum age and identification requirements for cigarettes and smokeless tobacco prohibiting sales of these tobacco products to individuals under 18 years of age. This proposed rule would extend those requirements to all covered tobacco products in order to curb initiation of other tobacco products among youth. We note that the definition of "covered tobacco products" would depend on the universe of tobacco products that would be covered this rule. Under Option 1, all cigars would be covered and, therefore, these additional provisions would apply to all cigars. However, under Option 2, only a subset of cigars (i.e., "covered cigars," which would exclude "premium" cigars) would be covered by the rule and, therefore, these additional provisions would apply to only a subset of cigars. Under section 906(d) of the Tobacco Control Act, the minimum age and identification restrictions FDA is proposing here are appropriate for the public health.

A. Effectiveness of Proposed Restrictions and Section 906(d) Standard

The age and identification restrictions that FDA is proposing on the sale of covered tobacco products meet the requirements of the section 906(d) standard and are appropriate for the protection of the public health. The goal of the proposed age restrictions is to reduce youth initiation of tobacco use, thereby reducing the number of people who suffer from tobacco-related illnesses and death and the number of people who are exposed to secondhand smoke.

Currently, not all states have laws preventing the sale of tobacco products that would be covered by this rule to those under the age of 18. This proposed action to prohibit sales of covered tobacco products to individuals under 18 years of age at a minimum would be the most

effective way to keep youth from going to another nearby jurisdiction that sells tobacco products to those under age 18. FDA intends to work with retailers to emphasize the importance of continued training for employees so that they will understand both the importance of the minimum age restriction as well as how to enforce it. The Center for Substance Abuse Prevention Draft Conference Edition Report on Responsible Retailing outlines how a "comprehensive program of responsible retailing, properly designed and implemented, can contribute to the elimination of sales of tobacco and other age-restricted products to minors" (Ref. 132 at 1) (see Refs. 133 and 134). FDA intends to use an aggressive nationwide enforcement program for any new Federal program which will, we believe, increase compliance and deter youth consumption of addictive tobacco products. FDA's current nationwide tobacco retail inspection enforcement program, which is implemented through contractual agreements between FDA and state or local partners, where feasible, will be able to incorporate new products or policies to provide additional uniformity to the enforcement of tobacco laws and regulations.

There is clear evidence that actively enforced minimum age requirements and identification requests in the states are useful in reducing illegal sales of tobacco to youth (Refs. 135, 136, 137, and 138). A literature review found that every intervention that prevented the sale of tobacco to minors has been associated with an observed reduction in tobacco product use by youth (Ref. 138). The author reviewed more than 400 published articles and 400 government reports concerning tobacco sales to minors (id.). There were 19 interventions in which the sale of tobacco to minors was disrupted (id.). In each case, the intervention was followed by a decline in youth tobacco use. Contrary to claims that efforts to disrupt the sale of tobacco to minors are futile because social sources would "fill the void making tobacco more available," adolescents

who purchase tobacco products "are the primary social sources for other youth" (id.). The disruption of commercial distribution to youth "creates supply shortages, driving up the cost of tobacco on the street and discouraging sharing among peers as smokers protect their supply" (id.). Declines in tobacco product use were seen in rural communities, suburban communities, across large regions or states, and countrywide. Moreover, among all the materials reviewed, none demonstrated a significant reduction in commercial distribution of tobacco to minors unaccompanied by reductions in the number of youth who use tobacco (id.). The author concluded that all available evidence indicates that interventions that successfully disrupt the sale of tobacco to minors can be expected to reduce the rate of tobacco product use among adolescents.

Three small, cross-sectional studies have also found reductions in tobacco product use following decreases in tobacco accessibility (Ref. 133 citing Refs. 134, 139, and 140). For example, the investigators in one study surveyed more than 600 7th and 8th grade students in Woodridge, IL, before and approximately 2 years after a local law on retailer licensing and youth possession of tobacco was passed (Ref. 139). With active enforcement of the law, illegal sales of tobacco to individuals under 18 years old were reduced from 70 percent of the sample of retailers surveyed to 5 percent at the end of the 2-year compliance review period (id.). Experimental smoking among middle school students studied dropped from 46 percent to 23 percent 2 years after the law's passage, and regular smoking rates dropped from 16 percent to 5 percent (id.).

Similarly, another study examined youth smoking rates and purchase behaviors in a longitudinal analysis of 12 communities (Ref. 141). Test purchases were conducted to determine whether merchant compliance with access restrictions can lead to lower youth smoking rates. Then these levels of merchant compliance were compared with youth smoking rates. From 1992

to 1996, frequent smoking increased by 28 percent in the communities with retailer compliance levels less than 80 percent, but frequent smoking decreased by 16 percent in the communities with retailer compliance levels greater than 80 percent (id.).

Moreover, a number of studies have observed at least some correlation between the enforcement of youth access restrictions and reduced tobacco product use among youth when enforcement is coupled with educational campaigns, and FDA has conducted and plans to continue to conduct various types of public education regarding tobacco products. For example, in a four-community study in Monterey County, CA, where sales of tobacco products to individuals under 18 were prohibited, researchers studied an intervention group (with educational campaigns for the community and merchants) and a control group. In communities with the tobacco intervention, the proportion of stores selling tobacco to individuals under 18 dropped from 75 percent at baseline to 0 percent after 34 months; while in the control communities, the proportion of stores selling tobacco to minors only dropped from 64 percent to 39 percent (Ref. 133). Additionally, 7th graders in the intervention communities were significantly less likely to use tobacco over the course of the study (13.1 percent at baseline vs. 12.6 percent post-test), while 7th graders in the comparison communities were significantly more likely to use tobacco (15.6 percent at baseline vs. 18.6 percent post-test) (id.). In communities using tobacco intervention policies, treatment effects were evident among the youngest students (7th grade at baseline) but were not sustained at 34 months, and no significant effects were found for 9th and 11th graders (id.). Based on these data, the authors concluded that there was some evidence, albeit inconsistent, that reducing tobacco sales to individuals under 18 lowered tobacco product use among this age group, and that younger adolescents are more responsive to educational campaigns for the community and merchants than older adolescents (id.).

Similarly, in a randomized community trial involving 14 Minnesota communities (7 intervention communities and 7 control communities), communities that passed a comprehensive youth tobacco access ordinance showed less pronounced increases in adolescent daily smoking relative to control communities (Ref. 137). During the intervention period, there was statewide media attention on youth access to tobacco. Additionally, during the intervention period, state retailer associations and the tobacco industry launched statewide campaigns to educate retailers and their employees about Minnesota tobacco age-of-sale law and ways to avoid violating it (id.). The authors posited that, to the extent both intervention and control communities showed reductions in illegal sales to individuals under 18, the community mobilization and education portions of the intervention may have played a role in increasing the perception among students that they would not be able to purchase tobacco or discouraged them from trying to do so (id.).

FDA is aware of two studies that question the link between actively enforced youth access laws and tobacco use. One 2-year controlled study in six Massachusetts communities (from 1994 to 1996) that examined the impact of enforcement of youth access restrictions on smoking behaviors found that despite a significant and continued increase in compliance by retailers, young people reported little decline in their ability to purchase tobacco products. The study also found no relationship between merchant compliance and smoking prevalence (Ref. 142).

In addition, a meta-analysis of previous studies showed no detectable relationship between the level of merchant compliance with youth access laws and 30-day or regular smoking prevalence and no visible evidence of a threshold effect after compliance reached a certain level (e.g., 80 or 90 percent) (Ref. 143). Although the authors noted that one limitation of the analysis was the relatively small number of controlled studies evaluating the effects of youth access

restrictions on teen smoking prevalence, they observed that the consistency of the results increased their confidence in the study's conclusions (id.). Researchers speculated that there was no reported reduction in youth access, despite increased compliance rates by retailers, either because youth went to other communities that did not rigorously enforce the minimum age requirement to purchase cigarettes or tricked retailers into believing that they were older (id.). While more data and a larger sample size are needed to support this hypothesis, these researchers did state that FDA regulations setting a national standard for tobacco sales could have an effect on tobacco product use nationwide if there were careful monitoring of compliance (id.).

Several studies discussed potential reasons for the mixed findings on the impact of youth access laws on youth tobacco use. Researchers found that when youth access laws exist and are enforced, youth users of tobacco, particularly beginning users, may resort to social sources of tobacco (such as friends, parents, or strangers) or to stealing (either from parents or from tobacco product retailers) (Ref. 141). This phenomenon may explain why some data show that where decreases in youth tobacco product use do result from youth access restrictions, the decreases are concentrated among heavier teen smokers and/or frequent smokers (Refs. 141 and 144).

Although the literature is mixed on the role compliance and enforcement plays in the ability of youth access restrictions to affect youth tobacco use, because the minimum age and identification requirements FDA is proposing here would be Federal requirements, they would apply across the entire United States. More uniform enforcement by FDA working in conjunction with states would minimize youth's ability to circumvent the current patchwork of youth access restrictions by attempting to buy tobacco products in jurisdictions where enforcement may be more lax. At least one study shows that perceived accessibility to tobacco products contributes to tobacco initiation and escalation among youth (Ref. 145). Accordingly,

FDA concludes that the proposed minimum age and identification restrictions, combined with comprehensive and consistent enforcement at the Federal level and in partnership with states, will decrease the likelihood of youth smoking initiation and, therefore, are appropriate for the protection of the public health under section 906(d) of the FD&C Act.

The proposed minimum age and identification restrictions for covered tobacco products are reasonable restrictions to curb youth tobacco product use that would not hamper adult access to these products. Adults seeking to purchase cigars or other covered tobacco products would continue to take the same steps as they had in the past to purchase these products. The only group that would find it more difficult to purchase these products would be the youth population. In addition, FDA believes that these restrictions are necessary to prevent reinforcement of existing misperceptions by youth that certain tobacco products--those for which there are no minimum age or identification requirements--are safe for their use. The absence of such requirements for covered tobacco products could give youth a false sense of security about the safety of those products sold without these restrictions.

Moreover, the proposed rule would simplify retailer compliance with tobacco access restrictions. This restriction would make all cigarettes, smokeless tobacco, and covered tobacco products in a retailer's establishment subject to the same age and identification requirements. The proposed restrictions would make compliance less cumbersome for retailers who sell tobacco products in stores throughout the United States, because they would have a uniform age and identification requirement to enforce across their stores (rather than several state and local laws that could result in differing age restrictions and application to types of tobacco products). Currently, the state and local age restrictions vary with respect to the types of tobacco products to which they apply. For example, while Kentucky prohibits the sale of tobacco products to

person under 18, the provision does not define "tobacco product" in this context and, therefore, may not cover proposed deemed tobacco products such as pipe tobacco and e-cigarettes (Ky Rev Stat. § 438.310). Similarly, Delaware's age restrictions apply to any product that "contains tobacco," which could be construed to apply less broadly than the proposed federal restriction that also would apply to products that are derived from tobacco (Del. Code Ann. tit. 11, §§ 1115, 1116). With a consistent Federal regulation, retailer owners would be able to more quickly train employees regarding the restriction without needing to differentiate between a variety of products that contain similar packaging and many of the same ingredients. Better retailer compliance and enforcement can make it more difficult for youth to access dangerous tobacco products, which FDA believes would, in turn, limit their use of such products.

B. Application to Proposed Vending Machine Restrictions

Section 1140.14(b)(3) of the proposed regulation would ban the sale of covered tobacco products in vending machines, unless the vending machine is located in a facility where the retailer ensures that individuals under 18 years of age are prohibited from entering at any time. This restriction is appropriate for the protection of the public health because it ensures that persons under the age of 18 cannot purchase covered tobacco products without a retailer having to verify their age and identification.

Section 1140.16(c) currently prohibits the sale of cigarettes and smokeless tobacco in vending machines except those located in facilities where individuals under 18 years of age are not permitted to enter at any time. The preamble to FDA's 1995 proposed rule regarding restrictions on youth access to cigarettes and smokeless tobacco identified numerous studies and surveys showing that significant percentages of young people are able to purchase cigarettes from vending machines (60 FR 41314 at 41324-41326, August 11, 1995). Based on studies

demonstrating how easily youth and young adults could purchase cigarettes from vending machines and surveys of actual purchasing behavior, the Agency concluded that the provision would eliminate a primary source of cigarettes for at least 2 percent of 17-year-old smokers and 22 percent of 13-to-17-year-old smokers (60 FR 41314 at 41324 and 41325; 61 FR at 44396 at 44449).

As with cigarettes and smokeless tobacco, a ban on vending machine sales in places accessible to individuals under 18 would eliminate an easy means of access to covered tobacco products, especially for younger children. In addition, this proposed restriction is an important adjunct to the proposed minimum age and identification requirements. Without the proposed restriction on vending machines, use of vending machines to obtain covered tobacco products would likely circumvent the proposed minimum age and identification restrictions. For example, a 2002 review of youth access policies found that although vending machines and shoplifting represented approximately 5 percent or less of youth supply, the flow of cigarettes comes from a variety of sources (Ref. 146). If it becomes more difficult for youth to buy cigarettes over the counter, greater numbers of youth will purchase them from vending machines or older peers, or borrow or steal from parents (id.). Thus, unless vending machines restrictions are part of this rule, these well-recognized substitution effects could limit the effectiveness of the minimum age and identification restrictions FDA is proposing (Refs. 133 and 140).

Furthermore, more recent research confirms that purchases of cigarettes from vending machines occur regardless of locks, warning signs, and other physical restrictions. A 2009 German study on youth access to tobacco vending machines concluded that electronic locking devices on vending machines were not sufficient to limit youth access to tobacco. The study also found that youth were able to circumvent the electronic locking devices and still obtain cigarettes

(Ref. 147). Accordingly, the proposed restriction is designed to prevent youth access to the vending machines themselves.

According to the most recent data that is currently available, tobacco product vending machine sales declined sharply in recent decades, with 2007 sales totaling $46.9 million (Ref. 148). Since 2007 there has been expansive growth in e-cigarette sales (which were negligible in 2007), and vending machine sales of e-cigarettes are not prohibited or restricted to any significant extent at the Federal, state, or local levels. The proposed rule produces public health benefits to the extent that e-cigarettes, cigars, and other proposed deemed products are currently being sold through vending machines or would be in the future.

We also note that FDA's proposed restriction regarding the use of vending machines is not intended to apply to facilities in which the retailer ensures that no person under 18 years of age is present. We believe this limitation is appropriate because this rule would prohibit access by youth without imposing additional requirements upon retailers who serve the over 18-year-old population.

VII. Proposed Required Warning Statements

FDA is proposing to require the following health warning on all covered tobacco products, as well as cigarette tobacco and roll-your-own tobacco: "WARNING: This product contains nicotine derived from tobacco. Nicotine is an addictive chemical." We note that the definition of "covered tobacco products" would depend on the universe of tobacco products that would be covered this rule. Under Option 1, all cigars would be covered and, therefore, this additional requirement would apply to all cigars. However, under Option 2, only a subset of cigars (i.e., "covered cigars," which would exclude "premium" cigars) would be covered by the rule and, therefore, this additional requirement would apply to only a subset of cigars. FDA is

proposing a self-certification option for manufacturers who certify that their tobacco product does not contain nicotine (and that they have data to support that assertion). Such a product would be required to bear the statement, "This product is derived from tobacco."

FDA is proposing that this warning statement be required to appear on the packages and in the advertisements for all proposed newly covered tobacco products and other tobacco products for which health warnings are not otherwise required by Federal law or regulation (i.e., cigarette tobacco and roll-your-own tobacco). As discussed in section V.A, the addictive nature of nicotine in tobacco products is clear.

In 2000, in settlements with the FTC, the seven largest U.S. cigar manufacturers agreed to include warnings about significant adverse health risks of cigar use in their advertising and packaging. (See, e.g., In re Swisher International, Inc., Docket No. C-3964.)

Under the 2000 FTC consent orders, virtually every cigar package and advertisement is required to clearly and conspicuously display one of several warnings on a rotating basis, including the following:

- Cigar Smoking Can Cause Cancers of the Mouth and Throat, Even If You Do Not Inhale.
- Cigar Smoking Can Cause Lung Cancer and Heart Disease.
- Cigars Are Not a Safe Alternative to Cigarettes.
- Tobacco Smoke Increases the Risk of Lung Cancer and Heart Disease, Even in Nonsmokers.

Based on FDA's authority under section 906(d) of the FD&C Act, FDA is proposing to adopt these four cigar warning statements from the FTC consent orders--which the vast majority of cigars already use--in addition to the warning statement regarding addictiveness. These warning statements will be randomly displayed and distributed on cigar product packages and

rotated in advertisements. For cigars sold individually that are not packaged, FDA is proposing that the cigar warnings 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. If FDA's proposal to deem tobacco products to be subject to its "tobacco product" authorities is finalized, FDA and the FTC will consult to harmonize national requirements for health warnings on cigar product packages and in advertisements. In addition, under Option 1, these warning requirements would now apply to all small and large cigars, not just to those manufactured by the seven companies subject to the FTC orders.

FDA's proposal that these cigar warnings be randomly distributed on packages and rotated in advertisements is consistent with the requirements established by Congress in the Tobacco Control Act for statutorily covered products. Section 4 of the Federal Cigarette Labeling and Advertising Act and section 204 of the Tobacco Control Act require the random distribution and rotation of warnings for cigarettes and smokeless tobacco products, respectively. Therefore, FDA is not proposing to treat cigars differently from currently regulated tobacco products. Further, rotation of warning labels already occurs under the FTC consent decrees. The WHO also has recognized the need to rotate health warnings for tobacco products. In the WHO's Framework Convention on Tobacco Control (FCTC),[4] an evidence-based treaty that provides a regulatory strategy for addressing the serious negative impacts of tobacco products, calls for warnings that are rotating, "large, clear, visible and legible." (WHO FCTC article 11.1(b).) However, FDA recognizes that the random distribution of warning statements on cigar product packages and the rotation of statements on advertisements can result in significant costs for cigar manufacturers. Therefore, FDA requests comments on other possible methods (e.g., randomly

[4] There are 168 signatories to the WHO's Framework Convention on Tobacco Control as of August 2010. At this time, the United States is a signatory but has not ratified this treaty.

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. FDA requests comments and data showing that such alternative methods would still achieve FDA's public health goals yet would reduce costs for cigar manufacturers.

In the following sections, we discuss the bases for the proposed warning statements. We discuss how FDA's proposed health warning statements and the exercise of authority in this area meet the requirements for implementing a restriction regarding the sale and distribution of a tobacco product under section 906(d) of the FD&C Act. We also explain the importance of including the proposed health warnings on small and large cigars given the scientific evidence regarding the serious adverse health risks associated with cigar use, the age of initiation of cigar use, and the increasing popularity of cigars among youth (in particular, small cigars), as well as the fact that many of these products already display most of these warnings. In addition, we explain that these warning statements, as well as the proposed additional warning for covered tobacco products (and cigarette tobacco and roll-your-own tobacco), will effectively communicate to consumers the addictive nature of the nicotine in these products. FDA believes that consumers should clearly understand and appreciate the dangers of tobacco use. Greater awareness and understanding of the dangerous health effects of tobacco product use will help consumers better understand the potential consequences of their purchase and use of tobacco products.

A. Requiring Health Warnings Is Appropriate for the Protection of the Public Health

The purpose of health warnings is to help current and potential tobacco users understand and appreciate the serious adverse health consequences associated with tobacco product use and

the addictive nature of tobacco products. Adolescents do not accurately understand the health risks associated with smoking, and smokers tend to underestimate the risk of harm (Ref. 149). FDA believes it is reasonable to apply this notion of imperfect smoking-related knowledge to other forms of tobacco product use as well. Given the dangers associated with continued use of tobacco products, FDA believes it is critical to include a warning on all such products to help consumers better understand and appreciate the addictive nature of these products.

For more than 45 years, Congress has required textual health warnings for cigarettes on product packages. Warnings in cigarette advertising have been required since the FTC issued its 1972 consent orders and since 1984 by statute. (See in re Lorillard et al., 80 FTC 455 (1972); Comprehensive Smoking Education Act, Pub. Law No. 98-474 (1984).) For almost 25 years, Congress has required textual health warnings for smokeless tobacco packages and advertisements. The FCTC also requires health warnings on tobacco product packages (article 11) and in tobacco product advertising (article 13). The 2000 consent orders between seven cigar manufacturers and the FTC required health warnings for cigar packages and advertisements. Thus, requiring health warnings on all tobacco products subject to the FD&C Act is consistent with existing laws, practices, and international standards.

The health warnings that FDA is proposing, which concern risks associated with the use of tobacco products, are clearly material with respect to the consequences that may result from the use of those products. For all covered tobacco products (as well as cigarette tobacco and roll-your-own tobacco) that contain nicotine, the proposed regulation would require a warning about the addictive nature of nicotine in the product. For small and large cigars, the warnings also convey information about health consequences, including certain cancers, cardiovascular disease, and effects on others exposed to secondhand smoke. It is important for consumers who are

making purchasing decisions to understand that, unlike most other consumer products, once tobacco product use is initiated, it can be very difficult to stop using the product.

Consumers also may be unaware of the presence and addictive nature of nicotine in all of these products, as they can be the first tobacco product that a young person uses before progressing to cigarette smoking or use of other tobacco products, as discussed in section V. In addition, once a user becomes addicted, he or she likely would increase use and, therefore, increase his or her risk of suffering from other negative health effects given the dose-response relationship associated with many of these products (Ref. 49). Therefore, the warnings FDA is proposing would provide highly material information that all consumers should know about the consequences of using tobacco products. Failure to disclose material facts about tobacco products, such as the presence and addictive nature of the nicotine in the products, is likely to mislead consumers. See In re Lorillard, et al., 80 FTC 455 (1972) (consent order resolving charges that failure to disclose statutory health warning for cigarettes in cigarette advertising was deceptive and unfair). See also In re Swisher International, Inc., Docket No. C-3964; In re Havatampa, Inc., Docket No C-3965; In re Consolidated Cigar Corp., Docket No. C-3966; In re General Cigar Holdings, Inc., Docket No. C-3967; In re John Middleton, Inc., Docket No. C-3968; In re Lane Limited, Docket No., C-3969; In re Swedish Match North America, Inc., Docket No. C-3970 (consent orders resolving allegations that failure to disclose the adverse health consequences of cigar use was deceptive and unfair).

The proposed requirements to include health warnings on tobacco product packages and in advertisements also would satisfy the standard in section 906(d) of the FD&C Act, which allows the Agency to issue a regulation to require restrictions on the sale or distribution of a tobacco product, if the regulation "would be appropriate for the protection of the public health."

According to the statute, the determination as to whether a regulation would be appropriate for the public health must be based on the risks and benefits to the population as a whole (including tobacco users and nonusers) and taking into account how the regulation could impact the likelihood of existing users stopping use of the product and the likelihood of new users starting to use the product (section 906(d)(1)(A) and (B) of the FD&C Act).

The public health benefits to both users and nonusers from this regulation would be significant. As discussed in sections V.B and VII.E, there is substantial evidence that certain tobacco products within the scope of this regulation cause serious diseases and death and that secondhand smoke causes deadly diseases in nonsmokers. The addictive nature of tobacco products also has been well-documented (see section V.A). These proposed warnings would help ensure that youth and young adults, who may be more susceptible to the addictiveness of nicotine, have a greater awareness of the dangers associated with these products before they might become addicted. As discussed in section VII.B, researchers have found that tobacco health warnings on product packages and in advertisements can effectively provide this important health information to consumers. FDA believes that the proposed warnings would help both users and nonusers better understand and appreciate these dangers.

B. Effectiveness of Warnings

The use of tobacco packages to help consumers better understand and appreciate tobacco-related health risks has a number of advantages. The frequency of exposure is high. In addition, package warnings are delivered both at the time of tobacco product use and at the point of purchase. Thus, the messages are delivered to tobacco users at the most important times--when they are considering using or purchasing the tobacco product. The messages on packages also help the public at large, including potential tobacco users, better understand and appreciate the

health and addictiveness risks of using the products (Ref. 56). Requiring health warnings in advertisements similarly is an important means of helping consumers better understand and appreciate the health consequences of tobacco use. (See In re Lorillard et al., 80 FTC 455 (1972); Federal Cigarette Labeling and Advertising Act (FCLAA), 15 U.S.C. 1331 et seq.; Comprehensive Smokeless Tobacco Health Education Act of 1986 (CSTHEA), 15 U.S.C. 4402 et seq.)

