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; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing this final rule to deem products meeting the statutory definition of ''tobacco product,'' except accessories of the newly deemed tobacco products, 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. With this final rule, FDA is extending the Agency's ''tobacco product'' authorities in the FD&C Act to all other categories of products that meet the statutory definition of ''tobacco product'' in the FD&C Act, except accessories of such newly deemed tobacco products. This final rule also prohibits the sale of ''covered tobacco products'' to individuals under the age of 18 and requires 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 reduce the death and disease from tobacco products. In accordance with the Tobacco Control Act, we consider and intend the extension of our authorities over tobacco products and the various requirements and prohibitions established by this rule to be severable.

DATES: This rule is effective August 8, 2016. See section IV of this document regarding compliance dates for certain provisions.

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Executive Summary

Purpose of the 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, the statute authorizes FDA to issue regulations ''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. This final rule has two purposes: (1) To deem all products that meet the definition of ''tobacco product'' under the law, except accessories of a newly deemed tobacco product, and subject them to the tobacco control authorities in chapter IX of the FD&C Act and FDA's implementing regulations; and (2) to establish specific restrictions that are appropriate for the protection of the public health for the newly deemed tobacco products. In accordance with section 5 of the Tobacco Control Act, we consider and intend the extension of our authorities over tobacco products and the various requirements and prohibitions established by this rule to be severable.

FDA is taking this action to reduce the death and disease from tobacco products. Deeming all ''tobacco products'' (including components and parts but excluding accessories of the newly deemed products) to be subject to the FD&C Act will result in significant benefits for the public health. The final rule defines ''component or part'' and ''accessory'' to provide additional clarity as to which products are subject to FDA's tobacco product authority. With respect to these definitions, FDA notes that ''component'' and ''part'' are separate and distinct terms within chapter IX of the FD&C Act. However, for purposes of this final rule, FDA is using the terms ''component'' and ''part'' interchangeably and without emphasizing the distinction between the terms. FDA may clarify the distinctions between 'component' and 'part' in the future. Specifically, ''Component or Part'' means ''any software or assembly of materials intended or reasonably expected: (1) To alter or affect the tobacco product's performance, composition, constituents or characteristics; or (2) to be used with or for the human consumption of a tobacco product. The term excludes anything that is an accessory of a tobacco product.'' Components and parts of the newly deemed tobacco products, but not their related accessories, are included in the scope of this final rule. The following is a nonexhaustive list of examples of components and parts used with electronic nicotine delivery systems (ENDS) (including e-cigarettes): E-liquids; atomizers; batteries (with or without variable voltage); cartomizers (atomizer plus replaceable fluid-filled cartridge); digital display/lights to adjust settings; clearomisers, tank systems, flavors, vials that contain e-liquids, and programmable software. Similarly, the following is a nonexhaustive list of examples of components and parts used with waterpipe tobacco: Flavor enhancers and the vials in which they are contained; hose cooling attachments; water filtration base additives (including those which are flavored); flavored waterpipe tobacco charcoals and the wrappers or boxes that contain the charcoals; and bowls, valves, hoses, and heads.

FDA is defining ''accessory'' to mean ''any product that is intended or reasonably expected to be used with or for the human consumption of a tobacco product; does not contain tobacco and is not made or derived from tobacco; and meets either of the following: (1) Is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product or (2) is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a tobacco product but (i) solely controls moisture and/or temperature of a stored product or (ii) solely provides an external heat source to initiate but not maintain combustion of a tobacco product.'' Examples of accessories are ashtrays, spittoons, hookah tongs, cigar clips and stands and pipe pouches, because they do not contain tobacco, are not derived from tobacco, and do not affect or alter the performance, composition, constituents, or characteristics of a tobacco product. Examples of accessories also include humidors or refrigerators that solely control the moisture and/or temperature of a stored product and conventional matches and lighters that solely provide an external heat source to initiate but not maintain combustion of a tobacco product. An electric heater or charcoal used for prolonged heating of waterpipe tobacco is not an accessory because it is maintaining the combustion of the tobacco. Accessories of newly deemed tobacco products are not included within the scope of this final rule, although accessories of cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco remain subject to FDA's tobacco product authorities. FDA is not regulating accessories of newly deemed tobacco products because accessories, unlike components or parts, are expected to have little direct impact on the public health.

This final deeming rule affords FDA additional tools to reduce the number of illnesses and premature deaths associated with tobacco product use. For example, FDA will be able to obtain critical information regarding the health risks of newly deemed tobacco products, including information derived from ingredient listing submissions and reporting of harmful and potentially harmful constituents (HPHCs) required under the FD&C Act. As of the effective date, persons who own or operate a domestic establishment engaged in the manufacture, preparation, compounding, or processing of tobacco products (hereinafter, ''manufacturing establishments'') will be subject to the registration requirements. FDA will thus receive information on the location and number of manufacturing establishments, which will allow the Agency to establish effective compliance programs. In addition, this rule authorizes FDA to take enforcement action against manufacturers who sell and distribute products with unsubstantiated modified risk tobacco product (MRTP) claims, or false or misleading claims on their labeling or advertising, thus allowing for better-informed consumers and helping to prevent the use of misleading campaigns targeted to youth populations. It will also prevent from entering the market new tobacco products that are not appropriate for the protection of public health, are not substantially equivalent to a valid predicate product, or are not exempt from substantial equivalence (SE). Finally, the newly deemed tobacco products may be subject to future regulations that FDA determines are

appropriate for the protection of public health.