For the communication to be effectively understood and appreciated, consumers must notice and pay attention to the warning. As discussed at length in this section, the size, placement, and other design features of the warning play a role in the effective communication of the underlying message. As discussed in sections VIII.C.2 and VIII.C.3, the proposed regulation would require that the health warning statements comprise 30 percent of the area of the two principal display panels of the package to help ensure that consumers notice and process the critical information conveyed in the required warning statements. The IOM, Congress, and Article 11 of the FCTC recognize the importance of having the warnings cover at least 30 percent of the area of the principal display panels, and users are more likely to recall warnings that are in a larger size and that appear on the front/major surfaces of the tobacco package (Ref. 58; 15 U.S.C. 4402(b); FCTC article 11). Because the warnings would be required to appear on 30 percent of the two principal display panels (which includes the front of the package), FDA believes that the proposed warnings will be effective in helping consumers better understand and appreciate critical information. We are proposing a 30-percent size requirement for product packages to be consistent with Congress' size requirements for similar text-only warnings for smokeless tobacco under CSTHEA (15 U.S.C. 4402(a)(2)(A)), rather than the 50-percent size

requirement that Congress chose for graphic warnings on cigarette packages. We invite comment on the appropriateness of this size requirement.

In addition, because a large font size increases the impact and legibility of the warning, FDA is proposing that the warning statement on packages and advertisements appear in the maximum font size that would fit into the warning area. Given the variety of packaging sizes for the tobacco products at issue in this regulation, it is not feasible to specify a single font size for all products within the scope of this regulation. Therefore, FDA is proposing that the font be as large as possible to ensure that the required warning statement will be noticed by consumers regardless of the package size. Research has shown that using the largest possible lettering can increase warning effectiveness and increasing font size aids communication (Ref. 150). Similarly, the proposed requirement that the warnings appear in black text on a white background or white text on a black background will improve the legibility and noticeability of the warnings (Refs. 58 and 150).

The format requirements that FDA is proposing are similar to those included in a 2001 European Union Directive, which have been shown to increase the effectiveness of health warnings. European Union (EU) Directive (2001/37/EC) requires that tobacco warnings in all member countries meet certain minimum standards that are similar to those that FDA is proposing (i.e., EU required health warnings comprise 30 percent of the area on the front of package and 40 percent on the back of the package; black Helvetica bold type on a white background; warnings to occupy the greatest possible proportion of the warning area set aside for the text required; messages centered in the warning area and surrounded by a black border of 3 to 4 millimeters (mm) in width). Prior to the 2001 Directive, warnings in most European Union countries were very small and general. In one study conducted for the European Commission, a

majority of respondents considered the Directive's new warning format more effective and more credible than the previous format (Ref. 151). A study of Spanish university students also concluded that text warnings based on the Directive significantly increased perceptions of the risk of tobacco products (Ref. 152). Additionally, in a study of similar warnings in the United Kingdom, smokers indicated that their awareness of the warnings increased along with thoughts about the health risks of smoking (Ref. 153).

FDA believes that the fundamental similarities between cigarettes and smokeless tobacco and other tobacco products allow for the application of data regarding the effectiveness of cigarette and smokeless tobacco warnings to warnings for other tobacco products. Research dating back to the late 1980s has found that small warning labels for cigarettes and small warning labels for smokeless tobacco products alike were rarely noticed and suffered from low rates of recall among youth (Refs.154, 155, and 156). For example, in one eye-tracking study, adolescents were asked to view five cigarette ads that included a health warning (Ref.155). The average viewing time of the health warning was only 8 percent of the total time spent viewing the ads, and participants subsequently demonstrated a low recall of the warnings (id.). Similarly, a study of health warnings on oral snuff and chewing tobacco pouches revealed that fewer than half of the subjects recalled seeing the warnings and approximately one-third of those who saw the warnings recalled the content (Ref. 156). These studies were all based on the small warning sizes then required by United States law. As discussed above, the Tobacco Control Act requires substantially larger warnings for cigarettes and smokeless tobacco products, and this proposed rule, if finalized, would require similarly sized warnings for other tobacco products. Warning size clearly matters, as recall increases significantly with font size (Ref. 156 at ii61). In a study of recall of health warnings in smokeless tobacco ads, conducted with 895 young males, 63

percent of participants recalled a high contrast warning in 10-point font; doubling the warning size to a 20-point font increased recall from 63 percent to 76 percent representing a 20-percent improvement in recall (Ref. 156 at ii61-ii62). Research on cigarette-package warnings confirms that larger warnings are better noticed and more likely to be recalled (Ref. 54 at 810; ref. 58 at App. C-3; ref. 150). These studies support FDA's belief that requiring that the proposed warnings appear in the maximum font size will improve their noticeability.

The content of the proposed messages also indicates that they should help consumers understand and appreciate the relevant health risks. In a qualitative study conducted for Health Canada, researchers tested text-only smokeless product health messages, some of which are similar to FDA's proposed health warnings for cigars. One of the tested Canadian messages (This product causes mouth diseases) generally was considered to be a low-impact message, which participants felt was not a deterrent but merely a reminder (Ref. 159 at 11). However, FDA's proposed message (adopting the existing FTC warning language) regarding mouth diseases is more specific and alerts consumers that not only do small and large cigars cause "mouth diseases," they also cause cancer of both the mouth and the throat. As the IOM explained with respect to cigarette warnings, specific unambiguous warnings are more likely to be noticed and less likely to be discounted than vague warnings (Ref. 58 at App C-3).

Another Canadian tested message (Use of this product can cause cancer) is similar to three of FDA's proposed warning messages. Most respondents in the Canadian study considered this message to be credible, although some found that the message was "too vague to be effective" (Ref. 159 at 12). However, FDA's proposed health warnings, adopting the existing FTC language, are more specific than the Canadian message (referring to specific types of cancers, noting the risk of mouth and throat cancers even for those that do not inhale, and

alerting users that the smoke released from their product can even cause cancer in nonsmokers) (Ref. 58). FDA believes, therefore, that the proposed warnings will be effective in helping current and potential smokers understand and appreciate the adverse health consequences related to cigar smoking.

Researchers have studied the relationship between substance use and memory for health warnings on cigarettes, smokeless tobacco, and alcohol. For smokeless tobacco, researchers confirmed a statistically significant correlation between use and recognition memory for the product's health warnings (Ref. 157 at 147).

Although there has not yet been extensive research regarding the effectiveness of health warnings on tobacco products other than cigarettes (Refs. 155, 156, 157, 158), existing studies support the use of these messages. Canada's text-only health warning messages for chewing tobacco and oral snuff packages (similar to the ones FDA is proposing to apply to cigars) were issued in 2000 (Ref. 159), which the qualitative study described above found to be effective at educating consumers about the dangers associated with their use. In the instances where consumers believed the messages were ineffective, FDA is proposing messages that differ significantly from the Canadian messages in that they provide additional, specific health information for consumers.

FDA intends to conduct research and keep abreast of scientific developments regarding the efficacy of the final health warnings and the ways in which their efficacy could be improved. We will use the results of our monitoring and such research to help determine whether any of the warning statements (if finalized) should be revised in a future rulemaking. Under Option 2, these warning label requirements would only apply to covered cigars and not to premium cigars.

C. Proposed Addictiveness Warning

To FDA's knowledge, all tobacco products currently on the market contain nicotine (Ref. 49 at 12). The Surgeon General has long recognized the addictive nature of tobacco products due to the presence of highly addictive nicotine that can be absorbed into the bloodstream (See, e.g., Ref. 49 at 6-9). Nicotine is psychoactive and can serve as a "reinforcer" to motivate tobacco-seeking and tobacco-using behavior (Ref. 49 at 7). The patterns of nicotine use are regular and compulsive, and a withdrawal syndrome usually accompanies tobacco abstinence (Ref. 49 at 13). Tolerance develops to nicotine such that repeated use results in diminished effects and can be accompanied by increased intake (Ref. 49 at 13). The pharmacologic and behavioral processes that determine tobacco addiction are similar to those that determine addiction to other drugs (Ref. 49 at ii). Leading national and international organizations, including WHO, the American Psychiatric Association (APA), the American Cancer Society, and the American Academy of Addiction Psychiatry, have recognized chronic tobacco product use as a drug addiction (Ref. 49 at iii). WHO and APA do not use identical definitions of "addiction"; however, they have in common several criteria for establishing a drug as addicting--such as the fact that the user's behavior is largely controlled by a psychoactive substance; the drug is reinforcing and the user can develop a tolerance to it; and withdrawal can occur following abstinence--and nicotine meets all these criteria (Ref. 49 at iv). See section V.A for additional information regarding the addictiveness of tobacco products.

Accordingly, FDA proposes to help consumers better understand and appreciate the addictiveness of tobacco product use by adding warnings on packages and in advertisements for all covered tobacco products and those products not already requiring a health warning under Federal law or regulation (i.e., cigarette tobacco and roll-your-own tobacco). FDA proposes that

such warning would state: "This product contains nicotine derived from tobacco. Nicotine is an addictive chemical."

1. Consumer Perceptions Regarding Addictiveness of Tobacco Products

This warning is particularly important given consumers' erroneous and unsubstantiated beliefs that tobacco products other than cigarettes are either less addictive than cigarettes or are not addictive at all. For example, in a survey of high school students, 46.3 percent of participants--83.3 percent of whom were waterpipe users--believed their product was less addictive and safer than cigarettes (Ref. 90 at 3, 4) (also citing several additional studies where young adult waterpipe users reported that their tobacco product was less addictive). Also, in a qualitative study prepared for Health Canada consisting of smokeless tobacco, cigars, and pipe users between the ages of 16 and 60 plus, most large cigar smokers thought that their product was less addictive than cigarettes or not addictive at all because they smoked for pleasure or did not smoke daily (Ref. 158 at 1, 40). Small cigar smokers in this study were split as to whether they believed their product of choice was addictive (Ref. 158 at 41). While most chewing tobacco and snuff users tended to believe these products were as addictive as cigarettes, some believed their chew was not addictive because the taste was such a turnoff (id.). Not only do these studies further indicate the need for a warning statement to ensure that consumers recognize that nicotine is addictive, but they also indicate that broader education regarding the addictiveness of tobacco products also may be necessary given that consumers in the Canadian study incorrectly believed an individual could not be addicted to a product that he or she "disliked" or did not use every day (id.).

FDA also believes that this warning is necessary to reduce youths' widely held but erroneous belief that certain tobacco products--those for which there currently are no warnings

regarding addictiveness--are safe for their use (Ref. 51). Youth believe that they will be able to stop using tobacco whenever they want to do so (id.). However, because of the addictiveness of nicotine, they often have great difficulty doing so. Thus, addiction warnings are particularly important for youth. Health warnings are currently required for cigarettes and smokeless tobacco under the Tobacco Control Act. The absence of a health warning requirement for other tobacco products could reinforce the existing false sense of security that youth have about the safety of those products.

Further, many consumers believe that the use of e-cigarettes will help them quit smoking, even though this has not been proven by long-term studies of significant numbers of e-cigarette users, and some consumers forego proven cessation methods due to those unsubstantiated beliefs. For example, in the ITC Four-Country Survey, 75.4 percent of respondents indicated that they used e-cigarettes to help them reduce their smoking and 85.1 percent reported using e-cigarettes to help them quit smoking (Ref. 36). In a survey of current and former smokers, 80 percent of respondents reported that they used e-cigarettes to help them reduce the number of cigarettes they use and 65 percent stated they used e-cigarettes to try to quit using cigarettes (id.). Section IV.D discusses the possible reduced usage of cigarettes that may be associated with e-cigarettes and the limitation of existing studies. We do not currently have sufficient data about these products to determine what effects e-cigarettes have on the public health.

2. Alternative Statement for Products Without Nicotine

The products for which FDA is proposing health warnings under this rule all contain nicotine. FDA is not aware of any currently marketed tobacco product that does not contain nicotine. However, in the event that such products are developed, FDA proposes that manufacturers of such products submit a certification of that fact (and the fact that they have the

data to support this assertion) to FDA. Products for which such a certification has been submitted would not contain any warning that would clearly indicate that it is a tobacco product. Accordingly, FDA is proposing that such products include the following alternative statement on their product packages and in their advertisements: "This product is derived from tobacco." FDA believes it is important to alert consumers and retailers as to which items are tobacco products. Even if a tobacco product does not contain nicotine, it can still contain other addictive chemicals (like anabasine or nornicotine, discussed in the preamble) or dangerous toxicants. Therefore, FDA believes consumers should be aware that the product is, in fact, a tobacco product. In addition, the statement would alert consumers as to which products would require identification for purchase and increase retailer awareness of the products for which they must verify the age of consumers. FDA requests comments on this alternative statement.

3. Request for Comments Regarding Addictiveness Warning for Certain Categories of Tobacco Products

FDA realizes that while all tobacco products are potentially harmful and potentially addictive, different categories of tobacco products may have the potential for varying effects on public health. For example, some have advanced views that certain new tobacco products that are non-combustible (such as e-cigarettes) may be less hazardous than combustible products, given the carcinogens in smoke and the dangers of secondhand smoke. Thus, 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.

In addition, we note that this requirement would apply to products that are derived from tobacco, and not just products that themselves contain tobacco, based on the definition of

"tobacco product" in section 201(rr) of the FD&C Act. As a result, FDA recognizes that the use of the words "tobacco product" in the warning might be thought to have the potential to confuse consumers. Accordingly, FDA request comments, including supporting facts, research, and other evidence regarding the following questions:

- 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?
- If there are concerns about the use of the word "tobacco product," what other language should FDA consider utilizing in this proposed warning?
- 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?

D. Age of Initiation for Cigar Smokers

FDA's proposed warning statements are intended to educate both youth and adults regarding the dangerous effects of cigar smoking in order to provide consumers with the information to better understand the potential consequences of their decisions, and in the case of youth, to prevent youths from initiating use. There is a common misconception that young people do not smoke cigars, and it is therefore unnecessary to warn them of the dangers of cigar smoking (Ref. 28 at 13). However, as discussed in this document, data show that a substantial number of young people smoke cigars (defined as cigars, little cigars, and cigarillos). Each day in the United States, more than 3,000 youth under age 18 smoke their first cigar (Ref. 81). In addition, young people who use both cigars and cigarettes are more likely to be frequent users of both products (Ref. 117 at 647). Therefore, the proposed warnings are necessary to alert young

people to the dangers of initiating cigar use, as well as to help current cigar smokers better understand and appreciate the health risks of using cigars.

Young adults appear to be particularly interested in cigarillos, as opposed to large cigars. The close resemblance of small cigars and many cigarillos to cigarettes have led consumers, particularly children and young adults, to substitute them for cigarettes (Ref. 160). Researchers assessing studies designed to measure cigar use have found significant increases in reported cigar prevalence when they reproduced the studies but added examples of little cigar and cigarillo brands, indicating consumer confusion between little cigars and cigarillos on one hand, and cigarettes on the other, as well as indicating consumer substitution of little cigars and cigarillos for cigarettes. For example, researchers re-administered the Youth Risk Behavior Survey to six Midwestern high schools and included a popular little cigar brand name to the item measuring cigar use (Ref. 65). When the survey was initially administered, the local rates of cigar and cigarette use were consistent with national rates (id.). However, when the cigar item was modified to include a little cigar brand-specific example, the percentage of high school students reporting cigar use nearly doubled--jumping from 12.9 percent to 20.7 percent (Ref. 65). Likewise, researchers assessing data from the 2009 Virginia Youth Tobacco Survey found that 57.3 percent of respondents who used a popular brand of little cigars and cigarillos erroneously reported no general cigar use (Ref. 66). These findings are consistent with focus group data for 2001, where researchers found that respondents generally (but wrongly) did not think inexpensive cigarillos or little cigars were "cigars," and where the rate of self-reported cigar use increased by 37.5 percent once the definition of cigar was clarified (Ref. 161). Moreover, in a secondary analysis of cigar use by persons aged 18 to 25 from the National Survey on Drug Use

and Health (2002-2008), researchers determined that the top five cigar brands most frequently smoked by current cigar users include little cigars or cigarillos (Ref. 162).

Research also shows that youth may be initiating cigar use as much as cigarette use. The National Survey on Drug Use and Health found that of the more than 2.9 million people aged 12 and above who first used cigars of any type in 2010, nearly 1.1 million (or approximately 37 percent) were under the age of 18 at initiation (Ref. 82). (This amounts to nearly 3,000 youths initiating cigar use every day.) By comparison, of the nearly 2.4 million people aged 12 and above who first used cigarettes in 2010, 1.4 million (or approximately 58.3 percent) were under the age of 18 at initiation (Ref. 82). (This amounts to 3,800 youths initiating cigarette use each day.) A 2009 study found similar results, reporting that approximately 14 percent of high school students had smoked cigars at least 1 day during the previous 30-day period, compared with 19.5 percent who had smoked cigarettes at least 1 day during the same period (Ref. 167 at 10, 12).

The Office of Inspector General of the Department of Health and Human Services (HHS) also published figures in 1999 regarding the patterns of cigar use. According to their survey, 76 percent of high school and junior high teens knew other teens about their age who smoked cigars (Ref. 35 at 4). While most teens' first exposure to tobacco was with cigarettes, 22 percent of students in this survey tried cigars first (Ref. 35 at 6). This is of particular concern given that young people who start as cigar-only users are more susceptible to becoming future cigarette users than other youth (id.). This report also notes that manufactured cigars (i.e., most types of small cigars and cigarillos) are most commonly used by teens due to their ease of purchase, low cost, sweetened flavors, and pleasant aromas (Ref. 35 at ii). More recent surveys have confirmed the popularity of small cigars and cigarillos is due at least in part to the availability of a wide variety of flavors (Ref. 162 citing Ref. 163; Ref. 164; Ref. 165). Young consumers appear to

view little cigars and cigarillos as being less expensive and more convenient than large and premium cigars, contributing to their popularity (Ref. 160).

In addition, according to the 2001 National Household Survey on Drug Abuse, the number of younger children initiating cigar use is beginning to exceed the number of young adults initiating cigar use, further highlighting the importance of health warnings. From 1965 until 1996, there were more cigar initiates among 18- to 25-year olds than among 12- to 17-year olds (Ref. 166). Yet, from 1997 to 2000, the number of new cigars users in the 12- to 17-year old group exceeded the 18- to 25-year-old initiates (id.).

In some states, cigar smoking among youth may be even more popular than cigarette smoking. For example, the 2009 Youth Risk Behavior Surveillance study found that 18 percent of high school boys in Massachusetts were cigarette smokers and 22 percent were cigar smokers (Ref. 167 at 66, 72). Similarly, an Ohio survey of 4,335 students showed cigars to be the most popular tobacco product among high school students (Ref. 11 at 647). (See also Ref. 164.) These data indicate that small and large cigars are no longer an "alternative" to cigarette use, but rather they are the most popular tobacco product for many young people.

E. Proposed Required Warning Statements for Small and Large Cigars

FDA is proposing five health warning statements for use on all cigar packages and in all cigar advertisements. Under Option 1, all cigars would be required to display these health warning statements. Under Option 2, only a subset of cigars (i.e., those defined as "covered cigars," which would exclude "premium" cigars) would be required to display these warning statements. The first four warnings (discussed in this document) are identical to four of the warnings included in the seven consent orders that the FTC entered into with the largest mass marketers of cigars. (See, e.g., In re Swisher International, Inc., Docket No. C-3964.). FDA is not

proposing the fifth FTC warning (Tobacco Use Increases The Risk Of Infertility, Stillbirth And Low Birth Weight), because although cigarette smoking has been shown to cause these health effects and cigar smoke is similar, the Agency is not aware of studies specifically linking cigars to these reproductive effects. FDA requests comment on its proposal to require the use of only four of the five current FTC warnings for cigars.

1. WARNING: Cigar Smoking Can Cause Cancers of the Mouth and Throat, Even if You Do Not Inhale

The NCI's Monograph No. 9 provides a comprehensive, peer-reviewed analysis of the trends in cigar smoking and potential public health consequences. NCI identified a dose-response relationship for cigar smoking and oral, laryngeal, pharyngeal, and esophageal cancers, finding an increased risk of these diseases with greater numbers of cigars smoked per day and deeper inhalation (Ref. 28 at 120-130). Cigar smoking can cause cancers of the mouth and throat even for smokers who do not inhale (id.). As a result, cigar smokers who do not inhale have disease risks higher than those who have never smoked (Ref. 28 at ii). FDA believes that a warning regarding these potential health consequences is necessary because of consumers' widely held, but erroneous, belief that cigars are safe products if users do not inhale the smoke (id.).

"The data clearly establish cigar smoking as a cause of oral cancer" (Ref. 28 at 127). Regular cigar smokers who have never smoked cigarettes, including those who do not inhale, experience significantly elevated risks for oral, laryngeal, pharyngeal, and esophageal cancers (Ref. 28 at ii and Ref. 62 at 738). While former cigarette smokers who currently smoke cigars are more likely to inhale deeply than cigar smokers who never smoked cigarettes, "the mouth and oral cavity are exposed to the carcinogens in smoke whether the smoke is inhaled or not" (Ref. 28 at 120). In addition, cigar smokers, including those who do not inhale, have a similar risk of

mouth and throat cancer as do cigarette smokers, with an overall risk 7 to 10 times higher than for those who have never smoked (Ref. 28 at 125). This similarity in risk is likely due to the similar doses of tobacco delivered directly to the oral cavity and esophagus by cigars and cigarettes (Ref. 30 at 738). Likewise, NCI researchers found that the data taken as a whole support cigar smoking as a cause of laryngeal cancer, noting that the relative risk for those who smoke five or more cigars per day or who inhale moderately or deeply approaches the risk for cigarette smokers (Ref. 28 at 130).

The data also establish cigar smoking as a cause of esophageal cancer (id.). Cigar smokers, regardless of whether they inhale, receive a high smoke exposure to the mouth and tongue, and the esophagus is exposed to the carcinogens of tobacco smoke, which collect on the mouth's surface and are swallowed with saliva (id.). The risk of esophageal cancer is several times higher among cigar smokers than among those who have never smoked, and the relative risk of occurrence is similar to that for cigarette smokers (id.).

Several multinational research studies also have noted that cigar smoking can cause oral cancers and other cancers, even for those who do not inhale. For example, the European Prospective Investigation into Cancer and Nutrition (EPIC) examined the effects on cancer incidence for exclusive cigar smokers, and for cigar smoking in combination with cigarettes, on 102,395 men from Denmark, Germany, Spain, Sweden, and the United Kingdom (Ref. 168 at 2402). According to the EPIC study findings, exclusive cigar smokers who did not inhale had approximately a two-fold higher risk of lung, upper aerodigestive tract (which includes oral cavity, pharynx, larynx, and esophagus), and bladder cancers combined, compared to those who never smoked, and this risk was six- or seven-fold higher in cigar smokers who inhaled (Ref. 168 at 2405). This increased risk was smallest for smokers who had quit both cigarettes and cigars in

the past and intermediate for those who switched to only cigars, demonstrating the additional risk associated with cigar smoking per se (Ref. 168 at 2409). Researchers confirmed a carcinogenic effect from cigar smoking for upper aerodigestive tract cancers and found that the risk of these hazards increased with increased duration of smoking over the smoker's lifespan, increased intensity per episode, and increased degree of smoke inhalation per episode (id.).

Similarly, the WHO International Agency for Research on Cancer (IARC) published a monograph evaluating the carcinogenic risk to humans from tobacco smoke and involuntary smoke exposure. The IARC explained: "Cigar and/or pipe smoking is strongly related to cancers of the oral cavity, oropharynx, hypopharynx, larynx, and oesophagus, the magnitude of risk being similar to that from cigarette smoking. These risks increase with the amount of cigar…smoking and with the combination of alcohol and tobacco consumption" (Ref. 169 at 1184).

2. WARNING: Cigar Smoking Can Cause Lung Cancer and Heart Disease

As discussed in this section, research has shown that cigar smoking can cause lung cancer and heart disease. Yet, national survey data found that while 46.6 percent of cigar smokers believe smoking is a high-risk behavior for developing cancer, they exhibit an "optimistic bias" in estimates of their own risk of developing cancer over 20 years--only 8.7 percent consider themselves to be at high risk (Ref. 30 at 737). FDA believes this proposed warning is necessary to help both consumers who may be considering smoking cigars and current smokers better understand and internalize these potential (and critical) health consequences.

a. Lung cancer.

The evidence clearly establishes that cigar smoking can cause lung cancer, but the rate of risk varies (Ref. 28 at 119-120 and Ref. 169 at 1180). Like the dose-response relationship

apparent from cigar smoking and mouth and throat cancers, the risk of dying from lung cancer increases as the number of cigars smoked per day and the depth of inhalation increase (Ref. 28 at 119-120). Overall lung cancer risk for cigar smokers also may be similar to the risk for cigarette smokers once the rates are adjusted for differences in inhalation levels and quantity of cigars smoked daily (Ref. 28 at 120). For example, cigar smokers smoking five or more cigars daily with moderate inhalation have lung cancer risks similar to pack-a-day cigarette smokers (Ref. 28 at 119).

Former cigarette smokers who currently smoke cigars are more likely to inhale deeply than cigar smokers who have never smoked cigarettes, increasing their lung cancer risk (Ref. 28 at 155). Cigarette smokers who switch to smoking only cigars have lung cancer risks that are lower than continuing cigarette smokers, but these risks appear to be substantially greater than for individuals who have quit smoking altogether (Ref. 28 at 120, 155).

Likewise, in an analysis of the data from the Cancer Prevention Study II (a large, long-term study of 1.2 million men and women), researchers found that the risk of lung cancer mortality was approximately 5 times higher for men who were current smokers of only cigars at the start of the 12-year followup study period, compared with men who never smoked (Ref. 170 at 334). This risk was higher for men who smoked 3 or more cigars per day, who reported inhaling cigar smoke, or who had smoked cigars for 25 years or more (id.). Notably, even cigar smokers who reported that they did not inhale were approximately three times more likely to die from lung cancer than those who never smoked (id.).

b. Heart disease.

Researchers have identified a pattern of elevated rates of coronary heart disease and aortic aneurysm among cigar smokers who smoke heavily or inhale deeply. Evidence from the

Cancer Prevention Study, Surgeon General's reports, and international studies further substantiate the need to provide clear warnings to consumers of the risk of heart disease associated with smoking cigars.

The Cancer Prevention Study I (CPS I), which studied nearly 1 million men and women in 25 states, found evidence that the rate of coronary heart disease increases with an increase in the numbers of cigars smoked and greater depth of inhalation (Ref. 28 at 144-145). Researchers also identified a significantly elevated risk of developing coronary heart disease in those who smoked five or more cigars per day and exhibited moderate and deep inhalation (id.). Data from CPS I also suggested that cigar smokers are at an increased risk for aortic aneurysm, experiencing a risk rate approaching the rate observed for cigarette smokers (Ref. 28 at 151-152).

Researchers analyzing data from the Cancer Prevention Study II (CPS II) also examined death rates due to coronary heart disease related to cigar smoking. The 1999 analysis looked at approximately 7,000 current cigar smokers, 7,000 former cigar smokers, and 113,000 men who had never regularly smoked tobacco to determine the risk of heart disease for cigar smokers (Ref. 30 at 739). Among men younger than 75 years old, current cigar smokers experienced a coronary heart disease death rate about one-third higher than those who had never smoked (id.).

In the 2010 Surgeon General's report on smoking hazards, titled "How Tobacco Smoke Causes Disease," the Surgeon General found that for older adult cigar smokers, particularly those who smoke more than one cigar per day or inhale the smoke, the risk of heart disease is moderately higher than that for nonsmokers (Ref. 50 at 362). Among the studies relied upon by the Surgeon General was a study published in the New England Journal of Medicine involving 17,774 men (1,546 who smoked cigars and 16,228 who did not) ages 30 to 85 at baseline (from 1964 through 1973), who reported that they had never smoked cigarettes and did not currently

smoke a pipe (Ref. 33 at 1773). The researchers determined that cigar smoking was associated with a moderate, but significant, increase in the risk of coronary heart disease (Ref. 33 at 1778-1779).

International researchers have reached similar conclusions regarding the impact of cigar smoking on the risk of developing heart disease. For example, in a study of more than 12,000 Danish people aged 30 and over, which looked at the risk of first acute myocardial infarction, researchers found highly significant effects related to the number of cigars used per day and the depth of inhalation of smoke (Ref. 28 at 143). Another Danish study found the highest rates of myocardial infarction for smokers of cheroots (a type of cigar) at the rate of six or more per day, with a relative risk of more than four times the risk for those who had never smoked (Ref. 28 at 142).

3. WARNING: Cigars Are Not a Safe Alternative to Cigarettes

Many consumers wrongly believe that cigars are a safe alternative to cigarettes. As discussed in section V.C, research suggests that youth perceive cigars in a more positive light than cigarettes and believe they are less harmful (Refs. 35 and 116). In addition, some cigar smokers believe that cigars are a safe alternative to cigarettes (Ref. 117). However, the dangers from cigar smoking are similar in nature and magnitude to the adverse health effects associated with cigarette smoking. FDA is proposing this health warning to dispel consumers' widespread, but false, belief that cigars are a safe alternative to cigarettes.

The tobacco smoke from both cigars and cigarettes is carcinogenic to humans, and the toxicants in cigar smoke may be even more dangerous than those in cigarette smoke (Ref. 28). The smoke from both tobacco products is formed largely from the incomplete combustion of tobacco, resulting in cigar smoke being composed of the same toxic and carcinogenic

constituents as are in cigarette smoke (Ref. 28 at 3). In addition, the lower porosity of cigar wrappers results in more carbon monoxide per gram of tobacco burned than with cigarettes, and the higher nitrate content of cigar tobacco causes higher concentrations of nitrogen oxides, carcinogenic N-nitrosamines and ammonia (id.). When bioassayed in animals (i.e., tested in animals to determine its potency), the tar of cigar smoke has been found to be more carcinogenic than the tar in cigarette smoke (id.). Data on cigarette smoking and disease risk are more extensive than the data available for cigars; however, given the similarities between the composition of cigar and cigarette smoke, it is reasonable to assume that most of the diseases caused by inhalation of tobacco smoke from cigarettes can be caused by inhalation of tobacco smoke from cigars (Ref. 28 at 113). Therefore, NCI found that "cigar smoke is as, or more, toxic and carcinogenic than cigarette smoke; and differences in disease risks produced by using cigarettes and cigars relate more to differences in patterns of use, and differences in inhalation, deposition and retention of cigar smoke than to differences in smoke composition" (Ref. 28 at 3).

The mortality rates for cigar smokers also illustrate that cigars are not a safe alternative to cigarettes. The overall mortality rates for cigar smokers are higher than rates for those who have never smoked, although they may be generally lower than the rates observed for cigarette smokers (Ref. 28 at 112). In addition, the overall mortality rates for those who inhale approach those rates for cigarette smokers (Ref. 28 at 110-112). Further, although data on the risk for those who switch from smoking cigarettes to only cigars are limited, the existing data suggest that the risk of developing lung cancer for persons who switch from cigarettes to cigars is substantially higher than the risk for cigarette smokers who stop smoking all tobacco products (Ref. 28 at 120). While those who smoke only cigars seem to have a lower risk of cardiovascular disease

than cigarette smokers, cigarette smokers who switch to cigars often inhale the smoke and thus are less likely to experience the lower risk of cardiovascular disease (Refs. 170 and 28 at 145).

4. WARNING: Tobacco Smoke Increases the Risk of Lung Cancer and Heart Disease, Even in Nonsmokers

In section VII.E.2, we explain the risk of lung cancer and heart disease associated with cigar smoke and the need to warn consumers about these potential health consequences. Extensive data also exists regarding the dangers of involuntary exposure to tobacco smoke, including cigar smoke. Accordingly, FDA proposes to require a warning on cigar packages and in advertisements to help cigar smokers and potential smokers understand and appreciate that all tobacco smoke increases the risk of lung cancer and heart disease for nonsmokers.

It is well established that secondhand smoke causes premature death and disease in youth and in adults who do not smoke (see, e.g., Ref. 171 at 11 and Ref. 172 at 83, 104). Adult exposure to secondhand smoke has immediate adverse effects on the cardiovascular system and can lead to lung cancer and coronary heart disease (Ref. 171 at 445, 532). Tobacco smoke contains over 4,000 compounds, and there are more than 50 carcinogens in sidestream and mainstream smoke generated from cigars (Ref. 28 at 96 and Ref. 171). Mainstream cigar smoke is the smoke that one draws into his or her mouth from the butt end or mouthpiece of a cigar; whereas sidestream cigar smoke is the smoke emitted from the burning cone of a cigar during the interval between puffs (Ref. 28 at 65). The Surgeon General recently reiterated that cigar smoke contains the same toxic substances as cigarette smoke, with varying concentrations of these constituents found in different types and sizes of cigars (Ref. 171 at 362 and Ref. 28 at 17-18). Even though tobacco users (on average) smoke more cigarettes than cigars, the overall level of toxicants in secondhand smoke from cigars actually is quantitatively higher than it is in the

secondhand smoke produced from cigarettes (Ref. 28 at 79). Cigars also produce much higher levels of many indoor pollutants than do cigarettes (Ref. 28 at iii). The smoke from one cigar can take 5 hours to dissipate, exposing household members to a considerable involuntary health risk (Ref. 28 at 163).

a. Lung cancer and secondhand smoke.

More than 50 carcinogens have been identified in sidestream and secondhand smoke (Ref. 171). Cigar smoke "tar" appears to be at least as carcinogenic as cigarette smoke "tar" (id.). Exposure of nonsmokers to secondhand smoke has been shown to cause a significant increase in urinary levels of metabolites of tobacco-specific nitrosamines, a carcinogen that specifically links exposure to secondhand smoke with an increased risk for lung cancer (Ref. 171 at 65). All cigars produce higher levels of carcinogenic tobacco-specific nitrosamines per gram in mainstream cigar smoke than cigarettes produce in mainstream cigarette smoke (Ref. 28 at 75-76). Cigar smoke also produces measurable amounts of lead and cadmium (Ref. 28 at 75-76). Little cigars with filter tips and regular cigars contain higher levels of certain nitrosamines in sidestream smoke than do filtered tip cigarettes (Ref. 28 at 81).

The Surgeon General recently reiterated that there was considerable evidence that certain nitrosamines are major factors in the development of lung cancer (Ref. 171 at 30). According to the Surgeon General, the evidence was sufficient to infer a causal relationship between secondhand smoke exposure and lung cancer among lifetime nonsmokers (Ref. 171 at 434). Individuals living with smokers had a 20 to 30 percent increase in risk of developing lung cancer from secondhand exposure (Ref. 171 at 445). Although the data to demonstrate a similar causal relationship is not available, FDA believes it is reasonable to expect that cigar smoke would produce similar effects, given that data from the NCI cigar monograph showed that some

carcinogens determined to cause lung cancer are present at higher levels in cigar smoke than in cigarette smoke and at comparable levels of other carcinogens linked to lung cancer (Ref. 28 at 76-93).

b. Heart disease and secondhand smoke.

The proposed health warning statement indicating that tobacco smoke can cause heart disease is thoroughly supported by the evidence reiterated in reports from the Surgeon General (as discussed in section VII.E.2). FDA believes it is reasonable to expect that this finding would produce similar effects with respect to secondhand cigar smoke exposure based on the similar smoke profiles for cigars and cigarettes, the risk of coronary heart disease associated with active cigar smoking, and the low levels of toxicant exposure that can cause coronary heart disease (Ref. 171).

In a 2006 report regarding the health effects of exposure to secondhand smoke, the Surgeon General concluded that exposure of adults to secondhand smoke had immediate adverse effects on the cardiovascular system and caused coronary heart disease (Ref. 171 at 11). Secondhand smoke increased the risk of coronary heart disease nearly as much as active heavy smoking. In fact, the estimated increase in risk of coronary heart disease from exposure to secondhand smoke was 25 to 30 percent above that of unexposed persons (Ref. 171 at 519 and Ref. 83 at 532). Based on these data, the Surgeon General concluded that "the evidence is sufficient to infer a causal relationship between exposure to secondhand smoke and increased risks of coronary heart disease morbidity and mortality among both men and women" (Ref. 171 at 15). The IOM agreed, concluding that there is a causal relationship between secondhand smoke exposure and cardiovascular disease, as well as a causal relationship between secondhand smoke exposure and acute myocardial infarction (Ref. 172 at 219).

Even a relatively brief exposure to secondhand tobacco smoke can lead to heart disease, as some studies have demonstrated. The IOM found there is compelling circumstantial evidence that a relatively brief exposure to secondhand smoke can bring about an acute coronary event (Ref. 172 at 220).

Given that the effects of secondhand smoke on coronary heart disease are linked to the combustion of tobacco itself, FDA concludes that exposure to secondhand cigar smoke can cause the same or similarly dangerous effects as exposure to secondhand cigarette smoke.

VIII. Description of the Proposed Rule

A. Proposed Part 1100--Tobacco Products Subject to FDA Authority

The proposed rule would add new part 1100 that would describe the scope of FDA's authority over tobacco products, the requirements that would apply to tobacco products, applicable definitions, and the effective date of the rule.

1. Proposed § 1100.1--Scope

Section 201(rr) of the FD&C Act defines the term "tobacco product," in part, as any product "made or derived from tobacco" that is not a "drug," "device," or combination product under the FD&C Act. The Tobacco Control Act permitted FDA to use the "tobacco product" authorities in the FD&C Act to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco automatically ("This chapter shall apply to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco" (section 901 of the FD&C Act)). Therefore, the provisions of the FD&C Act applicable to "tobacco products" currently apply only to those products.

Section 901 of the FD&C Act provides that the Secretary of HHS, and by delegation FDA, has the authority to "deem" any other tobacco products to be subject to the FD&C Act.

FDA is exercising this authority and is proposing, in Option 1 for proposed § 1100.1 of this rule, to deem all products meeting the definition of "tobacco product," as defined in section 201(rr) of the FD&C Act except accessories of a proposed deemed tobacco product, to be subject to the FD&C Act. Because the statutory definition of "tobacco product" includes "any component, part, or accessory" and FDA has chosen to exclude "accessory" from the scope of the deeming regulation at this time, the provisions of the FD&C Act related to "tobacco product" also would apply to only the components and parts of the proposed deemed tobacco products.

To date, FDA has issued and finalized one such implementing regulation: "Exemptions From Substantial Equivalence Requirements" (76 FR 38961, July 5, 2011). Therefore, if this rule is finalized, the requirements in those regulations would apply to proposed deemed tobacco products. Proposed deemed tobacco products also would be covered by the "Amendments to General Regulations of the Food and Drug Administration" rule that became effective on April 14, 2011 (76 FR 12563, March 8, 2011), and the "Further Amendments to General Regulations of the Food and Drug Administration to Incorporate Tobacco Products" rule that became effective on April 2, 2012 (77 FR 5171, February 2, 2012) (conforming amendment regulations). Any entity that manufactures, distributes, imports, or sells the proposed deemed products is invited to comment on the substantial equivalence and conforming amendment regulations. In addition, FDA will review existing guidance documents to determine whether they need to be revised in light of this rulemaking.

2. Proposed § 1100.2--Requirements

Option 1 for proposed § 1100.2 would state that cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, and all other tobacco products, as defined in section 201(rr) of the FD&C Act except the accessories of such other tobacco products, are subject to the FD&C

Act and its implementing regulations. As previously explained, FDA currently has authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco with the regulatory tools provided in the FD&C Act. If this proposed rule is finalized, all other tobacco products that meet the statutory definition, in addition to cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco, and including the components and parts but not accessories of such other tobacco products, would be subject to the FD&C Act and its implementing regulations. Option 2 would limit the type of cigars that would be subject to the FD&C Act and its implementing regulations. For Option 2, only those cigars the meet the definition of "covered cigar" would be subject to the FD&C Act and its implementing regulations. FDA is requesting comments as to whether it is appropriate to deem premium cigars and how non-combustible novel products like e-cigarettes should be regulated. (See sections IV.C and IV.D.)

3. Proposed § 1100.3--Definitions

Option 1 for proposed § 1100.3 would include one definition that would apply to this part.

The definition in proposed § 1100.3 is a restatement of the statutory definition of "tobacco product" found in section 201(rr) of the FD&C Act. FDA proposes to restate the definition of "tobacco product" in two parts: (1) Tobacco product means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (excluding raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product) and (2) tobacco product does not mean an article that is a drug, device, or combination product as those terms are defined in the FD&C Act. We are repeating the statutory definition of "tobacco product" in this proposed rule for easy reference for readers of this regulation.

Option 2 for this section would, in addition to defining "tobacco product," add definitions for "cigar" and "covered cigar." A "cigar" would be defined as a tobacco product that also meets two requirements: (1) It is not a cigarette and (2) it is a roll of tobacco wrapped in leaf tobacco or any substance containing tobacco. This definition was used in the seven consent orders that the FTC entered into with the largest mass marketers of cigars. (See, e.g., In re Swisher International, Inc., Docket No. C-3964.) "Covered cigar" would mean any cigar (as defined in § 1100.3), but excluding any cigar that meets the following requirements: (1) It is wrapped in whole tobacco leaf; (2) it contains a 100 percent leaf tobacco binder; (3) it contains primarily long filler tobacco; (4) it is made by combining manually the wrapper, filler, and binder; (5) it does not have a filter, tip or non-tobacco mouthpiece and the cap (or crown) of the cigar is added by hand; (6) it 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) it does not have a characterizing flavor other than tobacco; and (8) it weighs more than 6 pounds per 1000. FDA is proposing this definition to limit the scope of cigars covered under Option 2 by excluding "premium" cigars. As discussed earlier, FDA is soliciting comment on how this proposed rule should apply to cigars.

4. Proposed Effective Date

The requirements in the FD&C Act that currently apply to cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco became effective: (1) On the date of enactment of the Tobacco Control Act (i.e., June 22, 2009) (referred to in this document as the automatic provisions), (2) on deadlines based on or calculated from the date of enactment of the Tobacco Control Act, or (3) upon issuance of a guidance and/or rulemaking specified by the Tobacco Control Act.

Likewise, FDA is proposing that the effective date of parts 1100 and 1140 be the date of publication of a final rule (if this proposed rule is finalized) plus 30 days. All of the statutory provisions found in the FD&C Act that currently are in effect for cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco, or will be in effect as of 30 days after the date of publication of the final rule, would apply to proposed deemed tobacco products as a matter of law on this effective date. Provisions that have not yet become effective as of the date of publication of the final rule, but rather will become effective when FDA issues a regulation or guidance, would not yet be in effect for proposed deemed tobacco products (e.g., regulations implementing section 915(a) of the FD&C Act for testing, reporting, and disclosure of tobacco product constituents, ingredients, and additives, including smoke constituents, by brand and subbrand). These provisions would apply to all tobacco products subject to the FD&C Act (but not to accessories of a tobacco product) only when the regulation or guidance required by the statute is issued.

The final rule publication date plus 30 days was chosen as the proposed effective date to comply with 5 U.S.C. 553(d) (i.e., the Administrative Procedure Act requires that a substantive rule provide a 30-day period before its effective date) and to be consistent with the Tobacco Control Act. Many of the requirements in the FD&C Act became effective on the date that the Tobacco Control Act was enacted, such as sections 902 (adulterated tobacco products), 903 (misbranded tobacco products), and 904(b) (ability of FDA to request the submission of certain documents from tobacco product manufacturers or importers). See section VIII.A.1 where we discuss the effect of this rule on implementing regulations and guidance documents that FDA has already issued that pertain to "tobacco products."

5. Proposed Compliance Dates for Certain Provisions

As described in VIII.A.4, not all of the requirements in the FD&C Act became effective on the date of enactment of the Tobacco Control Act. The effective date of some requirements are based on or calculated from the date of enactment of the Tobacco Control Act, and some requirements become effective only upon issuance of a guidance and/or regulation specified by the Tobacco Control Act. For example, section 904(a)(1) of the FD&C Act requires each tobacco manufacturer to submit an ingredient listing to FDA "not later than 6 months after the date of enactment" of the Tobacco Control Act.

To avoid confusion, and to provide time for firms to comply with provisions that require labeling changes or information submissions to the Agency, FDA is proposing compliance timeframes for certain provisions. For consistency and fairness, FDA is generally using the existing dates found in the Tobacco Control Act as a guide for determining the timeframe for compliance with these provisions. Table 1B of this document lists certain provisions that would be applicable to proposed deemed tobacco products and the dates on which FDA proposes to start enforcing compliance with those provisions. FDA is seeking comment on the proposed compliance dates for the provisions listed in table 1B.

Table 1B.--Compliance Dates for Various Provisions

FD&C Act Citation	Provision	Compliance Date
903(a)(2)	A tobacco product shall be deemed misbranded if in package form unless it bears a label containing-- (A) the name and place of business of the tobacco product manufacturer, packer, or distributor; (B) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; (C) an accurate statement of the percentage of the tobacco used in the product that is domestically grown tobacco and the percentage that is foreign grown tobacco; and (D) the statement required under section 920(a), except that under subparagraph (B) reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.	24 months after the issuance of the final regulation

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 product to the extent required in regulations which shall be issued by the Secretary after an opportunity for a hearing.	Effective date of part 1100 PLUS 1 year
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 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.	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 draft guidance for registration.) The timeframes for paragraphs (c) and (d) take effect after the date specified for (b) occurs.
905(i)(1)	PRODUCT LIST.--Every person who registers with the Secretary under subsection (b), (c), (d), or (h) shall, at the time of registration under any such subsection, file with the Secretary a list of all tobacco products which are being manufactured, prepared, compounded, or processed by that person for commercial distribution and which have not been included in any list of tobacco products filed by that person with the Secretary under this paragraph or paragraph (2) before such time of registration. Such list shall be prepared in such form and manner as the Secretary may prescribe and shall be accompanied by-- (A) in the case of a tobacco product contained in the applicable list with respect to which a tobacco product standard has been established under section 907 or which is subject to section 910, a reference to the authority for the marketing of such tobacco product and a copy of all labeling for such tobacco product; (B) in the case of any other tobacco product contained in an applicable list, a copy of all consumer information and other labeling for such tobacco product, a representative sampling of advertisements for such tobacco product, and, upon request made by the Secretary for good cause, a copy of all advertisements for a particular tobacco product; and (C) if the registrant filing a list has determined that a tobacco product contained in such list is not subject to a tobacco product standard	Must submit at the time of initial registration; see date specified for 905(b).

	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.	
907(a)(1)(B)	(B) ADDITIONAL SPECIAL RULE.--Beginning 2 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, a tobacco product manufacturer shall not use tobacco, including foreign grown tobacco, that contains a pesticide chemical residue that is at a level greater than is specified by any tolerance applicable under Federal law to domestically grown tobacco.	Effective date of part 1100 PLUS 2 years
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. (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).	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)
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

In most circumstances, the compliance dates FDA is proposing for the proposed deemed tobacco products are similar to the timeframe in which cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco manufacturers or importers were required to comply with the corresponding requirement. For example, the labeling requirement in section 920(a)(1) of the FD&C Act required 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 to bear the statement "sale only allowed in the United States" beginning 1 year after the date of enactment of the Tobacco Control Act. In table 1, the proposed compliance date for this provision as applied to proposed deemed tobacco product manufacturers would be 2 years after the effective date of this rule. FDA is soliciting comments on the proposed compliance dates in table 1.

6. Proposed Regulatory Approach for Newly Deemed Tobacco Products

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 FD&C Act. A new tobacco product means "any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007" (section 910(a)(1) of the FD&C Act). In general, a tobacco product manufacturer has three pathways for legally marketing a new tobacco product: (1) The manufacturer obtains an order under section 910(c)(1)(A)(i) (order after review of a premarket application) before the manufacturer introduces a new tobacco product into interstate commerce (section 910 of the FD&C Act); (2) the manufacturer obtains an order finding substantial equivalence under section 910(a)(2)(A) of the FD&C Act (order after review of a section 905(j) report) before the manufacturer introduces a new tobacco product into interstate commerce (section 910 of the FD&C Act); and (3) the manufacturer makes a request under § 1107.1 (21 CFR 1107.1) and

obtains an exemption from the requirements related to substantial equivalence.[5] Tobacco products that were commercially marketed (other than for test marketing) in the United States as of February 15, 2007, are not "new tobacco products" subject to the premarket requirements, and FDA refers to these products as "grandfathered."

Based on initial information FDA has gathered and received from industry, many tobacco products we are proposing to deem that are currently being sold may not be "grandfathered" tobacco products because many were not commercially marketed or modified until after February 15, 2007. We understand that this may be particularly true in the case of e-cigarettes and similar novel products. Moreover, new products that come on the market in the future would never be grandfathered tobacco products because they would be coming on the market after February 15, 2007. We do not believe that we have the authority to alter or amend this grandfathering date, which is set by statute. Therefore, FDA believes most proposed deemed tobacco products would be considered new tobacco products and would be required to obtain an order from FDA prior to marketing under one of the three pathways listed in section VIII.A.6. As stated in sections VIII.A.6.c and VIII.A.6.d, FDA is proposing a 24-month compliance policy for manufacturers of proposed deemed products to submit marketing applications. FDA does not intend to initiate enforcement action against products on the market for failing to have an FDA marketing authorization until 24 months following the effective date of the final rule. In addition, as described in section VIII.A.6.c, we intend to continue that compliance policy pending review of marketing applications if those applications are submitted within the 24 months after the final rule's effective date. We intend to work with industry to assist them in making submissions. We expect that our proposed approach, as discussed in this section, would help minimize disruption

[5] See 21 CFR 1107.1(b) for information on requesting an exemption under section 905(j)(3) of the FD&C Act. Manufacturers who obtain an exemption must then submit a report under section 905(j)(1)(A)(ii) of the FD&C Act.

while FDA conducts its pre-market review. Further, we request comment on whether there are ways that we might provide additional flexibility with respect to PMTAs that would still be appropriately protective of the public health.

a. Premarket tobacco applications.

Before a new tobacco product may be introduced or delivered for introduction into interstate commerce, the manufacturer must obtain an order from FDA authorizing the marketing of the product (section 910(a)(2) of the FD&C Act). Where a new tobacco product is not substantially equivalent to a tobacco product commercially marketed in the United States as of February 15, 2007, or exempt from the requirement to obtain a substantial equivalence determination, the manufacturer must submit a premarket tobacco product application under section 910(b) of the FD&C Act and receive a marketing authorization order under section 910(c)(1)(A)(i) prior to marketing the product. Under section 902(6)(A) of the FD&C Act, a tobacco product is deemed adulterated if it is a new tobacco product and it "does not have an order in effect under section 910(c)(1)(A)(i)" as necessary under section 910(a) of the FD&C Act.

b. Substantial equivalence.