Summary of the Major Provisions of the Regulatory Action

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

Deeming Provisions—After thorough review of the comments and the scientific evidence, FDA has concluded that Option 1 (including all cigars, rather than a subset) more effectively protects the public health and, therefore, has made that the scope of the final rule. Accordingly, this final rule deems all products meeting the statutory definition of ''tobacco product,'' except accessories of the newly deemed tobacco products, to be subject to FDA's tobacco product authorities under chapter IX of the FD&C Act. 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)'' and does not mean ''an article that is a drug under subsection (g)(1), a device under subsection (b), or a combination product described in section 353(g) of this title.'' [1] Products that meet the statutory definition of ''tobacco products'' include currently marketed products such as dissolvables not already regulated by FDA, gels, waterpipe tobacco, ENDS (including e-cigarettes, e-hookah, e-cigars, vape pens, advanced refillable personal vaporizers, and electronic pipes), cigars, and pipe tobacco.

In addition, this final rule deems any additional current and future tobacco products that meet the statutory definition of ''tobacco product,'' except accessories of such newly deemed products, 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 through means (*e.g.,* via dermal absorption or intranasal spray) similar to currently marketed medicinal nicotine products, but which are not drugs or devices. These products would be ''tobacco products'' and subject to FDA's chapter IX authorities in accordance with this final deeming rule.

Upon the effective date of this final rule (*i.e.,* 90 days from the date of publication), the newly deemed products will be subject to the same FD&C Act provisions and relevant regulatory requirements to which cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco are subject, with respect to the following:

(1) Enforcement action against products determined to be adulterated or misbranded (other than enforcement actions based on lack of a marketing authorization during an applicable compliance period);

(2) Required submission of ingredient listing and reporting of HPHCs;

(3) Required registration of tobacco product manufacturing establishments and product listing;

(4) Prohibition against sale and distribution of products with modified risk descriptors (*e.g.,* ''light,'' ''low,'' and ''mild'' descriptors) and claims unless FDA issues an order authorizing their marketing;

(5) Prohibition on the distribution of free samples (same as cigarettes); and

(6) Premarket review requirements.

These actions will improve the public health by affording FDA critical information regarding the health risks of such products; preventing new products from entering the market unless such marketing is appropriate for the protection of public health, the products are found substantially equivalent to a valid predicate product, or the products are found exempt from the SE requirements; and preventing the use of unsubstantiated modified risk claims, which may mislead consumers and lead them 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 and implementing regulations that apply automatically to the newly deemed products, 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 is establishing three restrictions for covered tobacco products: (1) Requirement for a minimum age of purchase; (2) requirement for health warnings for product packages and advertisements (which FDA is also applying to cigarette tobacco and roll-your-own tobacco); and (3) prohibition of vending machine sales of such products, 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'' is 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 is not made or derived from tobacco. We have slightly modified the definition of ''covered tobacco products'' from the notice of proposed rulemaking (NPRM) to clarify that components or parts that are ''covered tobacco products'' include not only those that contain tobacco or nicotine, but also those that contain any tobacco derivative (*i.e.,* we have changed the NPRM definition, which excluded ''any component or part of a tobacco product that does not contain nicotine or tobacco,'' to exclude ''any component or part of a tobacco product that is not made or derived from tobacco'' as stated in this final rule).

Effective Dates—The deeming provisions (*i.e.,* those provisions that automatically apply to newly deemed products) and minimum age and identification and vending machine restrictions are effective 90 days from the date of publication of the final rule. The health warning requirements are effective 24 months from the date of publication of the final rule, with an additional 30-day period in which a manufacturer may continue to introduce into interstate commerce existing inventory manufactured before the effective date that does not contain the required warning statements on packaging.

This means that:

- After the effective date, no manufacturer, packager, importer, distributor, or retailer of cigarette tobacco, roll-your-own tobacco, cigars, or other covered tobacco products may advertise any such product if the advertisement does not comply with this rule;
- After the effective date, no person may manufacture for sale or distribution within the United States any such product the package of which does not comply with this rule;
- Beginning 30 days after the effective date, a manufacturer may not introduce into domestic commerce, any such product, irrespective of the date of manufacture, if its package does not comply with this rule (*i.e.,* non-compliant products manufactured prior to the effective date may not be

[1] FDA notes that some 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)). Taxation of tobacco products, as defined by the Internal Revenue Code, falls under the jurisdiction of the U.S. Department of the Treasury/Alcohol and Tobacco Tax and Trade Bureau (TTB). Neither FDA's act of ''deeming'' nor any other FDA regulations directly affect the taxation of any tobacco product.

distributed for retail sale after 30 days following the effective date);

- After the effective date, a distributor or retailer may not sell, offer to sell, distribute, or import for sale or distribution within the United States any such product the package of which does not comply with this regulation, unless the covered tobacco product was manufactured prior to the effective date; and
- After the effective date, however, a retailer may sell covered tobacco products in packages that do not have a required warning if the retailer demonstrates it falls outside the scope of this rule as described in 21 CFR 1143.3(a)(3) and 1143.5(a)(4).