Substantial equivalence is an alternate to the primary pathway of submitting a new tobacco product application under section 910(b) of the FD&C Act. To obtain an substantial equivalence order, a manufacturer must submit an SE report under section 905(j)(1) of the FD&C Act and receive a substantial equivalence order under section 910(a)(2).

Section 905(j)(1) of the FD&C Act requires that manufacturers submit SE reports under section 905(j) at least 90 days before introducing or delivering for introduction into interstate commerce for commercial distribution, a tobacco product intended for human use that was not

commercially marketed in the United States as of February 15, 2007. However, section 905(j)(2) of the FD&C Act provides that for tobacco products that were first introduced to the market between February 15, 2007, and March 22, 2011, SE reports were due 21 months from the date of enactment of the Tobacco Control Act (March 22, 2011). Products that met the requirements of section 905(j)(2) were permitted to remain on the market pending FDA review of their SE reports (referred to as "provisional reports") unless and until FDA issues an order finding them not substantially equivalent (section 910(a)(2)(B) of the FD&C Act). Under section 903(a)(6) of the FD&C Act, a tobacco product is deemed misbranded "if a notice or other information respecting it was not provided as required by such section or section 905(j)."

c. Compliance Policy for Substantial Equivalence (SE) Reports.

FDA is considering a compliance approach for proposed deemed products that is similar to the provisional approach set forth in sections 905(j)(2) and 910(a)(2)(B) of the FD&C Act. FDA is proposing the following compliance policy for submission of SE reports for all proposed deemed products.

If a new tobacco product meets the following…	FDA intends to enforce the FD&C Act as follows…
Is marketed between February 15, 2007, and [effective date of part 1100 plus 24 months] and the manufacturer submits a 905(j) report for the product by [effective date of part 1100 plus 24 months]	FDA does not intend to initiate enforcement action against the product for failing to have an FDA marketing authorization unless and until FDA issues an order denying your substantial equivalence submission under 910(a)(2). If FDA issues such an order, FDA intends to enforce the premarket authorization requirements with respect to your product.

Is marketed between February 15, 2007, and [effective date of part 1100 plus 24 months] and the manufacturer did not submit a 905(j) report for the product by [effective date of part 1100 plus 24 months] and has not obtained a marketing authorization order under section 910(c)(1)(A)(i)	FDA does not intend to initiate enforcement action against the product for failing to have an FDA marketing authorization until [effective date of part 1100 plus 24 months]. Thereafter, if no PMTA has been filed, FDA intends to enforce the premarket authorization requirements with respect to the product.
Would be marketed on or after [effective date of part 1100 plus 24 months]	FDA intends to enforce the premarket authorization requirements with respect to the product.

Therefore, FDA is proposing a compliance period of 24 months after the effective date of this rule--during which time FDA would not intend to initiate enforcement against the product on the market for failing to have a marketing order from FDA. Under FDA's proposal, FDA would not intend to initiate enforcement action for failure to have a marketing authorization against proposed deemed tobacco products first introduced or delivered for introduction into interstate commerce for commercial distribution after February 15, 2007, and prior to the 905(j) proposed compliance date (i.e., effective date plus 24 months), provided a 905(j) report is submitted no later than the proposed compliance date, and FDA has not issued an order finding the tobacco product to be not substantially equivalent. In these cases, the Agency would not intend to initiate enforcement action against the tobacco product on the market for failure to have a marketing authorization unless and until FDA issues an order that the tobacco product is not substantially equivalent to the predicate tobacco product (section 910(a)(2)(A) of the FD&C Act). FDA would consider taking different or additional actions if it believes particular circumstances warrant them. FDA would also consider revising its compliance policy should the Agency find that doing so is warranted, such as to better protect the public health.

FDA is soliciting data, research, information, and comments on this proposed approach to compliance for new tobacco products, including comments on the following questions:

- What are the benefits and/or disadvantages of a new product compliance period longer than the proposed 24-month period?
- If you disagree with the proposed 24-month new product compliance period, provide an alternative compliance date and supporting information.
- FDA is proposing that this compliance approach should be available to all proposed deemed tobacco products. However, should FDA take into account other factors, such as the type of product or other circumstances? Why or why not? If so, what factors or circumstances would be appropriate? For example, is there a justification for having the compliance policy instead apply to the following circumstances:
    - When marketing of the new tobacco product is limited to existing adult users of the product?
    - When marketing of the new tobacco product is unlikely to be seen or received by youth?
    - When the new tobacco product bears certain warnings?
- Given the express grandfather date and predicate restriction provided in the FD&C Act that govern the process for legally marketing a tobacco product, what are the implications for proposed deemed tobacco products?
- What is the impact on public health that proposed deemed tobacco products that entered the U.S. market after February 15, 2007, and have no viable predicate have available only the premarket application pathway?
- Provide examples of proposed deemed tobacco products that would likely be able to proceed to market via the SE pathway. Describe the range of predicates that would be available to demonstrate substantial equivalence.

- What other alternative marketing pathways or policy options should FDA consider if, in fact, no predicate is available?
- Are there other legal interpretations of the substantial equivalence grandfather provision that FDA should consider?

d. Compliance policy for premarket tobacco product applications.

FDA is not certain that manufacturers would in fact be able to use the SE pathway for many proposed deemed tobacco products because they may not be able to identify a viable predicate. Where this is in fact the case, manufacturers of proposed deemed tobacco products would have available only the premarket application pathway (section 910(b) of the FD&C Act). As for 905(j) reports, FDA is considering a compliance approach for premarket tobacco product applications (PMTAs) that is similar to the provisional approach set forth in sections 905(j)(2) and 910(a)(2)(B) of the FD&C Act. FDA is proposing the following compliance policy for submission of all PMTAs for proposed deemed products.

If a new tobacco product meets the following….	FDA intends to enforce the FD&C Act as follows….
Is marketed between February 15, 2007, and [effective date of part 1100 plus 24 months] and the manufacturer submits a PMTA for the product by [effective date of part 1100 plus 24 months]	FDA does not intend to initiate enforcement action against the product for failing to have an FDA marketing authorization unless and until FDA issues an order denying the PMTA under 910(c). If FDA issues such an order, FDA intends to enforce the premarket authorization requirements with respect to the product.
Is marketed between February 15, 2007, and [effective date of part 1100 plus 24 months] and the manufacturer did not submit a PMTA for the product by [effective date of part 1100 plus 24 months] and has not obtained a marketing authorization order under section 910(a)(2)	FDA does not intend to initiate enforcement action against the product for failing to have an FDA marketing authorization until [effective date of part 1100 plus 24 months]. Thereafter, FDA intends to enforce the premarket authorization requirements with respect to the product.

Would be marketed on or after [effective date of part 1100 plus 24 months]	FDA intends to enforce the premarket authorization requirements with respect to the product.

Therefore, as with products that may be eligible for the SE pathway, FDA is proposing a 24-month compliance period for products that may only be eligible for the PMTA pathway. Under FDA's proposal, FDA would not intend to initiate enforcement action for failure to have a marketing authorization against proposed deemed tobacco products first introduced or delivered for introduction into interstate commerce for commercial distribution after February 15, 2007, and prior to the proposed compliance date (i.e., effective date plus 24 months), provided a PMTA is submitted no later than the proposed compliance date, and FDA has not issued an order denying the PMTA. In these cases, the Agency would not intend to initiate enforcement action against the tobacco product for failure to have a marketing authorization unless and until FDA issues an order denying the PMTA under section 910(c) of the FD&C Act.

FDA is seeking data, research, information, and comments related to the following:

- Should 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 FDA consider ways to expedite the review of some or all premarket applications for proposed deemed products?
- If 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, FDA could establish factors based on certain categories of products and their relative impact on public health. FDA could use these factors in

guiding its enforcement policy. Examples of factors 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.

- What other FDA actions or regulatory approaches, if any, should FDA consider for proposed deemed tobacco products that are "new tobacco products" under section 910(a)(1) of the FD&C Act and why?
- Are there unique challenges faced by small manufacturers of proposed deemed tobacco products and how should they be addressed?
- FDA is collecting information as to how it can streamline review of new product applications. FDA expects that, in certain instances, it would be able to determine that a product meets the requirements of section 910 of the FD&C Act using information that might be less burdensome for a manufacturer to gather and submit to the Agency. 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, 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 FDA to make its required findings under section 910 of the FD&C Act, with types of information that would be less burdensome to collect than information needed for other product categories.

- Is there anything else 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 FD&C Act?

FDA is considering possible additional approaches to address this issue, including increasing the compliance policy period for SEs or PMTAs for new tobacco products. FDA would also consider revising its compliance policy should the Agency find that doing so is warranted, such as to better protect the public health. In addition, FDA may choose to implement this approach for only certain categories of proposed deemed products based on their impact on public health.

We are considering other options as well to best address this issue in a manner that is appropriate for the protection of the public health. FDA is seeking data, research, information, and comments on the previously referenced possible approaches.

e. Request for comments regarding possibility of staggered compliance dates.

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, FDA is considering whether it might be appropriate to stagger the compliance dates for certain provisions for different categories of products. For example, FDA may opt to provide different compliance dates for certain automatic provisions (e.g., ingredient listing under section 904 of the FD&C Act, 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. FDA requests comments, including supporting facts, research, and other evidence, regarding such an approach.

f. Request for comments regarding requirements for small tobacco product manufacturers.

As explained in the Initial Regulatory Flexibility Analysis, FDA finds that this rule would have a significant economic impact on a substantial number of small entities. This proposed rule would primarily affect domestic tobacco product manufacturers and importers. A number of small tobacco product manufacturers have expressed concern about their ability to comply with certain requirements found in the FD&C Act, such as registration and product listing, ingredient listing, substantial equivalence, and premarket tobacco product applications. FDA is seeking comments about any unique challenges faced by small manufacturers of proposed deemed tobacco products and how they should be addressed. Specifically, FDA would like comments on the following options that may help lessen the time and resources needed to comply with certain requirements:

- Extending the compliance period to provide more time to gather the required information to be included in a regulatory submission information
    - 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?
    - Are there FD&C Act provisions where an extended compliance period would not lessen the burden on small businesses?
    - If extending the compliance period is appropriate, how much more time should FDA provide and why?

- Staggered compliance dates based on the size of the firm: Instead of extending compliance periods outright, another option is to stagger compliance dates based on the size of the manufacturer. Under this option, compliance with certain provisions would be implemented in timed stages. For example, the reporting deadlines for registration and product listing and ingredient listing could be implemented as follows:

Size of firm	Reporting deadline
Large	Compliance date proposed in the rule
Medium	Compliance date proposed in the rule plus 1 year
Small	Compliance date proposed in the rule plus 2 years

  - Which provisions are appropriate to stagger in this manner and why? Which provisions should not be staggered in this manner and why?
  - If FDA were to stagger compliance dates based on the size of the manufacturer, how should FDA define the different sizes of firms?
- Instead of a comprehensive approach, should FDA consider the needs of individual tobacco product firms on a case-by-case basis? Under this scenario, a firm could request additional time to comply with certain requirements as the need arises. A tobacco product manufacturer would need to request additional time well in advance of a submission deadline and provide FDA with supporting documentation demonstrating undue hardship in meeting a particular deadline or requirement.

B. Proposed Changes to Part 1140--Cigarettes, Smokeless Tobacco, and Covered Tobacco Products

1. Proposed § 1140.1--Scope

The proposed rule would make several amendments to part 1140 in order to apply certain existing restrictions and access provisions to additional tobacco products. Currently, part 1140

generally applies to cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco products. Therefore, FDA is proposing to add the phrase "and covered tobacco products" to § 1140.1(a) and (b).

2. Proposed § 1140.2--Purpose

Like the proposed changes to § 1140.1, the proposed rule also would add "and covered tobacco products" to indicate that the purpose of this part is to establish restrictions on the sale, distribution, and access to covered tobacco products in addition to those already established for cigarettes and smokeless tobacco.

3. Proposed § 1140.3--Definitions

The proposed rule would revise or add several definitions that would apply to part 1140. FDA also proposes to revise the order of the definitions in § 1140.3 so that they appear alphabetically and to eliminate the individual paragraph designations.

Proposed § 1140.3 would define "cigar" as a tobacco product that also meets two requirements: (1) It is not a cigarette; and (2) it is a roll of tobacco wrapped in leaf tobacco or any substance containing tobacco. This definition was used in the seven consent orders that the FTC entered into with the largest mass marketers of cigars. (See, e.g., In re Swisher International, Inc., Docket No. C-3964.) As discussed earlier, FDA is soliciting comment on how this proposed rule should apply to cigars and is, therefore, also soliciting comment on how to further define categories of cigars, in particular premium cigars.

In addition, to exclude components and parts of tobacco products that do not contain tobacco or nicotine from the proposed restrictions in part 1140, we propose to define a "covered tobacco product" as any tobacco product deemed to be subject to the FD&C Act under § 1100.2, except for components or parts that do not contain tobacco or nicotine. The meaning of "covered

tobacco product" would depend on whether FDA selects Option 1 or Option 2 for any final rule. For purposes of this part, FDA considers any loose tobacco, including pipe tobacco, and the nicotine in e-cigarette cartridges to be within the definition of "covered tobacco product." FDA proposes to treat covered tobacco products in a manner consistent with FDA's treatment of cigarettes and smokeless tobacco throughout part 1140. See "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents "(75 FR 13225, March 19, 2010). In current part 1140, FDA imposes restrictions on cigarettes and smokeless tobacco, but not on the components, parts, and accessories of such products. 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 FDA determines it is appropriate for the protection of the public health to extend the restrictions in part 1140 to components and parts that do not contain nicotine or tobacco in the future, the Agency will issue a new rulemaking and provide notice and opportunity to comment on such proceeding. FDA seeks comment on this approach. Further, as stated throughout this document, FDA is not proposing to cover accessories of proposed deemed products within the scope of this deeming regulation and, therefore, accessories would not be subject to the additional restrictions in part 1140.

The proposed rule would add a definition of "importer," which would mean "any person who imports any tobacco product that is intended for sale or distribution to consumers in the United States." This definition is based on the definition in 21 CFR 1141.3 (included with the final rule published in the Federal Register of June 22, 2011 (76 FR 36627)).

The proposed rule also would update the following terms: "distributor," "manufacturer," "package," "point of sale," and "retailer." These revised definitions would ensure that the terms apply to tobacco products other than just cigarettes and smokeless tobacco.

The proposed rule would redefine "retailer" as "any person who sells tobacco products to individuals for personal consumption, or who operates a facility where vending machines or self-service displays are permitted under this part." The revised definition would ensure that it applies to tobacco products other than just cigarettes and smokeless tobacco.

Finally, the proposed rule would add a definition for "tobacco product." This definition would reiterate the portions of section 201(rr) of the FD&C Act, subsections (rr)(1) and (rr)(2), which establish the criteria for certain products to meet the definition of "tobacco product."

4. Proposed § 1140.10--General Responsibilities of Manufacturers, Distributors, Importers, and Retailers

In this section, for purposes of clarity, FDA proposes to add "and covered tobacco products" to the existing language. In addition, the Tobacco Control Act defines "tobacco product manufacturer" to include importers (section 900(20) of the FD&C Act), signaling Congress' intent for tobacco product importers to be subject to requirements like those in § 1140.10. Accordingly, FDA is proposing to revise this section to also cover importers.

This section currently sets forth the requirement for manufacturers, distributors, and retailers of cigarettes and smokeless tobacco to comply with the applicable requirements in part 1140. With this proposed change, proposed § 1140.10 also would provide that manufacturers, distributors, importers, and retailers are responsible for ensuring that the covered tobacco products (in addition to cigarettes and smokeless tobacco) that they manufacture, label, advertise,

package, distribute, import, sell, or otherwise hold for sale comply with all applicable requirements in part 1140.

5. Proposed § 1140.14--Additional Responsibilities of Retailers

In § 1140.14, FDA proposes to divide the section into responsibilities for retailers of cigarettes and smokeless tobacco products and responsibilities for retailers of covered tobacco products. Proposed new § 1140.14(a)(1) through (a)(5) would cover retailers of cigarettes and smokeless tobacco; proposed § 1140.14(b)(1) through (b)(3) would cover retailers of tobacco products other than cigarettes and smokeless tobacco. Accordingly, the proposed rule would create new § 1140.14(b)(1), which would prohibit retailers from selling covered tobacco products (tobacco products other than cigarettes and smokeless tobacco, which are discussed in proposed new § 1140.14(a)), to any individual younger than 18 years of age. This change also would require retailers of covered tobacco products to verify the purchaser's birth date by reviewing the individual's photographic identification. However, as noted in proposed § 1140.14(a)(2)(ii), a retailer is not required to verify the age of any person who is more than 26 years of age. Proposed § 1140.14(b)(3) would prohibit retailers from using electronic or mechanical devices, including vending machines, to sell covered tobacco products, except in locations where the retailer ensures that no person under the age of 18 is permitted. Because the proposed rule would prohibit retailers from selling covered tobacco products to individuals without verifying that they are at least 18 years of age, FDA believes it would not be logical to allow such individuals to purchase such products from vending machines or other mechanical devices. FDA believes it would not be practical or feasible for retailers to verify identification prior to the purchase of covered tobacco products using mechanical devices in facilities that allow individuals under 18 years of age to enter the premises.

C. Proposed Part 1143--Required Warning Statements

1. Proposed § 1143.1--Definitions

The proposed rule would add part 1143, which would contain provisions necessitating the use of "required warning statements" for covered tobacco products, as well as for roll-your-own and cigarette tobacco, for which health warnings are not already required by Federal statutes or regulations. Option 1 for proposed section 1143.1 contains four definitions to aid in the understanding of this part.

First, we propose to define "covered tobacco product" for the purposes of the proposed health warning requirements as those products deemed to be subject to the FD&C Act under § 1100.2, other than a component or part that does not contain tobacco or nicotine. As stated in proposed § 1140.3, the meaning of "covered tobacco product" would depend on whether FDA selects Option 1 or Option 2 for any final rule. In the event that FDA determines that there is sufficient scientific basis to add additional restrictions to components and parts that do not contain tobacco or nicotine in the future, FDA will issue a new rulemaking and provide notice and opportunity for public comment. Further, as stated throughout this document, FDA is not proposing to cover accessories of proposed deemed products within the scope of this deeming regulation and, therefore, accessories would not be subject to the additional restrictions in part 1143.

Second, we propose to define "package" as a "pack, box, carton, or container of any kind in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers." This definition is based on the definition of "package" in section 3 of FCLAA, 15 U.S.C. 1332.

Third, we propose to define "required warning statement" as a "textual warning statement required to be on packaging and in advertisements for cigarette tobacco, roll-your-own tobacco,

cigars, and other covered tobacco products." This term refers to the warning in proposed § 1143.3(a)(1) that would be required on packages and in advertisements for cigarette tobacco, roll-your-own tobacco, and covered tobacco products. It also refers to the warnings in proposed § 1143.5(a)(1) that would be randomly displayed on cigar packages and rotated quarterly on cigar advertisements.

Fourth, we propose to add a definition for "roll-your-own tobacco." This definition is identical to the definition of "roll-your-own tobacco" in section 900(15) of the FD&C Act.

In addition to these four definitions, Option 2 would also provide definitions for "cigar" and "covered cigar" and they would have the same meaning as these terms in Option 2 for proposed § 1100.3.

2. Proposed § 1143.3--Required Warning Statement Regarding Addictiveness of Nicotine

Proposed § 1143.3(a) of the proposed rule would require the use of a specific warning statement on packages of covered tobacco products other than cigars, and on packages of roll-your-own and cigarette tobacco, sold, distributed, or imported for sale within the United States. This required warning statement would be: "WARNING: This product contains nicotine derived from tobacco. Nicotine is an addictive chemical." Specifically, proposed § 1143.3(a)(1) would state that this requirement applies to cigarette tobacco, roll-your-own tobacco, and other tobacco products for which health warnings are not otherwise required by Federal law or regulation. This same warning statement would also be included as a required warning for cigars in proposed § 1143.5(a)(1).

"Cigarette tobacco" is currently defined under § 1140.3(b). In the proposed rule, and in accordance with the FD&C Act, "roll-your-own tobacco" would be defined in § 1140.3 as "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." The proposed rule also would define "covered tobacco product" in § 1143.1 as discussed in section VIII.C.1.

In addition, § 1143.3(a)(1) explains that the requirements of this subsection would not apply to tobacco products for which health warnings are already required by law or regulation. Specifically, health warnings for cigarette packages are already required by section 4(a) of FCLAA (15 U.S.C. 1333(a)). In addition, health warnings for smokeless tobacco product packages are required by section 3(a) of CSTHEA (15 U.S.C. 4402(a)).

Proposed § 1143.3(a)(2), like proposed § 1143.5(a)(2), would require that the required warning statement appear directly on the package and be clearly visible underneath any cellophane or other clear wrapping. Thus, any clear outer wrappings on the package would be required to allow the warning statement to be clearly visible and easily read by consumers. Proposed § 1143.3(a)(2)(i) through (a)(2)(v) would give additional explanation as to the size and placement of the required warning statement to ensure that it is easily viewed by consumers and would be identical to the requirements of proposed § 1143.5(a)(2)(i) through (a)(2)(v). For additional information regarding these requirements, see the analysis in section VIII.C.2 regarding proposed § 1143.5(a)(2).

Proposed § 1143.3(a)(3) provides the retailer exception, similar to the one included in proposed § 1143.5(a)(4). Under proposed § 1143.5(a)(4), to obtain the retailer exception for cigar packages, the packaging would have to be supplied by a manufacturer, importer, or distributor who has the required state, local or Alcohol and Tobacco Tax and Trade Bureau (TTB)-issued license or permit, if applicable. In contrast, under proposed § 1143.3(a)(3), for retailers to obtain the retailer exception, the packages would not need to be supplied by a license-

or permit-holding manufacturer, importer, or distributor. These requirements for retailers and the retailer exemption in proposed § 1143.3(c) are consistent with the requirements of the FCLAA, 15 U.S.C. 1333 et seq., as modified by section 201(a) of the Tobacco Control Act. FDA is not including the "license- or permit-holding" modifier for covered tobacco products other than cigars, because not all of these products are currently under the authority of the TTB. Therefore, manufacturers, importers, and distributors of such products currently do not need to obtain a license or permit to manufacture, import, or distribute them.

Proposed § 1143.3(b) requires the use of the warning statement, "WARNING: This product contains nicotine derived from tobacco. Nicotine is an addictive chemical." on advertisements for all covered tobacco products and products for which health warnings are not otherwise required by Federal law or regulation (i.e., cigarette tobacco and roll-your-own tobacco). For a description of the types of products that this proposed subsection would cover, see the previous discussion regarding proposed § 1143.3(a). This provision would require that manufacturers, packagers, importers, distributors, and retailers of such products include the required warning statement on all advertisements for such products within the United States. (See also section VIII.C.2 for examples of the types of advertisements that would be covered by this regulation.)

Under proposed § 1143.3(b)(2), the required warning statement must be located in the upper portion of the area of the advertisement within the trim area in order to maximize visibility. Proposed 1143.3(b)(2)(i) would require that the warning statement occupy at least 20 percent of the area of the advertisement, which is the same as the statutory requirement for press and poster advertisements for smokeless tobacco products. (See section 3(b)(2)(B) of CSTHEA (15 U.S.C. 4402(b)(2)(B)).) Proposed 1143.3(b)(2)(ii) through (b)(2)(v), which provide

specifications for the required warning statements on cigar advertisements, would be the same as proposed § 1143.3(a)(2)(ii) through (a)(2)(v), which provide the specifications for required warnings on cigar packages. Therefore, the description of proposed § 1143.3(a)(2)(ii) through (a)(2)(v) for cigar packages also applies to proposed § 1143.3(b)(2)(ii) through (b)(2)(v) for cigar advertisements.

Proposed § 1143.3(b)(2)(vi) would require that the warning statement be enclosed by a rectangle that is the same color as the text of the required warning statement. The border of the rectangle would be required to have a width that is between 3 and 4 mm. The border of the rectangle would be required to have a width that is between 3 and 4 mm. This border would allow the warning to be conspicuous among any other text or images in the advertisement, and the border is the standard size that is used in many countries and regions, including in the European Community (see, e.g., 2001/37/EC). Again, FDA would consider the required warning statement to be conspicuous and legible if the statement is printed in one to four lines of text, parallel to each other, and there is ample word and line spacing to allow the statement to be read easily. For additional information regarding those specifications and why FDA selected them, please see section VIII.C.2.

Proposed § 1143.3(b)(3) would apply the limited retailer exception to retailers of covered tobacco products (as well as roll-your-own and cigarette tobacco), which would be identical to the retailer exception for cigar advertisements in proposed § 1143.5(b)(3). For additional information regarding the requirements to meet this exception, see the discussion in section VIII.C.2.

Proposed § 1143.3(c) would provide an exemption to a product manufacturer that otherwise would be required to include the warning statement in proposed § 1143.3(a)(1) on its

packages and in its advertisements. To obtain this exemption, the manufacturer would be required to certify to FDA that its product does not contain nicotine and that the company has data to support that assertion; therefore, the product does not warrant the proposed addictiveness warning. For any product that obtains this exemption, the proposed provision would require that the product still bear the message: "This product is derived from tobacco." The parties that package and label such products would share responsibility for ensuring that this alternative statement is included on product packages and in advertisements. FDA believes it is important to alert consumers and retailers as to which items are tobacco products. Even if a tobacco product does not contain nicotine, it can still contain other addictive chemicals (like anabasine or nornicotine, discussed in the preamble) or dangerous toxicants. Therefore, FDA believes consumers should be aware that the product is, in fact, a tobacco product. In addition, this statement would alert consumers as to which products would require identification for purchase and increase retailer awareness of the products for which they must verify the age of consumers. While FDA is not aware of any currently marketed tobacco products that do not contain nicotine, the proposed rule would permit companies to use this alternative statement in the event that such tobacco products are developed in the future. FDA requests comments on this alternative statement.

FDA recognizes that certain tobacco products include constituents, in addition to nicotine, that may cause addiction. For example, tobacco products with nicotine removed or with only trace levels of nicotine may have other addictive constituents. Certain other constituents of smoke may contribute to sensory qualities of addiction, including flavorings and other potentially addictive components such as monoamine oxidase inhibitors (Refs. 173, 174, 175, 176, 177, 178, and 179).

Research also has shown that several constituents found in tobacco or tobacco smoke (e.g., nornicotine, acetaldehyde, and anabasine) have the potential to produce dependence and be addictive ("dependence potential"), as demonstrated by animal research. For example, the chemical nornicotine has the potential to be addictive in humans. Nornicotine causes increased dopamine (DA) levels and/or increased dopaminergic neuronal activity in the midbrain (Refs. 180 and 181). When released in the midbrain (including the nucleus accumbens and striatum), DA is widely thought to be involved in the maintenance of positively reinforced behavior, including feeding and drug taking (Ref. 182). Drugs that cause increased DA in these areas of the brain are thought to have dependence potential (Ref. 183). In addition, nornicotine substitutes for nicotine in drug discrimination testing[6] and maintains self-administration[7] in animals (Ref. 184). Acetaldehyde also likely has dependence potential as indicated by effects on midbrain DA and self-administration studies, along with data using place conditioning methods (Refs.188, 189, and 190).[8] Early data on effect on DA levels suggest that anabasine may also have some dependence potential (Ref. 192). Given that scientific research indicates that nicotine is the primary addictive component, FDA has proposed to include only nicotine in the addictiveness warning. Nevertheless, FDA requests comment as to whether the proposed addictiveness warning also should cover other substances that may cause addiction.

Manufacturers who submit a false certification to FDA would be subject to serious penalties. Knowingly and willfully submitting a false certification would be punishable as a

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[6] Drug discrimination is effective in evaluating shared central mechanisms of action (Refs. 185, 186, and 187). For example, stimulant drugs such as caffeine, cocaine, and amphetamine, partially or fully substitute for nicotine, and vice versa.

[7] Self-administration procedures allow an animal to perform a behavior to receive a dose of drug (Ref. 179). Drugs that support self-administration in animals are thought to have high dependence potential in humans.

[8] Place conditioning is a paradigm that evaluates the rewarding ("place preference") or aversive ("place avoidance") effects of drugs (Ref. 191). Place conditioning with drugs of abuse such as nicotine, cocaine, amphetamine, morphine, and ethanol results in preference.

criminal offense under 18 U.S.C. 1001. In addition, a product that did not contain the required warning statement on its packages or in its advertisements (once the regulation is finalized) would be misbranded under section 903(a)(1) of the FD&C Act, as well as other provisions of the Tobacco Control Act and subject the manufacturer to enforcement action, including civil money penalties and product seizure. FDA intends to issue guidance regarding this self-certification process if the regulation is finalized.

3. Proposed § 1143.5--Required Warning Statements for Cigars

Proposed § 1143.5 of the proposed rule would set forth the required warning statements for cigars. The proposed definition of "cigar" would be defined in § 1140.3 as "a tobacco product that (1) is not a cigarette and (2) is a roll of tobacco wrapped in leaf tobacco or any substance containing tobacco." We are proposing two options (Option 1 and Option 2) for this section. Option 1 would apply these requirements to all cigars. Option 2 would apply these requirements to a subset of cigars (i.e., covered cigars as defined in Option 2 for proposed § 1143.1). As discussed throughout this document, 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.

Proposed § 1143.5 contains the proposed requirements for packages, advertisements, and marketing. Proposed § 1143.5(a) contains the proposed requirements for cigar packages only. Proposed § 1143.5(a)(1) would make it unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import cigars without one of the proposed warnings on cigar packages. Four of the five warnings that would be required to be randomly displayed on packages would be the same as those currently included on certain cigar packages and advertisements as a result of seven consent orders that the FTC entered into in 2000 with the largest mass marketers of cigars.

(See, e.g., In re Swisher International, Inc., Docket No. C-3964.) Under Option 1, all cigars would now be subject to these warning requirements, except the package requirements for those sold individually and not in product packages. Option2 would apply the warning requirements to a subset of cigars (i.e., covered cigars as defined in Option 2 for section 1143.1). The fifth health warning regarding the addictiveness of nicotine is the same warning that would be required for covered tobacco products (as well as cigarette tobacco and roll-your-own tobacco) included in proposed § 1143.3(a)(1).

Proposed § 1143.5(a)(2) would mandate that the required warning statements appear directly on the package and be clearly visible underneath any cellophane or other clear wrapping enclosing the cigar(s). Thus, any outer wrappings on the package would have to allow the required warning statement to be clearly visible and easily read by consumers. Similarly, any other material that is placed on the outside of packages, such as price information or promotional material (e.g., coupons) would not be permitted to be placed over or otherwise obscure the required warning statement. Paragraphs (a)(2)(i) through (a)(2)(v) of proposed § 1143.5 would provide additional explanation as to the size and placement of the required warning statement to ensure that it is easily viewed by consumers. Proposed § 1143.5(a)(2)(i) would require that the warning statement be located in a conspicuous and prominent place on the two principal display panels of the package. For the warning to be "conspicuous and prominent," it must be in a location where it is likely to be read and understood by the ordinary individual under customary conditions of purchase and use. However, FDA would not consider the required warning statement to be "conspicuous and prominent" if it: (1) Appears or is affixed on the bottom of the package; (2) is printed or affixed on the tear line; or (3) is printed or affixed in any other location that would cause the warning to be obscured, damaged, or destroyed when the package is open.

(See 16 CFR 307.6(a) (FTC regulations implementing CSTHEA labeling requirements, which were rescinded due to FTC's transfer of authority over smokeless warnings to FDA that was required by the Tobacco Control Act; these regulations have served as a guide for some of FDA's regulatory decisions regarding health warnings).)

"Principal display panels" refers to the two panels of the package that contain the brand name, logo, and/or selling message for the product. The principal display panels (PDPs) are those panels that are most likely to be displayed, presented, shown, or examined under the normal and customary conditions of display for retail sale and use. Where the package contains the brand name, logo, and/or selling message on only one surface of the product package, the second PDP would be the surface opposite the PDP containing the brand name, logo, and/or selling message. This term will vary based on the type of packaging used for the tobacco product.

In addition, proposed § 1143.5(a)(2)(i) would require that the warning statement comprise at least 30 percent of each of the principal display panels. We are proposing a 30 percent size requirement for product packages to be consistent with Congress' size requirements for similar text-only warnings for smokeless tobacco under CSTHEA (15 U.S.C. 4402(a)(2)(A)), rather than the 50 percent requirements that Congress chose for graphic warnings on cigarette packages.

Proposed § 1143.5(a)(2)(ii) would require that the warning statement appear in the maximum font size that would fit into the warning area. This would ensure that the warning is large enough to be prominent and clearly visible to consumers. FDA would work with companies to ensure that the warnings are being printed on the proper display panels for a particular product.

Proposed § 1143.5(a)(2)(iii) would require that the warning statement be printed in a conspicuous and legible Helvetica bold or Arial bold type, which are included in common printing software. This provision would provide persons printing the required warning statements on packages with the choice of printing the required warning statement in black text on a white background, or white text on a black background, as long as the statement is printed in a manner that contrasts by typography, layout, or color with all other printed material on the package. This proposed requirement is consistent with the requirement for smokeless tobacco product packages included in section 3(a)(2)(B) of CSTHEA (15 U.S.C. 4402(a)(2)(B)), and the same as the requirement for cigarette packages under section 4(a)(2) of FCLAA (15 U.S.C. 1333(a)(2)). FDA would consider the required warning statement to be conspicuous and legible if the statement is printed in one to four lines of text, parallel to each other, and there is ample word and line spacing to allow the statement to be read easily.

Proposed § 1143.5(a)(2)(iv) would require that the warning statements be capitalized and punctuated as indicated in proposed § 1143.5(a)(1). No person would be permitted to edit the capitalization, punctuation, or text of the five required warning statements listed in proposed § 1143.5(a)(1).

Proposed § 1143.5(a)(2)(v) would require that the warning statement be centered in the warning area. This requirement would help ensure that the textual statement is conspicuous and legible. This paragraph also would require that the text of the statement and any other information on the PDP have the same orientation. Requiring all text on the PDP of a package to be oriented in the same direction would help ensure that the warnings are noticed and read by consumers and, therefore, would be appropriate for the protection of the public health.

Proposed § 1143.5(a)(3) proposes a different requirement for cigars sold individually and not in a product package or outer covering.[9] FDA is aware that premium cigars, as well as certain other cigars, are frequently sold to consumers individually and not in product packaging or an outer covering. Requiring a health warning for cigars that are not sold to consumers in a product packaging, therefore, is impractical. Thus, in lieu of such a requirement, proposed § 1143.5(a)(3) would provide that a person who sells or distributes cigars individually and without an outer package, would not be required to comply with the package requirements in proposed § 1143.5(a)(1) and (a)(2), but instead would be required to post the five required warning statements for cigars (as written in proposed § 1143.5(a)(1)) on a sign which would be posted at the point-of-sale at each register of any retail establishment that sells individual cigars that do not contain any product packaging. Retail establishments that sell such products would be required to prepare these simple black and white signs in accordance with the specifications in proposed § 1143.5(a)(3). Retailers may wish to place the sign in a sign holder to ensure that the warnings listed on the sign would be appropriately visible. FDA believes this requirement will ensure that premium cigar purchasers, as well as purchasers of other individual cigars, receive the critical health warnings while allowing persons selling or distributing such cigars to maintain existing business practices. In addition, any person that manufactures cigars also must continue to comply with all other packaging and labeling requirements under the Tobacco Control Act.

FDA is specifically requesting comments on whether the special rule in proposed § 1143.5(a)(3) for cigars sold individually would be effective in helping consumers better

[9] In general, pursuant to the Internal Revenue Code at 26 U.S.C. 5751, a tobacco product cannot be sold at retail unless it is in the package in which the product is removed, upon payment of Federal excise tax, from the factory or from customs custody. Section 5751(a)(3) and TTB regulations at 27 CFR 46.166(a) state that tobacco products may be sold, or offered for sale, at retail from such packages, provided the products remain in the packages until removed by the customer or in the presence of the customer.

appreciate and understand the relevant health risks or whether there are more effective means for doing so. For example, would it be feasible for machine-made cigars that are sold individually to bear the warning on the cigars themselves or in some other way, and would that be a more effective means of conveying the warning? In addition, the Agency also seeks comments on whether there should be different requirements for certain types of cigars and whether these proposed warning requirements are contrary to requirements for any cigars covered by the FTC consent decrees. It is not FDA's intent to allow any cigar that currently bears a warning pursuant to the FTC consent decrees to no longer be required to do so.

As stated throughout this document, Option 2 for proposed § 1143.5 would apply these requirements to a subset of cigars (defined as covered cigars). Therefore, under this option, this special rule for proposed § 1143.5(a)(3) would apply to only those covered cigars that are sold individually and not in a product package. We note that those cigars not meeting the definition of "covered cigars" would not be required to provide any warning statements on packages and in advertisements. FDA requests comment about this special rule.

Like the warning statements required in proposed § 1143.5(a)(1) and (a)(2), the sign required to be posted at any point of sale where consumers purchase cigars sold without a product package would have to be clear, legible, and conspicuous. Therefore, the warning statements included on the sign must be large enough for consumers to easily read it. The sign must be posted on or within 3 inches of each cash register where payment may be made. Therefore, certain retailers would be required to post multiple signs throughout their establishments. As stated in proposed § 1143.5(a)(3)(i), the warning statements would have to be printed in black Helvetica bold or Arial bold type against a solid white background in at least 17-point type to ensure maximum visibility. This 17-point type size is consistent with the standard

that Congress required under section 3(a)(2)(B) of CSTHEA (15 U.S.C. 4402(a)(2)(B)), as amended by section 204 of the Tobacco Control Act. The five individual warning statements must be appropriately spaced on the 8.5 x 11 inch sign so that each individual warning is conspicuous and legible. Also, as required in proposed § 1143.5(a)(3)(i), and like section 3(a)(2)(B) of CSTHEA (15 U.S.C. 4402(a)(2)(B)) for smokeless products, the warning would be printed so that it contrasts by typography, layout, or color with all other printed material. Further, as provided in the proposed required warning statements for product packages, no person would be permitted to edit the capitalization, punctuation, or text of the five required warning statements listed in proposed § 1143.5(a)(1). The requirements in this paragraph would operate together to ensure that the required warning statements included at the point-of sale for cigars sold without a product package could be easily read and understood. If a retailer offers for sale both cigars sold without a product package and cigars sold with product packages, the retailer would be required to post a warning sign in accordance with this paragraph.

Proposed § 1143.5(a)(4) would provide that a cigar retailer would not be in violation of the regulations if cigar packages displayed or sold by the retailer do not comply with all the requirements set forth in the proposed rule, as long as the packages contain a health warning; are supplied by a manufacturer, importer, or distributor who has the required state, local, or TTB-issued license or permit (if applicable); and are not altered by the retailer in a way that materially affects the display of the required warning statements on the packages. For example, if a retailer were to tear the warning in any way or place a sticker or other material over the warning, this likely would affect the display of the warning statements and this retailer exemption would not apply. However, if a retailer were to crop the paper containing the warning statement, but the warning statement has been unaffected and the size of the warning remains the same (and the

other requirements for this exemption were met), then the retailer exemption would apply. Thus, cigar manufacturers, distributors, and importers would have primary responsibility for ensuring that the warnings on cigar packages comply with the requirements of proposed § 1143.5, but retailers would have some responsibility as well. Specifically, retailers would be responsible for ensuring that all cigar packages they display or sell contain a warning regarding the health risks associated with smoking cigars. In addition, retailers could not alter the warning statement in a way that is material to the requirements of proposed § 1143.5, including by obscuring the warning (e.g., by placing a sticker or other item on top of it), by shrinking or severing the warning (in whole or in part), or by otherwise changing it in a material way. However, retailers would not be responsible for verifying that the warnings on packages they display or sell contain the precise wording, capitalization, and punctuation in the required warning statements listed in proposed § 1143.5(a)(1) or that they comply with other specifications required in this proposed subsection. This exception for cigar retailers is the same as the exception for cigarette retailers in section 4(a)(4) of FCLAA (15 U.S.C. 1333(a)(4)), implemented by § 1141.1(c) of FDA's regulations, as well as section 3(a)(5) of CSTHEA (15 U.S.C. 4402(a)(5)) for retailers of smokeless products.

Proposed § 1143.5(b) would explain the requirements for placement of health warnings on cigar advertisements. Specifically, proposed § 1143.5(b)(1) would require that manufacturers, packagers, importers, distributors, and retailers include a required warning statement in all cigar advertisements within the United States, similar to the existing FTC consent orders with which the major cigar manufacturers currently comply. Thus, this proposed rule adopts many of the parameters of the industry/FTC consent orders and current practice and proposes that all advertisements, regardless of form--which could include materials such as magazine and

newspaper ads, pamphlets, leaflets, brochures, coupons, catalogues, retail or point-of-sale displays (including functional items such as clocks or change mats), posters, billboards, direct mailers, and Internet advertising (e.g., Web pages, banner ads, etc.)--would have to contain required warning statements.

Proposed § 1143.5(b)(2) would require that the required warning statement be located in the upper portion of the area of the advertisement within the trim area, in order to maximize visibility. Proposed § 1143.5(b)(2)(i) through (b)(2)(vi) would provide the specifications for such advertisements, which would be identical to the specifications in proposed § 1143.3(b)(2)(i) through 1143.3(b)(2)(vi).

Proposed § 1143.5(b)(3), like proposed § 1143.5(a)(4), would provide that a retailer would not be considered to be in violation of this provision if it posts an advertisement that does not comply with all of the proposed requirements, as long as the advertisement was not created by or on behalf of the cigar retailer and the retailer is not otherwise responsible for inclusion of the required warning statements in the advertisement. This section is akin to the requirement in section 4(c)(4) of FCLAA (15 U.S.C. 1333(4)(c)(4)) and section 3(b)(3)(D) of CSTHEA (15 U.S.C. 4402(b)(3)(D)), which includes the same type of exception for retailers displaying cigarette and smokeless advertisements, respectively. Note that any manufacturer, packager, distributor, importer, or retailer who is responsible for the creation of a cigar advertisement would be responsible for complying with this proposed provision. Proposed § 1143.5(b)(3) also specifies that this provision would not relieve a retailer of liability if it publicly displays an advertisement that fails to contain a health warning or if it materially affects the display of the required warning statement. Therefore, except when responsible for the creation of an advertisement or otherwise responsible for the inclusion of the warning statement, a retailer

would not be responsible for ensuring that its cigar advertisements comply with the specific requirements of proposed § 1143.5(b)(3). However, retailers would be required to ensure that their cigar advertisements contain a warning of smoking's risks. They would also be responsible for complying with other requirements applicable to cigar retailers, including those in 21 CFR part 1140.

Marketing requirements for cigars are included in proposed § 1143.5(c). Specifically, proposed § 1143.5(c)(1) states that the required warning statements for cigar packages would be required to be randomly displayed in each 12-month period, in as equal a number of times as possible on each brand of cigar. FTC previously defined "equal number of times as possible" as permitting deviations of 4 percent or less in a 12-month period and the major cigar manufacturers agreed and currently comply with this standard, and FDA proposes to continue to adhere to FTC's definition. For packages, the required warning statements in proposed § 1143.5(a)(1) also would be required to be randomly distributed in all areas of the United States in which the product is marketed. We note that FDA is proposing to allow manufacturers to continue to introduce into domestic commerce existing inventory that may not contain the health warnings required under a final rule for an additional 30 days after the effective date of any final rule.

This proposed random display and distribution of required warning statements for cigar packages would be in accordance with a warning plan submitted by the cigar manufacturer, importer, distributor, or retailer to, and approved by, FDA. The proposed requirements for random display and distribution, as well as the submission of a warning plan, would be similar to those for cigarettes and smokeless tobacco products, as mandated by section 4(c)(1) of FCLAA (15 U.S.C. 1333(c)(1)) and section 3(a)(3)(A) of CSTHEA (15 U.S.C. 4402(a)(3)(A)),

respectively. For cigars sold individually and without product packaging, there would be no requirement to rotate and/or randomly distribute warnings, because all five warnings would be displayed at the point-of-purchase.

Proposed § 1143.5(c)(2) also would require that the required warning statements be rotated quarterly in alternating sequence in each advertisement for each brand of cigar, regardless of whether the cigar is sold in product packaging. This proposed rotation of warning statements in cigar advertisements also would be in accordance with an FDA-approved warning plan.

4. Proposed § 1143.7--Language Requirements for Required Warning Statements

Consistent with section 4(b) of FCLAA (15 U.S.C. 1333(b)) and section 3(b) of CSTHEA (15 U.S.C. 4402(b)), proposed § 1143.7 would require that the warning statement appear in the English language, with two exceptions. First, under proposed § 1143.7(a), if an advertisement appears in a non-English language publication, the required warning statement would need to appear in the predominant language of the publication. The predominant language is the primary language used in the nonsponsored content in the publication. For example, in the case of a newspaper where the nonsponsored content (e.g., news stories, articles of opinion, and features) is in a foreign language but the sponsored content (e.g., advertising) is wholly or partially in English, the predominant language would be the foreign language used in the nonsponsored content, and the required warning statement would have to appear in that foreign language. Because such non-English language publications in the United States are targeted towards consumers who speak the predominant language of the publication, this would help ensure that the target audience of publication is able to read and understand the required warning statement in the advertisement.

Second, under proposed § 1143.7(b), if an advertisement is in an English language publication but is presented in a language other than English, the required warning statement would need to be presented in the same foreign language principally used in the advertisement. English language publications in the United States are generally targeted towards the consumer population as a whole or towards consumers with a particular interest in the subject matter of the publication rather than towards consumers who speak a particular language; however, foreign language advertisements in English-language publications are targeted towards consumers who speak the foreign language used in the advertisement. Therefore, requiring foreign language advertisements in English-language publications to present the required warning statement in the same language that is used elsewhere in the advertisement will help ensure that the target audience of the advertisement is able to read and understand both the promotional content and the important warning information. These two proposed exceptions are the same as the exceptions in § 1141.10(b)(2) and section 4(b)(2) of FCLAA (15 U.S.C. 1333(b)(2)) for the textual portion of the required warnings in cigarette advertisements, as well as section 3(b)(G) of CSTHEA (15 U.S.C. 4402(3)(b)(G)) for the required warning statements in smokeless tobacco advertisements.

5. Proposed § 1143.9--Irremovable or Permanent Required Warning Statements

Proposed § 1143.9 would require that the required warning statement be indelibly printed on or permanently affixed to packages and advertisements. Removable or impermanent warning displays on packages and in advertisements could become separated from the package or advertisement and thus would not meet the requirement that they be conspicuous on the package or advertisement. Removable warnings would run counter to FDA's purpose of effectively conveying risk information to consumers. For example, if the required warning statement were

printed or stickered on a clear outer wrapper, and this wrapper was meant to be removed for access to the package (or the tobacco products within the package), the consumer could access the tobacco product package numerous times without viewing the warning and receiving the impact of the critical health message. This same requirement is contained in § 1141.10(c) regarding health warnings on cigarette packages and in advertisements.

6. Proposed § 1143.11--Does Not Apply to Foreign Distribution

Proposed § 1143.11 would limit the applicability of the proposed requirements by clarifying that these requirements would not apply to manufacturers or distributors of tobacco products that do not manufacture, package, or import the products for sale or distribution within the United States.

7. Proposed § 1143.13--Effective Date

This proposed section would provide that part 1143 would take effect 24 months after the date that the final rule publishes in the Federal Register. During this time, parties should take whatever steps they need to plan and implement business operations that will comply with the final rule. As of the effective date, no manufacturer, packager, importer, distributor, or retailer would be permitted to advertise or cause to be advertised within the United States any tobacco product subject to part 1143 unless the advertising complies with the final regulation. Also, product packages which do not comply with the requirements of the final rule must not be manufactured for sale or distribution in the United States as of the effective date.

Further, a product that is manufactured prior to the effective date of the final rule that does not have the required warning statements on its package may not be introduced into commerce in the United States after 30 days following the effective date. Therefore, manufacturers could continue to introduce into domestic commerce existing inventory that may

not contain the warning statements required under the final rule for an additional 30 days after the effective date of any final rule. This is consistent with the approach taken in FCLAA (15 U.S.C. 1333(4)(b)), and CSTHEA (15 U.S.C. 4402(3)(b)). After the 30-day period, manufacturers would not be permitted to introduce into domestic commerce any product packages that do not contain the health warning statements required under the final rule, irrespective of the date of manufacture. While this limitation would apply to manufacturers only, we note that keeping products without the new warnings on the market for an extended period of time is not in the interest of public health.

IX. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by the OMB under the PRA (44 U.S.C. 3501-3520). A description of these provisions is given in the Description section with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Deeming Tobacco Products To Be Subject to the Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products

Description: On June 22, 2009, the President signed the Tobacco Control Act into law. In this proposed rule, the Agency is proposing to extend FDA's "tobacco product" authorities in the FD&C Act to all other categories of products meeting the statutory definition of "tobacco product" in section 201(rr) of the FD&C Act, excluding accessories of proposed deemed tobacco products. (Two options are presented in the proposed rule related to what constitutes a covered tobacco product.) The proposed rule also would prohibit the sale of covered tobacco products to individuals under the age of 18 and prohibit the sale of covered tobacco products using the assistance of any retail-based electronic or mechanical device (such as a vending machine) except in facilities where the retailer ensures that no person younger than 18 years of age is present, or permitted to enter, at any time. This prohibition on sales from electronic or mechanical devices is not intended to impact the sale of any tobacco product via the Internet. Lastly, the proposed rule would require specified health warnings for covered tobacco products (as well as cigarette tobacco and roll-your-own tobacco) on tobacco product packages and advertisements.

The information collection provisions for which we are seeking comment in this proposed rule have either: (1) Existing burdens associated with tobacco products currently subject to the FD&C Act (i.e., cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco) with approved OMB control numbers; (2) burdens associated with tobacco products currently subject to the FD&C Act, but have not yet been approved by OMB; or (3) a new burden that would apply only to proposed deemed covered tobacco products. The following

burden tables for which we are seeking comment are organized according to these three categories.

A. Existing Burdens Associated With Tobacco Products Currently Subject to the FD&C Act (i.e., Cigarettes, Cigarette Tobacco, Roll-Your-Own Tobacco, and Smokeless Tobacco) With Approved OMB Control Numbers

The burden estimates found in this section involve existing collections that have already been approved by OMB and cover tobacco products that are already subject to the FD&C Act (i.e., cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco). FDA is making them available for public comment because the collections have been revised to cover proposed deemed tobacco products. In developing these new burden estimates for proposed deemed tobacco products, FDA based the new estimates on the existing collections already approved by OMB that currently cover cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. Burden estimates are based on Option 1.

1. Tobacco Product Establishment Registration and Submission of Certain Health Information (OMB control number 0910-0650)

Description of Respondents: The respondents to this collection of information are manufacturers, importers, or agents of new and existing tobacco product establishments regulated by FDA who are required to register under sections 904 and 905 of the FD&C Act. They are persons engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products who will be registering their product establishments and must file with FDA a list of all tobacco products being manufactured, prepared, compounded, or processed by that person for commercial distribution at the time of registration. They also must submit a listing of all ingredients whenever additives or the quantities of additives are changed.

Section 101 of the Tobacco Control Act amended the FD&C Act by adding sections 905 and 904. Section 905(b) of the FD&C Act requires that 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 register with FDA the name, places of business, and all establishments owned or operated by that person. Section 905(i)(1) of the FD&C Act requires that all registrants must, at the time of registration, file with FDA a list of all tobacco products which are being manufactured, prepared, compounded, or processed by that person for commercial distribution, along with certain accompanying consumer information, such as all labeling and a representative sampling of advertisements.

Section 904(a)(1) of the FD&C Act requires each tobacco product manufacturer or importer, or agent thereof, to submit a listing of all ingredients, including tobacco, substances, compounds, and additives that are 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. Section 904(c) of the FD&C Act also requires submission of information whenever additives, or the quantities of additives, are changed.

FDA issued guidance documents on both (1) "Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments" (74 FR 58298, November 12, 2009) and (2) "Listing of Ingredients in Tobacco Products" (74 FR 62795, December 1, 2009) to assist persons making these submissions to FDA under the FD&C Act. Although electronic submission of registration and product listing information and ingredient listing information are not required, FDA is strongly encouraging electronic submission to facilitate efficiency and timeliness of data management and collection. To that end, FDA designed the eSubmitter application to streamline the data entry process for registration and product listing

and for ingredient listing. This tool allows for importation of large quantities of structured data, attachments of files (e.g., in portable document format (PDFs) and certain media files), and automatic acknowledgement of FDA's receipt of submissions. FDA also developed paper forms (Form FDA 3742--Registration and Listing for Owners and Operators of Domestic Tobacco Product Establishments and Form FDA 3743--Listing of Ingredients in Tobacco Products) as alternative submission tools. Both the eSubmitter application and the paper forms can be accessed at http://www.fda.gov/tobacco.

FDA estimates the additional annual burden for the information collection as a result of this proposed rule as follows:

Table 2.--Estimated Annual Reporting Burden[1]

Activity	No. of Respondents	No. of Responses per Respondent[2]	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
Tobacco Product Establishment Registration (electronic and paper submission):					
Cigar Manufacturers (Including Large and Small)	121	1.0	121	3	363
Pipe Tobacco Manufacturers	73	1.0	73	3	219
Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers	140	1.0	140	3	420
Importers of Cigars (222) and Pipe Tobacco (48) Who Are Considered Manufacturers[3]	270	1.0	270	3	810
Total Tobacco Product Establishment Registration					1,812
Tobacco Product Listing (electronic and paper submission):					
Cigar Manufacturers (Including Large, Small, and Importers)	343	32.6	11,169	0.75 (45 minutes)	8,377
Pipe Tobacco Manufacturers	73	12.3	901	0.75 (45 minutes)	676
Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers	188	8.9	1,675	0.75 (45 minutes)	119
Total Hours Tobacco Product Listing					10,309
Obtaining a Dun and Bradstreet (DUNS) Number:					
Cigar Manufacturers (Including Large and Small)	121	1.0	121	0.5 (30 minutes)	61
Pipe Tobacco Manufacturers	73	1.0	73	0.5 (30 minutes)	37

Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers	140	1.0	140	0.5 (30 minutes)	70
Importers of Cigars (222) and Pipe Tobacco (48) Who Are Considered Manufacturers	270	1.0	270	0.5 (30 minutes)	135
Total Hours Obtaining DUNS Number					303
Total Hours Registration, Product Listing, and DUNS Number					12,424
Tobacco Product Ingredient Listing (electronic and paper submission):					
Cigar Manufacturers (Including Large, Small, and Importers)	343	32.6	11,169	3	33,507
Pipe Tobacco Manufacturers	73	12.3	901	3	2,703
Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers	188	8.9	1,675	3	5,025
Total Hours Tobacco Product Ingredient Listing					41,235
Total Burden Tobacco Product Establishment Registration and Submission of Certain Health Information					53,659

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] This number is estimated to be the total annual responses divided by the number of respondents, rounded to the nearest tenth.
[3] Under 21 U.S.C. 387(20), a "tobacco product manufacturer" includes any person who "imports a finished tobacco product for sale or distribution in the United States."

Based on aggregate information for 2012 obtained from TTB, FDA estimates that 194 domestic manufacturers of cigars and pipe tobacco and 270 importers of cigars and pipe tobacco would be required to register under section 905 of the FD&C Act. Based on FDA's own research, FDA estimates another 140 manufacturers of other tobacco products (non-cigar and non-pipe) would be subject to registration requirements. FDA estimates that the submission of registration information required by section 905 of the FD&C Act will take 3 hours per establishment, with a total of 604 establishments that would be required to register under this proposed rule, for a total of 1,812 hours (604 × 3).

The estimate for the number of product listing submissions for cigars is derived by using Perelman's Pocket Cyclopedia of Cigars (Ref. 193). FDA used a count of products offered on a single Web site with a broad product offering, http://www.pipesandcigars.com/, to derive the product listing count for pipe tobacco. FDA derives the product listing estimate for other

proposed deemed tobacco products (excluding cigars and pipe tobacco) using an assumption of 15 percent of the number of machine-made cigar products and Universal Product Codes (see also Ref. 192, table C4). FDA estimates that the submission of product listing information required by section 905 of the FD&C Act will take 45 minutes per submission for 13,745 submissions for a total of 10,309 hours.

FDA estimates that obtaining a DUNS number will take 30 minutes. FDA assumes that all the establishment facilities that would be required to register under section 905 of the FD&C Act would obtain a DUNS number, with a total of 604 establishments that would need to obtain this number. The total burden to obtain a DUNS number is 303 hours.

FDA estimates that the submission of ingredient listing information as required by section 904 of the FD&C Act will take 3 hours per tobacco product based on the estimates found in the existing collection. The Agency estimates that approximately 13,745 ingredient listings will be submitted based on the methodology used for estimating the number of product listing submissions described in this section. The total ingredient listing reporting is 41,235 hours (13,745 × 3).

FDA is soliciting comments on these estimates and the methodology for estimating the respondent numbers.

2. Tobacco Health Document Submission (OMB control number 0910-0654)

Description of Respondents: Respondents to this collection of information are tobacco product manufacturers, importers, or agents who will submit all documents developed after June 22, 2009, that relate to health, toxicological, behavioral, or physiologic effects of current or future tobacco products to FDA.

Section 904(a)(4) of the FD&C Act requires each tobacco product manufacturer or importer, or agent thereof, to submit 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 (herein referred to as "tobacco health documents"). Information submissions required under section 904(a)(4) were due to FDA beginning December 22, 2009, for tobacco products currently subject to the FD&C Act.

FDA is collecting the information submitted under section 904(a)(4) of the FD&C Act through an electronic portal and through a paper form (Form FDA 3743) for those individuals who choose not to use the electronic portal.

FDA estimates the additional annual burden for the information collection as a result of this proposed rule as follows:

Table 3.--Estimated Annual Reporting Burden[1]

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
Cigar Manufacturers (Including Large and Small)	2	4	8	50	400
Pipe Tobacco Manufacturers	1	4	4	50	200
Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers	1	4	4	50	200
Importers of Cigars and Pipe Tobacco Who Are Considered Manufacturers	1	4	4	50	200
Total Hours Health Document Submission					1,000

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA estimates that a tobacco health document submission for cigars, pipe tobacco, other tobacco, and importers of cigars and pipe tobacco required by section 904(a)(4) of the FD&C Act, will take approximately 50 hours per submission based on the existing collection that applies to tobacco products currently subject to the FD&C Act and FDA experience. To derive

the number of respondents for this provision, FDA assumes that very few of the respondents subject to registration requirements would have health documents to submit. Therefore, the Agency estimates that approximately five submissions (two for cigar manufacturers, one for pipe tobacco manufacturers, one for other tobacco product manufacturers, and one for importers of cigars and pipe tobacco who are considered manufacturers) will be submitted on an annual basis. FDA estimates the total number of hours is 1,000 hours (5 submissions multiplied by 4 times per year multiplied by 50 average burden hours.)

FDA is soliciting comments on these estimates and the methodology for estimating the respondent numbers.

3. Exemptions From Substantial Equivalence Requirements (OMB control number 0910-0684)

Description of Respondents: Respondents to this collection of information are manufacturers of proposed deemed tobacco products who are requesting an exemption from the substantial equivalence requirements of the FD&C Act.

In a final rule that published on July 5, 2011 (76 FR 38961), FDA established a pathway for manufacturers to request exemptions from the substantial equivalence requirements of the Tobacco Control Act (SE exemptions final rule). The SE exemptions final rule implements section 905(j)(3) of the FD&C Act, under which FDA may exempt tobacco products that are modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive, if FDA determines that: (1) The modification would be a minor modification of a tobacco product that can be sold under the FD&C Act, (2) a report is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for protection of the public health, and (3) an exemption is otherwise appropriate.

The exemption request may be made only by the manufacturer of a legally marketed tobacco product for a minor modification to that manufacturer's product and the request (and supporting information) must be submitted in an electronic format that FDA can process, review, and archive. In addition, the request and all supporting information must be legible and in (or translated into) the English language.

An exemption request must be submitted with supporting documentation and contain:

- The manufacturer's address and contact information;
- identification of the tobacco product(s);
- a detailed explanation of the purpose for the modification;
- a detailed description of the modification; a detailed explanation of why the modification is a minor modification of a tobacco product that can be sold under the FD&C Act;
- a detailed explanation of why a report under section 905(j)(1)(A)(i) intended to demonstrate substantial equivalence is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for the protection of the public health;
- a certification summarizing the supporting evidence and providing the rationale for why the modification does not increase the tobacco product's appeal to or use by youth, toxicity, addictiveness, or abuse liability;
- other information justifying an exemption; and
- an environmental assessment under part 25 (21 CFR part 25) prepared in accordance with § 25.40.

The exemption request must contain a certification by a responsible official summarizing the supporting evidence and providing the rationale for the official's determination that the modification will not increase the product's toxicity, addictiveness, or appeal to/use by youth and

include other information justifying an exemption. This information will enable FDA to determine whether the exemption request would be appropriate for the protection of the public health. There is also a procedural mechanism for rescinding an exemption where necessary to protect the public health. In general, FDA would rescind an exemption only after providing the manufacturer notice of the proposed rescission and an opportunity for an informal hearing under part 16 (21 CFR part 16). However, FDA may rescind an exemption prior to notice and opportunity for a hearing under part 16 if the continuance of the exemption presents a serious risk to public health. In that case, FDA would provide the manufacturer an opportunity for a hearing as soon as possible after the rescission.

FDA reviews the information submitted in support of the request and determines whether to grant or deny the request based on whether the criteria specified in the statute are satisfied. If FDA determines that the information submitted is insufficient to enable it to determine whether an exemption is appropriate, FDA may request additional information from the manufacturer. If the manufacturer fails to respond within the timeframe requested, FDA will consider the exemption request withdrawn.

FDA estimates the additional annual burden for the information collection as a result of this proposed rule as follows:

Table 4.--Estimated Annual Reporting Burden (when manufacturers choose to seek exemption from substantial equivalence)[1]

21 CFR and Activity	No. of Respondents	No. of Responses per Respondent[2]	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
§ 1107.1(b) Optional Preparation of Tobacco Product Exemption From Substantial Equivalence Request:					
Cigar Manufacturers (Including Large, Small, and Importers)	343	0.96	328	12	3,936
Pipe Tobacco Manufacturers (Including Importers)	121	0.58	70	12	840
Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers	140	0.50	70	12	840

Total Hours (§ 1107.1(b))					5,616
§ 1107.1(c) Preparation of Additional Information for Tobacco Product Exemption From Substantial Equivalence Request:					
Cigar Manufacturers (Including Large, Small, and Importers)	343	0.29	98	3	294
Pipe Tobacco Manufacturers (Including Importers)	121	0.17	21	3	63
Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers	140	0.15	21	3	63
Total Hours (§ 1107.1(c))					420
§ 25.40 Preparation of an Environmental Assessment:					
Cigar Manufacturers (Including Large, Small, and Importers)	343	0.96	328	12	3,936
Pipe Tobacco Manufacturers (Including Importers)	121	0.58	70	12	840
Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers	140	0.50	70	12	840
Total Hours (§ 25.40)					5,616
Section 905(j)(1)(A)(ii) of the FD&C Act: If exemption granted, report submitted to demonstrate tobacco product is modified under section 905(j)(3), modifications are to a product that is commercially marketed and compliant, and modifications covered by exemptions granted by Secretary under section 905(j)(3):					
Cigar Manufacturers (Including Large, Small, and Importers)	343	1.43	491	3	1,473
Pipe Tobacco Manufacturers	121	0.87	105	3	315
Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers	140	0.75	105	3	315
Total Hours (section 905(j)(1)(A)(ii))					2,103
Total Hours Exemptions From Substantial Equivalence Requirements					13,755

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] This number is estimated to be the total annual responses divided by the number of respondents, rounded to the nearest hundredth.

The estimated average burden per response (in hours) is based on the burdens associated with the existing information collection that applies to tobacco products currently subject to the FD&C Act (i.e., cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco). Of an estimated 2,806 new products entering the market through substantial equivalence exemptions (table 4) and SE reports (table 5), FDA estimates that 25 percent (701) will enter through substantial equivalence exemptions. FDA estimates that exemption requests will be used for an average of 1.5 products each; therefore, 468 requests for exemption (701 products divided by 1.5

requests) will be submitted annually, and it will take approximately 12 hours to prepare an exemption request for a total of 5,616 hours (468 × 12 hours).

FDA estimates, based on the existing information collection that applies to tobacco products currently subject to the FD&C Act, that 30 percent of the initial requests for information (468 × 0.30) will require additional information in support of the initial exemption request, and it is expected that it will take an average of 3 hours to prepare the additional information for a total of 420 hours (468 × 0.30 × 3).

FDA estimates that 604 manufacturers will submit 468 Environmental Assessments, and each EA is expected to take approximately 12 hours to prepare and submit one environmental assessment under part 25 in accordance with the requirements of § 25.40, as referenced in § 1107.1(b)(9) for a total of 5,616 hours (468 × 12).

FDA estimates that 604 respondents will prepare 701 responses (604 × 1.16) and each response will take approximately 3 hours to prepare the report required by section 905(j)(1)(A)(ii) for a total of 2,103 hours (701 × 1 × 3). This collection of information requires a manufacturer to submit a report at least 90 days prior to making an introduction or delivery into interstate commerce for commercial distribution of a tobacco product. The report should contain the manufacturer's basis that the tobacco product is modified within the meaning of the exemption provision in section 905(j)(3) of the FD&C Act, the modifications are to a product that is commercially marketed and compliant with the FD&C Act, the modifications are covered by exemptions granted under section 905(j)(3), and a listing of actions taken to comply with any applicable requirements of section 907 of the FD&C Act.

FDA's estimates are based on full analysis of economic impacts (Ref. 194) and information gathered from other FDA-regulated products.

4. Reports Intended to Demonstrate the Substantial Equivalence of a New Tobacco Product (OMB control number 0910-0673)

Description of Respondents: Respondents to this collection of information are manufacturers of proposed deemed tobacco products who seek to submit a report to FDA demonstrating substantial equivalence for tobacco products under section 905(j)(1)(A)(i) of the FD&C Act.

Section 905(j)(1) of the FD&C Act authorizes FDA to establish the form and manner for the submission of information related to substantial equivalence. FDA issued guidance intended to assist persons submitting reports under section 905(j) of the FD&C Act and to explain, among other things, FDA's interpretation of the statutory sections related to substantial equivalence (see the guidance for industry and FDA staff on "Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products" (76 FR 789, January 6, 2011)).

FDA estimates the additional annual burden for the information collection as a result of this proposed rule as follows:

Table 5.--Estimated Annual Reporting Burden[1]

Activity	No. of Respondents	No. of Responses per Respondent[2]	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
Sections 905(j)(1)(A)(i) and 910(a):					
Cigar Manufacturers (Including Large, Small, and Importers)	343	4.29	1,472	180	264,960
Pipe Tobacco Manufacturers (Including Importers)	121	2.61	316	180	56,880
Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers	140	2.26	316	180	56,880
Total Hours (sections 905(j)(1)(A)(i) and 910(a))					378,720
§ 25.40 Environmental Assessments:					
Cigar Manufacturers (Including Large, Small, and Importers)	343	4.29	1,472	12	17,664
Pipe Tobacco Manufacturers (Including Importers)	121	2.61	316	12	3,792

Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers	140	2.26	316	12	3,792
Total Environmental Assessment					25,248
Total Hours ("Reports Intended to Demonstrate the Substantial Equivalence of a New Tobacco Product")					403,968

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] This number is estimated to be the total annual responses divided by the number of respondents, rounded to the nearest hundredth.

FDA has based these estimates on the full analysis of economic impacts (Ref. 194) and experience with the existing information collection that applies to tobacco products currently subject to the FD&C Act (i.e., cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco). Of an estimated 2,806 new products entering the market through substantial equivalence exemptions (table 4) and SE reports (table 5). FDA estimates that approximately 75 percent of the products (2,104) will enter the market through SE reporting. Therefore, FDA estimates that 604 respondents will prepare and submit 2,104 section 905(j)(1)(A)(i) SE reports each year and that it will take a manufacturer approximately 180 hours per report to prepare the reports of substantial equivalence for a new tobacco product. Therefore, FDA estimates the burden for submission of substantial equivalence information will be 378,720 hours (2,104 responses × 180 hours = 378,720 hours.) In addition, anyone submitting a report of substantial equivalence is also expected to submit an environmental assessment report under § 25.40. Six hundred and four respondents are expected to submit 2,104 reports, and take 12 hours to complete a single report, for a total of 25,248 burden hours (2,104 reports × 12 hours = 25,248 hours.)

FDA requests comments on these estimates and the methodology used to estimate the burdens.

5. Electronic Importer's Entry Notice (OMB control number 0910-0046)

Description of Respondents: Respondents to this collection of information are importers of tobacco products offered for import into the United States whose products meet the same requirements of the Tobacco Control Act as domestic tobacco products.

With the passage of the Tobacco Control Act, section 801 of the FD&C Act (21 U.S.C. 381) was amended to add tobacco products to the inventory of FDA-regulated products. The revised section 801 charges the Secretary of HHS, through FDA, with the responsibility of assuring foreign-origin, FDA-regulated foods, drugs, cosmetics, medical devices, radiological health, and tobacco products offered for import into the United States meet the same requirements of the FD&C Act as do domestic products and the responsibility for preventing products from entering the country if they are not in compliance. The discharge of this responsibility involves close coordination and cooperation between FDA headquarters and field inspectional personnel and the U.S. Customs and Border Protection (CBP), as CBP is responsible for enforcing the revenue laws covering tobacco products. This collection of information in this section is being used by FDA to review and prevent imported products from entering the United States if the products do not meet the same requirements of the FD&C Act as do domestic products.

Until October 1995, importers were required to file manual entry on OMB-approved forms, which were accompanied by related documents. Information provided by these forms included information such as country of origin, name of the importing vessel, entry number (assigned by CBP), port of entry, the port of lading and unlading, value in U.S. dollars, shipper or manufacturer, importer of record, original consignee, broker, broker's reference number and CBP house box number, bill of lading numbers, and location of goods. FDA stopped using these

paper forms effective October 1, 1995, to eliminate duplication of information and to reduce the paperwork burden both on the import community and FDA. FDA then developed and implemented an automated nationwide entry processing system, which enabled FDA to more efficiently obtain and process the information it requires to fulfill its regulatory responsibility.

Most of the information FDA requires to carry out its regulatory responsibilities under section 801 of the FD&C Act is already provided electronically by filers to CBP. Because CBP relays this data to FDA using an electronic interface, the majority of data submitted by the entry filer need be done only once.

FDA estimates the additional annual burden for the information collection as a result of this proposed rule as follows:

Table 6.--Estimated Annual Reporting Burden[1]

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
Importers of Cigars who are Considered Manufacturers	222	159	35,224	0.14 (8 ½ minutes)	4,931
Importers of Pipe Tobacco Who Are Considered Manufacturers	48	123	5,916	0.14 (8 ½ minutes)	828
Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers	140	68	9,520	0.14 (8 ½ minutes)	1,333
Total Hours Importation of Tobacco Products					7,092

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA estimates the burden hours to be 7,092 burden hours (4,931 + 1,295 + 1,333 hours). This reflects the addition of proposed deemed tobacco products to the list of FDA's regulated products. The original (nontobacco) hourly burden for this information collection was based on FDA's estimate of imported tobacco products obtained from the United States Customs and Border Protection (CBP). When testing the use of electronic and paper forms, FDA determined that the average time for completing either electronic or manual entries was the same.

Based on the original data collected by FDA when the importer entry notice information collection was most recently approved, it is expected that each respondent will take 0.14 hour (8 ½ minutes) to respond. The estimated hours per response are expected to remain the same for tobacco importers.

FDA estimates that there will be no additional costs to provide import data electronically to FDA, as filers already have equipment and software in place to enable them to provide data to CBP via the automated system. Therefore, no additional software or hardware need be developed or purchased to enable filers to file the FDA data elements at the same time they file entries electronically with CBP.

6. Further Amendments to General Regulations of the Food and Drug Administration to Incorporate Tobacco Products (OMB control number 0910-0690)

Description of Respondents: Respondents are manufacturers, distributors, and other persons who export tobacco products not intended for sale in the United States.

In a rule published on February 2, 2012 (77 FR 5171), FDA amended certain of its general regulations to include tobacco products, where appropriate, in light of FDA's authority to regulate these products under the Tobacco Control Act (conforming amendments rule). The conforming amendments rule subjects tobacco products to the same general requirements that apply to other FDA-regulated products, where appropriate.

The conforming amendments rule amended 21 CFR 1.101(b), among other sections, to require persons who export human drugs, biologics, devices, animal drugs, cosmetics, and tobacco products that may not be sold in the United States to maintain records demonstrating their compliance with the requirements in section 801(e)(1) of the FD&C Act. Section 801(e)(1) requires exporters to keep records demonstrating that the exported product: (1) Meets with the

foreign purchaser's specifications; (2) does not conflict with the laws of the foreign country; (3) is labeled on the outside of the shipping package that is intended for export; and (4) is not sold or offered for sale in the United States. These criteria also could be met by maintaining other documentation, such as letters from a foreign government agency or notarized certifications from a responsible company official in the United States stating that the exported product does not conflict with the laws of the foreign country.

FDA estimates the annual burden for the information collection as a result of this proposed rule as follows:

Table 7.--Estimated Annual Recordkeeping Burden[1]

Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Record (in hours)	Total Hours
21 CFR 1.101(b):					
Cigar Manufacturers (Large and Small)	42	3	126	22	2,772
Pipe Tobacco Manufacturers	10	3	30	22	660
Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers	27	3	81	22	1,782
Total Further Amendments to General Regulations of the Food and Drug Administrations to Incorporate Tobacco Products					5,214

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The Agency has estimated the number of respondents and burden hours associated with the recordkeeping requirements by reviewing Agency records and using Agency expert resources, and conferring with another Federal Agency with experience and information regarding tobacco product exporters. FDA estimates that 79 establishments (half of the 158 estimated total of all tobacco manufacturers listed in the collection of information approved under OMB control number 0910-0046 who manufacture cigars, pipe tobacco, and other tobacco products) could be involved in the exporting of all tobacco products annually. Based on previous recordkeeping estimates for the exporter's reporting burden in the existing OMB-approved collection of information (OMB control number 0910-0482, "Export Notification and

Recordkeeping Requirements"), each establishment will maintain an average of three records per year, and it will take each recordkeeper an average of 22 hours per recordkeeper to maintain each record. The Agency estimates 5,214 burden hours will be needed for tobacco product exporters to create and maintain records demonstrating compliance with section 801(e)(1) of the FD&C Act (79 recordkeepers × 3 records per year × 22 hours per record = 5,214).

B. Burdens Associated With Tobacco Products Currently Subject to the FD&C Act But Not Yet Approved by OMB

The information collections described in this section also involve collections that have been previously made available for public comment because they involved tobacco products currently subject to the FD&C Act. However, these information collections have not yet been approved by OMB. FDA is making them available for public comment again because we have revised the burdens to include proposed deemed tobacco products. In developing the burden estimates for proposed deemed tobacco products, FDA based the estimates on the existing collections that were previously made available for comment. FDA requests comments on these estimates and the methodology used to estimate the burdens.

1. Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007

Description of Respondents: Respondents to this collection of information are manufacturers of tobacco products who wish to demonstrate that their tobacco product was commercially marketed in the United States as of February 15, 2007, and is a grandfathered product not subject to premarket review.

On April 25, 2011, FDA announced the availability of a draft guidance document entitled "Establishing That a Tobacco Product Was Commercially Marketed in the United States as of

February 15, 2007" (76 FR 22903). This draft guidance provides information on how a manufacturer may demonstrate that a tobacco product was commercially marketed in the United States as of February 15, 2007, and is, therefore, a grandfathered product not subject to premarket review. The draft guidance recommends that the manufacturer provide evidence that may include, among other things, dated copies of advertisements, dated catalog pages, dated promotional material, and dated bills of lading. FDA recommends that the manufacturer submit as much information as possible to demonstrate that the tobacco product was commercially marketed in the United States as of February 15, 2007. FDA has not yet finalized this draft guidance.

The estimate for the number of hours in the existing collection is FDA's estimate of how long it might take one to review, gather, and submit dated information if making a request for an Agency determination.

FDA estimates the annual burden for the information collection as a result of this proposed rule as follows:

Table 8.--Estimated Annual Reporting Burden[1]

Activity	No. of Respondents	No. of Responses per Respondent[2]	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
Cigars--2 Largest Manufacturers	2	25	50	10	500
Other Cigar Manufacturers (excluding 2 largest manufacturers and including large and small cigars, and importers)	341	2.8	947	10	9,470
Pipe Tobacco Manufacturers (Including Importers)	121	1.7	204	10	2,040
Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers	140	1.5	210	10	2,100
Total Hours Establishing that a Tobacco Product was Commercially Marketed in the United States as of February 15, 2007					14,110

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] This number is estimated to be the total annual responses divided by the number of respondents, rounded to the nearest tenth.

FDA is basing the current estimates on the existing collection that applies to tobacco products currently subject to the FD&C Act. Annually, 2 large cigar manufacturers each are expected to submit 25 grandfathered product status requests each, for a total of 50 applications. The remaining cigar manufacturers are expected to submit 2.8 reports each annually. The total number of reports expected annually under sections 905(j)(1)(A)(i) and 910 of the FD&C Act for cigar manufacturers is 997 annually, which is 71 percent of the total number of grandfathered product applications expected annually. FDA also estimates it would take a cigar manufacturer approximately 10 hours to complete and submit for FDA review the evidence required by this collection of information and estimates that it should take approximately 9,970 hours annually (50 responses times 10 hours plus 947 responses times 10 hours for each response) for cigar manufacturers to respond to this collection of information.

Annually, the number of reports expected to be submitted under sections 905(j)(1)(A)(i) and 910 of the FD&C Act for pipe tobacco manufacturers is 1.7 product applications each. FDA estimates it would take a pipe tobacco manufacturer approximately 10 hours to complete and submit for FDA review the evidence required by this collection of information. Therefore, FDA estimates that it should take approximately 2,040 hours annually (204 responses times 10 hours for each response) for pipe tobacco manufacturers to respond to this collection of information.

Annually, other tobacco manufacturers (i.e., excluding cigars and pipe tobacco) are expected to submit 1.5 grandfathered product applications each. FDA estimates that it will take these manufacturers 10 hours to complete and submit for FDA review the evidence required by this collection of information. Therefore, FDA estimates that it should take approximately 2,100 hours (210 total annual responses times 10 hours for each response) for other manufacturers to respond to this collection of information.

The total number of burden hours, therefore, is 14,110 (500 hours + 9,470 hours + 2,040 hours + 2,100 hours). FDA has based these estimates on information from interactions with firms already subject to the FD&C Act and comments received regarding the submission of reports establishing that a tobacco product was commercially marketed in the United States as of February 15, 2007, from a notice of proposed information collection that covered tobacco products currently subject to the FD&C Act (76 FR 22903, April 25, 2011).

2. Applications for Premarket Review of New Tobacco Products

Description of Respondents: The respondents to this collection of information are manufacturers who are responsible for creating and submitting new tobacco product premarket applications and who wish to obtain an FDA order to allow them to market their product.

On September 28, 2011, FDA announced the availability of a draft guidance entitled "Applications for Premarket Review of New Tobacco Products" (76 FR 60055). This guidance, when finalized, will provide industry with information on how to submit an application for premarket review of new tobacco products as required by section 910 of the FD&C Act. Section 910(a)(1) of the FD&C Act requires persons who either create a new tobacco product that was not commercially marketed in the United States as of February 15, 2007, or modify a tobacco product in any way after February 15, 2007, including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery, or form of nicotine, or any other additive or ingredient, to submit a premarket tobacco product application and obtain an order from FDA authorizing the marketing of the product before the product may be introduced or delivered for introduction into interstate commerce. This requirement applies unless the product has been shown to be substantially equivalent to a tobacco product

commercially marketed in the United States as of February 15, 2007, or is exempt from an SE determination under an issued regulation.

The draft guidance "Applications for Premarket Review of New Tobacco Products" explains the requirements and provides recommendations for the contents of an application for premarket review of a new tobacco product. Contents include a cover letter; an executive summary; full reports of all investigations of health risks; a full statement of all components, ingredients, additives, and properties, and of the principle or principles of operation of such tobacco product; a full description of methods of manufacturing and processing; a listing of all manufacturing, packaging, and control sites for the product; an explanation of how the product complies with applicable tobacco product standards; samples and components; and proposed labeling. If an applicant does not submit information on any of the previously mentioned items, the application should include a statement indicating which information is not being submitted and an explanation of why the information is not being submitted.

FDA also encourages persons who would like to study their new tobacco product to meet with the Office of Science at the Center for Tobacco Products (CTP) to discuss their investigational plan prior to distributing the product for investigational purposes. The request for a meeting should be sent in writing to the Director of CTP's Office of Science and should include adequate information for FDA to assess the potential utility of the meeting and to identify FDA staff necessary to discuss proposed agenda items. FDA is required to deny a PMTA and issue an order that the product may not be introduced or delivered for introduction into interstate commerce under section 910(c)(1)(A)(ii) of the FD&C Act if FDA finds that:

- The manufacturer has not shown that the product is appropriate for the protection of the public health,

- the manufacturing methods, facilities, or controls do not conform to manufacturing regulations issued under section 906(e) of the FD&C Act,
- the proposed labeling is false or misleading, or
- the manufacturer has not shown that the product complies with any tobacco product standard in effect under section 907 of the FD&C Act.

Under section 902(6)(A) of the FD&C Act, a tobacco product is deemed adulterated if it is a new tobacco product and does not have an order in effect under section 910(c)(1)(A)(i) of the FD&C Act. Under section 301(a) of the FD&C Act (21 U.S.C. 331(a)), the introduction or delivery for introduction into interstate commerce of any adulterated tobacco product is a prohibited act. Violations of section 910 of the FD&C Act are subject to regulatory and enforcement action by FDA, including, but not limited to, seizure and injunction.

FDA estimates the annual burden for the information collection as a result of this proposed rule as follows:

Table 9.--Estimated Annual Reporting Burden[1]

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
Obtaining an FDA Order Authorizing Marketing of Tobacco Product (the application):					
Cigar Manufacturers (Including Large, Small, and Importers)	1	1	1	5,000	5,000
Pipe Tobacco Manufacturers (Including Importers)	1	1	1	5,000	5,000
Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers	25	1	25	5,000	125,000
Total Hours Obtaining an FDA order authorizing marketing of tobacco product (the application)					135,000
Request for Meeting with CTP's Office of Science to Discuss Investigational Plan:					
Cigar Manufacturers (Including Large, Small, and Importers)	1	1	1	4	4
Pipe Tobacco Manufacturers (Including Importers)	1	1	1	4	4
Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers	25	1	25	4	100
Total Hours Request for Meeting with CTP's Office of Science to Discuss Investigational Plan					108

§ 25.40 Environmental Assessments:					
Cigar Manufacturers (Including Large, Small, and Importers)	1	1	1	12	12
Pipe Tobacco Manufacturers (Including Importers)	1	1	1	12	12
Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers	25	1	25	12	300
Total Hours § 25.40 Environmental Assessments					324
Total Hours "Applications for Premarket Review of New Tobacco Products"					135,432

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA estimates that it will take each respondent approximately 5,000 hours to obtain an order from FDA allowing the marketing of a new tobacco product. FDA's estimate includes anticipated burden for the writing of an application, including intra-company edits and approvals, of approximately 200 hours. In addition, FDA expects that conducting the necessary scientific investigations for a new tobacco product (either in-house or via a third-party consultant) will require, on average, 4,800 hours. FDA also estimates the number of PMTA applications that FDA expects to receive annually will be 27 (1 each from cigar and pipe tobacco manufacturers, and 25 from other tobacco manufacturers.) Therefore, the total annual burden for submitting PMTA applications is estimated to be 135,000 hours (27 respondents × 5,000 hours).

FDA notes that this 5,000 hour burden estimate is consistent with the burden included in the notice announcing the availability of the draft guidance "Applications for Premarket Review of New Tobacco Products" (76 FR 60055). We are clarifying here that a PMTA may require one or more types of studies including chemical analysis, nonclinical studies, and clinical studies. FDA expects that chemical and design parameter analysis would include the testing of applicable HPHCs and nonclinical analysis would include literature synthesis and, as appropriate, some combination of in vitro or in vivo studies, and computational analyses. For the clinical study component, one or more types of studies may be included to address, as needed, perception, use pattern, or health impact. It is possible that an applicant may not need to conduct any new

nonclinical or clinical studies. We note that for most applications, FDA does not expect that applicants will include standardized clinical trials, like those conducted to support drug and device approvals.

For tobacco products already on the market at the time of the final rule, much of the information required to support a PMTA may be obtained from previously published research on similar products. Therefore, FDA expects that a large portion of applications may be reviewed with no or minimal new nonclinical or clinical studies being conducted to support an application. In contrast, several nonclinical and clinical studies may be required for market authorization of a new product for which there is little to no understanding of its potential impact. The range of hours involved to compile these two types of applications would be quite variable.

FDA anticipates that the 27 potential respondents to this collection may need to meet with CTP's Office of Science to discuss their investigational plans. To request this meeting, applicants must compile and submit information to FDA for meeting approval. FDA estimates that it will take approximately 4 hours to compile this information, for a total of 108 hours additional burden (27 respondents × 4 hours).

FDA also estimates that the 27 potential respondents will take approximately 12 hours to prepare and submit an environmental assessment (for a total of 324 hours) in accordance with the requirements of section § 25.40, as referenced in § 1107.1(b)(9).

The total reporting burden is estimated to be 135,432 hours burden (135,000 hours + 108 hours + 324 hours.). FDA's estimates are based on the corresponding information collection estimates that apply to tobacco products currently subject to the FD&C Act and an assumption that manufacturers would submit applications for the premarket review of tobacco products.

FDA requests comments on these estimates and the methodology used to derive the estimates.

C. New Collections of Information That Applies Only to Proposed Deemed Tobacco Products

1. Exemption From the Required Warning Statement Requirement

Description of Respondents: Respondents are manufacturers and other persons who, to obtain an exemption from the required warning statement requirement, would be required to certify to FDA that their product does not contain nicotine, that the company has data to support that assertion, and, therefore, the product does not warrant the proposed addictiveness warning.

This proposed rule contains a new information collection that pertains to an exemption process related to the requirement to include the warning statement in proposed § 1143.3(a)(1). Proposed § 1143.3(c) would provide an exemption to the manufacturer of a product that otherwise would be required to include the warning statement in proposed § 1143.3(a)(1) on its packages and in its advertisements (i.e., "WARNING: This product contains nicotine derived from tobacco. Nicotine is an addictive chemical."). To obtain this exemption, a manufacturer would be required to certify to FDA that its product does not contain nicotine, that the company has data to support that assertion, and, therefore, the product does not warrant the proposed addictiveness warning. For any product that obtains this exemption, the proposed section requires that the product bear the message: "This is product derived from tobacco." The parties that package and label such products would share responsibility for ensuring that this alternative statement is included on product packages and in advertisements. While FDA is not aware of any currently marketed tobacco products that do not contain nicotine, the proposed rule would permit companies to obtain an exemption from this warning requirement in the event that such tobacco products are developed in the future.

FDA estimates the annual burden for the information collection as a result of this proposed rule as follows:

Table 10.--Estimated Annual Reporting Burden[1]

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
Certification Statement	1	1	1	20	20
Total Exemptions From the Required Warning Statement Requirement					20

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimated average burden per response is based on information collection estimates that apply to tobacco products currently subject to the FD&C Act. While very few certifications are expected for tobacco products that do not contain nicotine, FDA estimates that the number of certification submissions could rise if the Agency decides in the future to address not only nicotine, but any other addictive substances.

The estimated hours listed in the burden table for certification submissions reflect the time needed to test the product for nicotine and preparation and submission of the self-certification request. FDA expects that these types of certifications will be very rare and estimates that the Agency will receive on average one submission per year.

FDA notes that the labeling statements in proposed §§ 1143.3(a)(1) and 1143.5(a)(1) and the proposed alternative warning statement in proposed § 1143.3(c) (i.e., "This product is derived from tobacco") do not constitute a "collection of information" under the PRA. Rather, these labeling statements are "public disclosure" of information originally supplied by the Federal Government to the recipient for the purpose of "disclosure to the public" (5 CFR 1320.3(c)(2)).

The total burden for these new collections of information in this rulemaking is 629,036 reporting hours (53,659 + 1,000 + 13,755 + 403,968 + 7,092 + 14,110 + 135,432 + 20) and 5,214 recordkeeping hours for a total of 634,250 burden hours.

To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-6974, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the title "The Food and Drug Administration Deems Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations Restricting the Sale and Distribution of Tobacco Products and Required Warnings for Tobacco Product Packages and Advertisements."

In compliance with the PRA (44 U.S.C. 3407(d)), the Agency has submitted the information collection provisions of this proposed rule to OMB for review. These requirements will not be effective until FDA obtains OMB approval. FDA will publish a notice concerning OMB approval of these requirements in the Federal Register.

X. Executive Order 13132; Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires Agencies to "construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute."

Section 916(a)(1) of the FD&C Act (21 U.S.C. 387p) expressly preserves the authority of State, local, and tribal governments to "to enact, adopt, promulgate, and enforce any law, rule, regulation, or other measure with respect to tobacco products that is in addition to, or more stringent than, requirements established under this chapter [21 U.S.C. 387 et seq.]," except as

expressly preempted by section 916(a)(2) of the FD&C Act. With the exception of the limited category of regulatory actions preempted by section 916(a)(2), State and local governments may adopt or continue to enforce all requirements pertaining to tobacco products that are in addition to, or more stringent than, the requirements of the Tobacco Control Act and its implementing regulations, including requirements relating to or prohibiting the sale and distribution of tobacco products, the advertising and promotion of tobacco products, and the use of tobacco products by individuals of any age.

Section 916(a)(2) of the FD&C Act is an express preemption provision. Section 916(a)(2)(A) expressly preempts any State or local requirement "which is different from, or in addition to, any requirement under [chapter IX of the FD&C Act] relating to tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk products." However, section 916(a)(2)(B) of the FD&C Act states that the express preemption provision in subparagraph (A) "does not apply to requirements relating to" among other things "the sale, distribution, possession, information reporting to the State, exposure to, access to, the advertising and promotion of, or use of, tobacco products by individuals of any age."

Executive Order 13132 requires Agencies to consult, to the extent, practicable, with State and local officials if the Agency foresees the possibility of a conflict between State law and Federally protected interests. FDA has not identified any State or local laws that would be preempted by these proposed restrictions. Nevertheless, FDA intends to consult with State and local jurisdictions about the potential impact this rule could have on their requirements.

XI. Environmental Impact

The Agency has carefully considered the potential environmental effects of deeming products to be subject to the FD&C Act and the proposed age and identification restrictions. FDA has concluded that the actions will not have a significant impact on the human environment, and that an environmental impact statement is not required. The Agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Division of Dockets Management (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday.

The Agency also has determined under 21 CFR 25.30(k) that the labeling requirement is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required for the proposed health warning statements.

XII. Analysis of Impacts: Summary

FDA has examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule would be an economically significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. FDA has determined that this

proposed rule would have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $141 million, using the most current (2013) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would result in a one-year expenditure that meets or exceeds this amount.

The proposed rule consists of two coproposals, Option 1 and Option 2. The proposed Option 1 deems all products meeting the statutory definition of "tobacco product," except accessories of a proposed deemed tobacco product, to be subject to chapter IX of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Option 1 proposes additional provisions that would apply to proposed deemed products as well as to certain other tobacco products. Once deemed, tobacco products become subject to the FD&C Act and its implementing regulations. The FD&C Act requirements that would apply to proposed deemed products include establishment registration and product listing, ingredient listing, submissions prior to the introduction of new products, and labeling requirements. Free samples of proposed deemed tobacco products would also be prohibited. The additional provisions of this proposed rule include minimum age and identification requirements, vending machine restrictions, and required warning statements for packages and advertisements. Although deeming and the associated "automatic provisions" of

the FD&C Act could be implemented on their own, the additional provisions could not be implemented for proposed deemed products without deeming.

While FDA currently has authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco under chapter IX of the FD&C Act, all additional tobacco products that meet the statutory definition, except accessories of those proposed deemed tobacco products, would be subject to chapter IX of the FD&C Act and its implementing regulations under the proposed rule. These products would include cigars, pipe tobacco, hookah tobacco, electronic cigarettes, and other novel tobacco products such as dissolvable products and gels. Of these products to be deemed, cigars are the most commonly used.

The other coproposal, Option 2, is the same as Option 1 except that it exempts premium cigars. The proposed rule would define premium cigars as cigars that are wrapped in whole tobacco leaf; contain a 100 percent leaf tobacco binder; contain primarily long filler tobacco; are made by manually combining the wrapper, filler, and binder; have no filter, tip, or non-tobacco mouthpiece and are capped by hand; do not have a characterizing flavor other than tobacco; weigh more than 6 pounds per 1000 units; and sell for $10 or more per cigar.

The proposed deeming action differs from most public health regulations in that it is an enabling regulation. In other words, in addition to directly applying the substantive requirements of chapter IX of the FD&C Act and its implementing regulations to proposed deemed tobacco products, it enables FDA to issue further public health regulations related to such products. We expect that asserting our authority over these tobacco products will enable us to propose further regulatory action in the future as appropriate, and those actions will have their own costs and benefits. Without deeming these products to be subject to the FD&C Act, FDA would lack the authority to collect vital ingredient and health information about them. We would also lack the

authority to take regulatory action with respect to them, if we determined it was appropriate to do so.

The direct benefits of making each of the proposed deemed tobacco products subject to the requirements of chapter IX of the FD&C Act are difficult to quantify without additional data, and we cannot predict the size of these benefits at this time. Among other effects, new products would be subject to evaluation to ensure they are appropriate for public health before they could be marketed, labeling could not contain misleading statements, and FDA would be made aware of the ingredients in proposed deemed tobacco products. If, without the proposed rule, new products would be developed that pose substantially greater health risks than those already on the market, the premarket requirements made effective by this proposed rule would prevent such products from appearing on the market and worsening the health effects of tobacco product use. The warning statements required by this proposed rule would provide information to consumers about the risks and characteristics of tobacco products. Consumers may act on this information by reducing their use of tobacco products. Consumers may also act on this information through compensating health behaviors. These responses would generate benefits associated with improved health and longevity.

The proposed rule as a whole would impose costs in the form of registration, submission, and labeling requirements. The deeming provision would impose immediate costs because manufacturers and importers of newly-regulated tobacco products would have to comply with registration, submission, and labeling requirements. Manufacturers of proposed deemed products, as well as some manufacturers of currently-regulated products, would have to comply with the warning label provisions, including costs for signs with warnings at point-of-sale for

cigars sold singly without packaging. There would also be potential costs for removing noncompliant point-of-sale advertising and complying with vending machine restrictions.

The upfront costs for Option 1 are estimated to range from $74.3 to $347.0 million , with a primary estimate of $171.1 million, while the costs in subsequent years are estimated to range from $20.8 to $49.0 million, with a primary estimate of $30.6 million. The primary estimate for the present value of total quantified costs over 20 years is approximately $592.0 million at a 3 percent discount rate and $467.6 million at a 7 percent discount rate.

The upfront costs for Option 2 are estimated to range from $60.5 to $258.5 million , with a primary estimate of $132.8 million, while the costs in subsequent years are estimated to range from $17.4 to $38.4 million, with a primary estimate of $25.0 million. The primary estimate for the present value of total quantified costs over 20 years is approximately $476.4 million at a 3 percent discount rate and $375.0 million at a 7 percent discount rate.

The quantified costs of both options for the proposed rule can also be expressed as annualized values, as shown in Table 11.

Table 11.--Summary of Quantified Costs Over 20 Years ($ million)

	Lower Bound (3%)	Primary (3%)	Upper Bound (3%)	Lower Bound (7%)	Primary (7%)	Upper Bound (7%)
Present Value Option 1	365.2	592.0	1,010.1	281.4	467.6	810.2
Present Value Option 2	304.0	476.4	779.2	233.8	375.0	622.6
Annualized Value Option 1	23.8	38.6	65.9	24.8	41.2	71.5
Annualized Value Option 2	19.8	31.1	50.8	20.6	33.1	54.9

In addition to the benefits and costs of both options for the proposed rule, we assess the benefits and costs of several alternatives to the proposed rule, although we note that some may be outside of our current legal authority: deeming only, but exempt proposed deemed products from all labeling changes and premarket submission requirements; enforce premarket requirements only for machine-made cigars; change the grandfather date for new products to the date of final regulation; deeming only, but exempt proposed deemed products from all labeling

changes; exempt handmade cigars from labeling changes; deeming only (no additional provisions); alter the compliance period for labeling changes.[10]

Primary estimates of the costs of the regulatory alternatives appear as present values and annualized values in Table 12.

Table 12.--Primary Estimate of Quantified Costs for Regulatory Alternatives (Present and Annualized Values, $ million)[1]

Alternative	Present Value (3%)	Present Value (7%)	Annualized Value (3%)	Annualized Value (7%)
1--Deeming only; exempt from labeling changes and new product submissions	10.3	8.3	0.7	0.7
2--Enforce premarket requirements only for machine-made cigars	176.3	156.0	11.5	13.8
3--Change grandfather date to date of regulation	422.1	333.0	27.5	29.4
4--Deeming only; exempt from labeling changes	475.9	360.8	31.1	31.8
Proposed Rule Option 2: Exempt Premium Cigars from Regulation	476.4	375.0	31.1	33.1
5--Exempt handmade cigars from labeling changes	500.0	384.2	32.6	33.9
6--Deeming only; no additional provisions	541.6	425.3	35.3	37.5
7a-- 36-month compliance period for labeling changes	572.3	447.1	37.3	39.4
Proposed Rule Option 1 – 24-month compliance period for labeling changes	592.0	467.6	38.6	41.2
7b--12-month compliance period for labeling changes	646.1	523.2	42.2	46.2

[1] Nonquantified benefits are described in the text.

The majority of the compliance costs of this proposed rule are fixed, but a portion of the costs are variable. The costs imposed will be borne primarily by manufacturers and importers; some of the costs will be passed on to consumers in the form of higher prices. The average increase in the price of proposed deemed tobacco products, however, would be very small relative to current prices.

[10] We note that not all of these regulatory alternatives are necessarily legally permissible.

In addition to the costs described in Tables 11 and 12, the proposed rule would lead to private costs in the form of reduced revenues for firms in affected sectors. Additionally, if excise taxes on tobacco products remain at current levels, annual tax revenues would fall with reduced use.

Domestic tobacco product manufacturers and importers, most of which are small, would be the entities primarily affected by this rule. In particular, we expect domestic cigar manufacturers to be affected because they are more likely than importers to be completely specialized in a newly regulated product, and the handmade segment of the cigar market is characterized by a large number of low-volume products. Even though user fees are a transfer payment and not a societal cost, they are a cost from the standpoint of the manufacturers who must pay them. Therefore, user fees are included in the estimated burden for small domestic cigar manufacturers. For Option 1, the estimated upfront costs range from $390,000 to $759,000 per domestic cigar manufacturing establishment, and the average annual costs are estimated to range from $450,000 to $541,000. Several of the regulatory alternatives that would reduce costs are analyzed as potential regulatory relief options for small businesses.

The full analysis of economic impacts is available in the docket for this proposed rule (Ref. 193) and at http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.

FDA requests comments on all inputs, methods and results that appear in the economic analysis.

XIII. Request for Comments

A. General Information About Submitting Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document.

B. Public Availability of Comments

Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov. As a matter of Agency practice, FDA generally does not post comments submitted by individuals in their individual capacity on http://www.regulations.gov. This is determined by information indicating that the submission is written by an individual, for example, the comment is identified with the category "Individual Consumer" under the field titled "Category (Required)," on the "Your Information" page on www.regulations.gov. For this proposed rule, however, FDA will not be following this general practice. Instead, FDA will post on http://www.regulations.gov comments to this docket that have been submitted by individuals in their individual capacity. If you wish to submit any information under a claim of confidentiality, please refer to 21 CFR 10.20.

C. Information Identifying the Person Submitting the Comment

Please note that your name, contact information, and other information identifying you will be posted on http://www.regulations.gov if you include that information in the body of your comments. For electronic comments submitted to http://www.regulations.gov, FDA will post the body of your comment on http://www.regulations.gov along with your state/province and

country (if provided), the name of your representative (if any), and the category identifying you (e.g., individual, consumer, academic, industry). For written submissions submitted to the Division of Dockets Management, FDA will post the body of your comments on http://www.regulations.gov, but you can put your name and/or contact information on a separate cover sheet and not in the body of your comments.

XIV. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m. Monday through Friday, and are available electronically at http://www.regulations.gov. (FDA has verified all the Web site addresses in this reference section, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

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194. Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products; Proposed Rule: Preliminary Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis, and Unfunded Mandates Reform Act Analysis; available at http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/.

List of Subjects

21 CFR Part 1100

Smoking, Tobacco.

21 CFR Part 1140

Advertising, Labeling, Smoking, Tobacco.

21 CFR Part 1143

Advertising, Labeling, Packaging and containers, Smoking, Tobacco.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR chapter I be amended as follows:

1. Add part 1100 to subchapter K to read as follows:

PART 1100--TOBACCO PRODUCTS SUBJECT TO FDA AUTHORITY

Sec.

1100.1 Scope.

1100.2 Requirements.

1100.3 Definitions.

Authority: 21 U.S.C. 387a(b), 387f(d); Secs. 901(b) and 906(d), Pub. L. 111-31; 21 CFR 16.1 and 1107.1; 21 CFR 1.1, 1.20, 14.55, 17.1, and 17.2.

§ 1100.1 Scope.

Option 1

In addition to FDA's authority over cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco, FDA deems all other products meeting the definition of tobacco product under section 201(rr) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(rr)), except

accessories of such other tobacco products, to be subject to the Federal Food, Drug, and Cosmetic Act.

Option 2

In addition to FDA's authority over cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco, FDA deems all other products meeting the definition of tobacco product under section 201(rr) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(rr)), except accessories of such other tobacco products and cigars that are not within the scope of the covered cigar definition in § 1100.3, to be subject to the Federal Food, Drug, and Cosmetic Act.

§ 1100.2 Requirements.

Option 1

Cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, and all other tobacco products, except accessories of such other tobacco products, are subject to chapter IX of the Federal Food, Drug, and Cosmetic Act and its implementing regulations. Tobacco product is defined in section 201(rr) of the Federal Food, Drug, and Cosmetic Act.

Option 2

Cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, covered cigars, and all other tobacco products, except accessories of such other tobacco products and cigars that are not within the scope of the covered cigar definition in § 1100.3, are subject to chapter IX of the Federal Food, Drug, and Cosmetic Act and its implementing regulations. Tobacco product is defined in section 201(rr) of the Federal Food, Drug, and Cosmetic Act.

§ 1100.3 Definitions.

Option 1

Tobacco product. As stated in section 201(rr) of the Federal Food, Drug, and Cosmetic Act in relevant part, a tobacco product:

(1) Means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product); and

(2) Does not mean an article that is a drug defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act, a device defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act, or a combination product described in section 503(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)).

Option 2

Cigar means a tobacco product that:

(1) Is not a cigarette and

(2) Is a roll of tobacco wrapped in leaf tobacco or any substance containing tobacco.

Covered cigar means any cigar as defined in this part, except a cigar 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.

Tobacco product. As stated in section 201(rr) of the Federal Food, Drug, and Cosmetic Act in relevant part, a tobacco product:

(1) Means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product); and

(2) Does not mean an article that is a drug defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act, a device defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act, or a combination product described in section 503(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)).

PART 1140--CIGARETTES, SMOKELESS TOBACCO, AND COVERED TOBACCO PRODUCTS

2. The heading for part 1140 is revised to read as shown above.

3. The authority citation for 21 CFR part 1140 continues to read as follows:

Authority: 21 U.S.C. 301 et seq.; Sec. 102, Pub. L. 111-31.

4. Revise § 1140.1 to read as follows:

§ 1140.1 Scope.

(a) This part sets out the restrictions under the Federal Food, Drug, and Cosmetic Act on the sale, distribution, and use of cigarettes, smokeless tobacco, and covered tobacco products.

(b) The failure to comply with any applicable provision in this part in the sale, distribution, and use of cigarettes, smokeless tobacco, and covered tobacco products renders the product misbranded under the Federal Food, Drug, and Cosmetic Act.

(c) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

5. Revise § 1140.2 to read as follows:

§ 1140.2 Purpose.

The purpose of this part is to establish restrictions on the sale, distribution, and use of cigarettes, smokeless tobacco, and covered tobacco products in order to reduce the number of children and adolescents who use these products, and to reduce the life-threatening consequences associated with tobacco use.

6. Revise § 1140.3 to read as follows:

§ 1140.3 Definitions.

For the purposes of this part:

Cigar means a tobacco product that:

(1) Is not a cigarette and

(2) Is a roll of tobacco wrapped in leaf tobacco or any substance containing tobacco.

Cigarette. (1) 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

(2) 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.

Cigarette tobacco means any product that consists of loose tobacco that is intended for use by consumers in a cigarette. Unless otherwise stated, the requirements applicable to cigarettes under this chapter also apply to cigarette tobacco.

Covered tobacco product means any tobacco product deemed to be subject to the Federal Food, Drug, and Cosmetic Act pursuant to § 1100.2 of this chapter, but excludes any component or part that does not contain tobacco or nicotine.

Distributor 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 the purposes of this part.

Importer means any person who imports any tobacco product that is intended for sale or distribution to consumers in the United States.

Manufacturer means any person, including any repacker and/or relabeler, who manufactures, fabricates, assembles, processes, or labels a finished tobacco product.

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.

Package means a pack, box, carton, or container of any kind in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers.

Point of sale means any location at which a consumer can purchase or otherwise obtain tobacco products for personal consumption.

Retailer means any person who sells tobacco products to individuals for personal consumption, or who operates a facility where vending machines or self-service displays are permitted under this part.

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.

Tobacco product. As stated in section 201(rr) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(rr)) in relevant part, a tobacco product:

(1) Means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product) and

(2) Does not mean an article that is a drug defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act, a device defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act, or a combination product described in section 503(g) of the Federal Food, Drug, and Cosmetic Act.

7. Revise § 1140.10 to read as follows:

§ 1140.10 General responsibilities of manufacturers, distributors, and retailers.

Each manufacturer, distributor, importer, and retailer is responsible for ensuring that the cigarettes, smokeless tobacco, or covered tobacco products it manufactures, labels, advertises, packages, distributes, imports, sells, or otherwise holds for sale comply with all applicable requirements under this part.

8. Revise § 1140.14 to read as follows:

§ 1140.14 Additional responsibilities of retailers.

(a) In addition to the other requirements under this part, each cigarette and smokeless tobacco retailer is responsible for ensuring that all sales of cigarettes or smokeless tobacco to any person comply with the following requirements:

(1) No retailer may sell cigarettes or smokeless tobacco to any person younger than 18 years of age;

(2)(i) Except as otherwise provided in paragraph (a)(2)(ii) of this section and in § 1140.16(c)(2)(i), each retailer must verify by means of photographic identification containing the bearer's date of birth that no person purchasing the product is younger than 18 years of age;

(ii) No such verification is required for any person over the age of 26;

(3) Except as otherwise provided in § 1140.16(c)(2)(ii), a retailer may sell cigarettes or smokeless tobacco only in a direct, face-to-face exchange without the assistance of any electronic or mechanical device (such as a vending machine);

(4) No retailer may break or otherwise open any cigarette or smokeless tobacco package to sell or distribute individual cigarettes or a number of unpackaged cigarettes that is smaller than the quantity in the minimum cigarette package size defined in § 1140.16(b), or any quantity of cigarette tobacco or smokeless tobacco that is smaller than the smallest package distributed by the manufacturer for individual consumer use; and

(5) Each retailer must ensure that all self-service displays, advertising, labeling, and other items, that are located in the retailer's establishment and that do not comply with the requirements of this part, are removed or are brought into compliance with the requirements under this part.

(b) Notwithstanding the requirements in paragraph (a) of this section and in addition to the other requirements under this part, each retailer of covered tobacco products is responsible for ensuring that all sales of such covered tobacco products to any person comply with the following requirements:

(1) No retailer may sell covered tobacco products to any person younger than 18 years of age;

(2)(i) Except as otherwise provided in paragraph (a)(2)(ii) of this section and in § 1140.16(c)(2)(i), each retailer must verify by means of photographic identification containing the bearer's date of birth that no person purchasing the product is younger than 18 years of age;

(ii) No such verification is required for any person over the age of 26; and

(3) A retailer may not sell covered tobacco products with the assistance of any electronic or mechanical device (such as a vending machine), except in facilities where the retailer ensures that no person younger than 18 years of age is present, or permitted to enter, at any time.

9. Add part 1143 to subchapter K to read as follows:

PART 1143--REQUIRED WARNING STATEMENTS

Sec.

1143.1 Definitions.

1143.3 Required warning statement regarding addictiveness of nicotine.

1143.5 Required warning statements for cigars.

1143.7 Language requirements for required warning statements.

1143.9 Irremovable or permanent required warning statements.

1143.11 Does not apply to foreign distribution.

1143.13 Effective date.

Authority: 21 U.S.C. 387a(b), 387f(d); Pub. L. 111-31, 123 Stat. 1776.

§ 1143.1 Definitions.

Option 1

For purposes of this part:

Covered tobacco product means any tobacco product deemed to be subject to the Federal Food, Drug, and Cosmetic Act pursuant to § 1100.2 of this chapter, but excludes any component or part of a tobacco product that does not contain nicotine or tobacco.

Package means a pack, box, carton, or container of any kind in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers.

Required warning statement means a textual warning statement required to be on packaging and in advertisements for cigarette tobacco, roll-your-own tobacco, cigars, and other covered tobacco products.

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.

Option 2

For purposes of this part:

Cigar means a tobacco product that:

(1) Is not a cigarette and

(2) Is a roll of tobacco wrapped in leaf tobacco or any substance containing tobacco.

Covered cigar means any cigar as defined in this part, except a cigar 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.

Covered tobacco product means any tobacco product deemed to be subject to the Federal Food, Drug, and Cosmetic Act pursuant to § 1100.2 of this chapter, but excludes any component or part of a tobacco product that does not contain nicotine or tobacco.

Package means a pack, box, carton, or container of any kind in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers.

Required warning statement means a textual warning statement required to be on packaging and in advertisements for cigarette tobacco, roll-your-own tobacco, covered cigars, and other covered tobacco products.

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.

§ 1143.3 Required warning statement regarding addictiveness of nicotine.

(a) Packages. (1) For cigarette tobacco, roll-your-own tobacco, and covered tobacco products other than cigars, it is unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States such product unless the

tobacco product bears the following required warning statement on each product package: "WARNING: This product contains nicotine derived from tobacco. Nicotine is an addictive chemical."

(2) The required warning statement must appear directly on the package and must be clearly visible underneath any cellophane or other clear wrapping as follows:

(i) Be located in a conspicuous and prominent place on the two principal display panels of the package and the warning area must comprise at least 30 percent of each of the principal display panels;

(ii) Be printed in a font size that ensures that the text occupies the greatest possible proportion of the warning area set aside for the text required;

(iii) Be printed in conspicuous and legible Helvetica bold or Arial bold type and in black text on a white background or white text on a black background in a manner that contrasts by typography, layout, or color, with all other printed material on the package;

(iv) Be capitalized and punctuated as indicated in paragraph (a)(1) of this section; and

(v) Be centered in the warning area in which the text is required to be printed and positioned such that the text of the required warning statement and the other information on the principal display panel have the same orientation.

(3) A retailer of any tobacco product covered by paragraphs (a)(1) and (2) of this section will not be in violation of this section for packaging that:

(i) Contains a health warning;

(ii) Is supplied to the retailer by the tobacco product manufacturer, importer, or distributor, and

(iii) Is not altered by the retailer in a way that is material to the requirements of this section.

(b) Advertisements. (1) For cigarette tobacco, roll-your-own tobacco, and covered tobacco products other than cigars, it is unlawful for any tobacco product manufacturer, packager, importer, distributor, or retailer of the tobacco product to advertise or cause to be advertised within the United States any tobacco product unless each advertisement bears, in accordance with the requirements of this section, the required warning statement specified in paragraph (a)(1) of this section.

(2) The required warning statement must appear in the upper portion of the area of the advertisement within the trim area as follows:

(i) Occupy at least 20 percent of the area of the advertisement;

(ii) Be printed in a font size that ensures that the text occupies the greatest possible proportion of the warning area set aside for the text required;

(iii) Be printed in conspicuous and legible Helvetica bold or Arial bold type and in black text on a white background or white text on a black background in a manner that contrasts by typography, layout, or color, with all other printed material on the advertisement;

(iv) Be capitalized and punctuated as indicated in paragraph (a)(1) of this section;

(v) Be centered in the warning area in which the text is required to be printed and positioned such that the text of the required warning statement and the other textual information in the advertisement have the same orientation; and

(vi) Be surrounded by a rectangular border that is the same color as the text of the required warning statement and that is not less than 3 millimeters (mm) or more than 4 mm.

(3) This paragraph (b) applies to a retailer only if that retailer is responsible for or directs the health warning required under the paragraph. However, this paragraph does not relieve a retailer of liability if the retailer displays, in a location open to the public, an advertisement that does not contain a health warning or contains a health warning that has been altered by the retailer in a way that is material to the requirements of this section.

(c) Self-certification. A tobacco product that would otherwise be required to bear the warning in paragraph (a)(1) of this section but does not contain nicotine is not required to bear the warning in paragraph (a)(1) of this section on packages or advertisements if the manufacturer of the tobacco product has submitted to FDA a confirmation statement certifying to be true and accurate that the product does not contain nicotine and that the manufacturer has data to support that assertion. Any product not required to bear the warning in paragraph (a)(1) of this section must include the following statement "This product is derived from tobacco." on all packages and advertisements in accordance with the requirements of this part.

§ 1143.5 Required warning statements for cigars.

Option 1

(a) Packages. (1) It is unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any cigar the package of which fails to bear one of the following required warning statements on each product package:

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

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

(iii) WARNING: Cigars are not a safe alternative to cigarettes.

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

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

(2) Each required warning statement must appear directly on the package and must be clearly visible underneath any cellophane or other clear wrapping as follows:

(i) Be located in a conspicuous and prominent place on the two principal display panels of the package and the warning area must comprise at least 30 percent of each of the principal display panels;

(ii) Be printed in a font size that ensures that the text occupies the greatest possible proportion of the warning area set aside for the text required;

(iii) Be printed in conspicuous and legible Helvetica bold or Arial bold type and in black text on a white background or white text on a black background in a manner that contrasts by typography, layout, or color, with all other printed material on the package;

(iv) Be capitalized and punctuated as indicated in paragraph (a)(1) of this section; and

(v) Be centered in the warning area in which the text is required to be printed and positioned such that the text of the required warning statement and the other information on that principal display panel have the same orientation.

(3) No person may manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any cigar without a required warning statement, except for cigars that are sold individually and not in a product package. For cigars that are sold individually and not in a product package, the required warning statements must be posted at the retailer's point-of-sale in accordance with the following:

(i) The warnings in paragraph (a) of this section must be placed on a sign that is a minimum of 8.5 × 11 inches, posted on or within 3 inches of each cash register where payment may be made so that the sign(s) are unobstructed in their entirety and can be read easily by each consumer making a purchase;

(ii) The sign must be clear, legible, and conspicuous and be printed in black Helvetica bold or Arial bold type against a solid white background in at least 17 point type with appropriate space between the warning statements

(iii) Be printed in a manner that contrasts by typography, layout, or color, with all other printed material; and

(iv) Be capitalized and punctuated as indicated in paragraph (a)(1) of this section.

(4) A retailer of any cigar covered by paragraphs (a)(1) and (2) of this section will not be in violation of this section for packaging that:

(i) Contains a health warning;

(ii) Is supplied to the retailer by a manufacturer, importer, or distributor who has the required state, local, or Alcohol and Tobacco Tax and Trade Bureau (TTB)-issued license or permit, if applicable, and

(iii) Is not altered by the retailer in a way that is material to the requirements of this section.

(b) Advertisements. (1) It is unlawful for any tobacco product manufacturer, packager, importer, distributor, or retailer of cigars to advertise or cause to be advertised within the United States any cigar unless each advertisement bears, in accordance with the requirements of this section, one of the required warning statements specified in paragraph (a)(1) of this section.

(2) Each required warning statement must appear in the upper portion of the area of the advertisement within the trim area as follows:

(i) Occupy at least 20 percent of the area of the advertisement;

(ii) Be printed in a font size that ensures that the text occupies the greatest possible proportion of the warning area set aside for the text required;

(iii) Be printed in conspicuous and legible Helvetica bold or Arial bold type and in black text on a white background or white text on a black background in a manner that contrasts by typography, layout, or color, with all other printed material on the advertisement;

(iv) Be capitalized and punctuated as indicated in paragraph (a)(1) of this section;

(v) Be centered in the warning area in which the text is required to be printed and positioned such that the text of the required warning statement and the other textual information in the advertisement have the same orientation; and

(vi) Be surrounded by a rectangular border that is the same color as the text of the required warning statement and that is not less than 3 mm or more than 4 mm.

(3) This paragraph (b) applies to a retailer only if that retailer is responsible for or directs the warning statements required under the paragraph. However, this paragraph of this section does not relieve a retailer of liability if the retailer displays, in a location open to the public, an advertisement that does not contain a health warning or contains a health warning that has been altered by the retailer in a way that is material to the requirements of this section.

(c) Marketing requirements. (1) The warning statements required in paragraph (a)(1) of this section must be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of cigar sold in product packaging and be randomly distributed in all areas of the United States in which the product is marketed in accordance with a plan submitted

by the cigar manufacturer, importer, distributor, or retailer to, and approved by the Food and Drug Administration.

(2) The warning statements required in paragraph (a)(1) of this section must be rotated quarterly in alternating sequence in each advertisement for each brand of cigar in accordance with a plan submitted by the cigar manufacturer, importer, distributor, or retailer to, and approved by the Food and Drug Administration.

Option 2

(a) Packages. (1) It is unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any covered cigar the package of which fails to bear one of the following required warning statements on each product package:

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

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

(iii) WARNING: Cigars are not a safe alternative to cigarettes.

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

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

(2) Each required warning statement must appear directly on the package and must be clearly visible underneath any cellophane or other clear wrapping as follows:

(i) Be located in a conspicuous and prominent place on the two principal display panels of the package and the warning area must comprise at least 30 percent of each of the principal display panels;

(ii) Be printed in a font size that ensures that the text occupies the greatest possible proportion of the warning area set aside for the text required;

(iii) Be printed in conspicuous and legible Helvetica bold or Arial bold type and in black text on a white background or white text on a black background in a manner that contrasts by typography, layout, or color, with all other printed material on the package;

(iv) Be capitalized and punctuated as indicated in paragraph (a)(1) of this section; and

(v) Be centered in the warning area in which the text is required to be printed and positioned such that the text of the required warning statement and the other information on that principal display panel have the same orientation.

(3) No person may manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any covered cigar without a required warning statement, except for covered cigars that are sold individually and not in a product package. For covered cigars that are sold individually and not in a product package, the required warning statements must be posted at the retailer's point-of-sale in accordance with the following:

(i) The warnings in paragraph (a) of this section must be placed on a sign that is a minimum of 8.5 × 11 inches, posted on or within 3 inches of each cash register where payment may be made so that the sign(s) are unobstructed in their entirety and can be read easily by each consumer making a purchase;

(ii) The sign must be clear, legible, and conspicuous and be printed in black Helvetica bold or Arial bold type against a solid white background in at least 17 point type with appropriate space between the warning statements;

(iii) Be printed in a manner that contrasts by typography, layout, or color, with all other printed material; and

(iv) Be capitalized and punctuated as indicated in paragraph (a)(1) of this section.

(4) A retailer of any covered cigar covered by paragraphs (a)(1) and (2) of this section will not be in violation of this section for packaging that:

(i) Contains a health warning;

(ii) Is supplied to the retailer by a manufacturer, importer, or distributor who has the required state, local, or TTB-issued license or permit, if applicable, and

(iii) Is not altered by the retailer in a way that is material to the requirements of this section.

(b) Advertisements. (1) It is unlawful for any tobacco product manufacturer, packager, importer, distributor, or retailer of covered cigars to advertise or cause to be advertised within the United States any covered cigar unless each advertisement bears, in accordance with the requirements of this section, one of the required warning statements specified in paragraph (a)(1) of this section.

(2) Each required warning statement must appear in the upper portion of the area of the advertisement within the trim area as follows:

(i) Occupy at least 20 percent of the area of the advertisement;

(ii) Be printed in a font size that ensures that the text occupies the greatest possible proportion of the warning area set aside for the text required;

(iii) Be printed in conspicuous and legible Helvetica bold or Arial bold type and in black text on a white background or white text on a black background in a manner that contrasts by typography, layout, or color, with all other printed material on the advertisement;

(iv) Be capitalized and punctuated as indicated in paragraph (a)(1) of this section;

(v) Be centered in the warning area in which the text is required to be printed and positioned such that the text of the required warning statement and the other textual information in the advertisement have the same orientation; and

(vi) Be surrounded by a rectangular border that is the same color as the text of the required warning statement and that is not less than 3 mm or more than 4 mm.

(3) This paragraph (b) applies to a retailer only if that retailer is responsible for or directs the warning statements required under the paragraph. However, this paragraph of this section does not relieve a retailer of liability if the retailer displays, in a location open to the public, an advertisement that does not contain a health warning or contains a health warning that has been altered by the retailer in a way that is material to the requirements of this section.

(c) Marketing requirements. (1) The warning statements required in paragraph (a)(1) of this section must be randomly displayed in each 12-month period, in as equal a number of times as is possible on each applicable brand of covered cigar and be randomly distributed in all areas of the United States in which the product is marketed in accordance with a plan submitted by the cigar manufacturer, importer, distributor, or retailer to, and approved by the Food and Drug Administration.

(2) The warning statements required in paragraph (a)(1) of this section must be rotated quarterly in alternating sequence in each advertisement for each applicable brand of covered

cigar in accordance with a plan submitted by the cigar manufacturer, importer, distributor, or retailer to, and approved by the Food and Drug Administration.

§ 1143.7 Language requirements for required warning statements.

The text in each required warning statement required in § 1143.3 or § 1143.5 must be in the English language, except as follows:

(a) In the case of an advertisement that appears in a non-English publication, the text in the required warning statement must appear in the predominant language of the publication whether or not the advertisement is in English, and;

(b) In the case of an advertisement that appears in an English language publication but that is not in English, the text in the required warning statement must appear in the same language as that principally used in the advertisement.

§ 1143.9 Irremovable or permanent required warning statements.

The required warning statements required by this section must be indelibly printed on or permanently affixed to the package or advertisement. These warnings, for example, must not be printed or placed on a product label affixed to a clear outer wrapper that is likely to be removed to access the product within the package.

§ 1143.11 Does not apply to foreign distribution.

The provisions of this part do not apply to a manufacturer or distributor of tobacco products that does not manufacture, package, or import tobacco products for sale or distribution within the United States.

§ 1143.13 Effective date.

This part will take effect 24 months after [date of publication of final rule]. The effective date will be with respect to the date of manufacture, provided that, in any case, beginning 30

days after the effective date, a manufacturer may not introduce into the domestic commerce of the United States any product, irrespective of the date of manufacture that is not in conformance with this part.

Dated: April 22, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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