Compliance Policy for Premarket Review—Manufacturers of newly deemed products that are ''new tobacco products'' as defined in section 910(a)(1) of the FD&C Act will be required to obtain premarket authorization of their products through one of three pathways—SE., exemption from SE., or premarket tobacco product applications (sections 905 and 910 of the FD&C Act). As stated in the NPRM, we understand that, for some newly deemed tobacco products, particularly novel products, there may not be appropriate predicate products that were on the market on February 15, 2007, to support a SE claim. Accordingly, in the NPRM, FDA contemplated a compliance period of 24 months after the effective date of the final rule for the submission of applications for all newly deemed, new tobacco products under all three marketing pathways—premarket tobacco applications (PMTAs), SE reports, and SE exemption requests.[2]

FDA carefully considered numerous comments regarding the contemplated compliance period. Many comments expressed concern that newly deemed, new tobacco products would remain available and could continue to be marketed indefinitely without scientific review. Other comments expressed concern, and some submitted data, regarding the effect that flavors have on youth and young adult use of tobacco products. FDA also received comments and data regarding the potential for some net public health benefits that could accrue if flavored ENDS remain available. After carefully considering all of these comments, FDA here announces a revised compliance policy as well as the final rule. (Agency compliance/enforcement policies are not subject to the requirements that govern notice-and-comment rulemaking. *Prof'ls & Patients for Customized Care* v. *Shalala,* 56 F.3d 592 (5th Cir. 1995) (a compliance policy guide is not a substantive rule and not subject to the Administrative Procedure Act's (APA) notice-and-comment rulemaking); *Takhar* v. *Kessler,* 76 F.3d 995, 1002 (9th Cir. 1996) (FDA compliance policy guides were not required to go through notice-and-comment procedures). But because the relevant time periods are of obvious interest, FDA laid out its anticipated compliance policy in the NPRM, and for similar reasons, is announcing its revised compliance policy here, rather than in a separate guidance document.) As a result of FDA's compliance policy, we expect that many manufacturers will keep their products on the market beyond the effective date of this final rule. However, if a manufacturer of a product is unable to support an SE claim for its product (*e.g.,* is unable to identify a valid predicate, or does not submit an SE report with a valid predicate within the compliance period, or does not receive authorization within a continued compliance period) and does not obtain authorization under one of the other available marketing pathways before the end of an applicable compliance period, such products remaining on the market will be subject to enforcement (*e.g.,* seizure, injunction) for failure to have a marketing authorization under sections 905 and 910 of the FD&C Act.

FDA's NPRM included detailed requests for comments on different possible compliance policy approaches. 79 FR at 23175–77. FDA received many comments on these compliance-policy issues. For example, comments jointly submitted by 24 health and medical organizations stated that the contemplated 24-month compliance period and indefinite period of continued marketing during FDA review included in the NPRM would prolong the public's exposure to products that contain nicotine, a highly addictive substance, and that do not meet the statutory standard for the grant of a marketing order (Comment No. FDA–2014–N–0189–79772.). They stated that this approach would allow manufacturers to market the newly deemed products in ways that appeal to youth and to manipulate the content of these products in uncontrolled ways for an indefinite period (id.). Ranking minority members of the Energy and Commerce Committee, Health Subcommittee, and Oversight and Investigations Subcommittee, U.S. House of Representatives also called for a more protective compliance period than the one contemplated in the NPRM, arguing that the proposed compliance period ''puts the nation's youth at risk'' (Comment No. FDA–2014–N–0189–80119). Further, a network of tobacco control policy and legal specialists expressed concern regarding the effect of continued marketing of tobacco products that have not been reviewed under the applicable public health standards of the Tobacco Control Act (Comment No. FDA–2014–N–0189–81044). FDA also received comments suggesting that the agency should stagger the compliance periods for different product classes based on the continuum of risk, with ENDS having a longer compliance period than other product classes (*e.g.,* Comment No. FDA–2014–N–0189–81859; Comment No. FDA–2014–N–0189–10852). FDA also received comments and new data regarding the effect of flavored tobacco products on youth and young adult use.

FDA understands that the appeal of flavors and use of flavored tobacco products have an important role in the initiation and continued use of tobacco products, and in the health risks associated with use of these products. Based on all of these comments, we have determined that exercising enforcement discretion indefinitely could put youth and young adults at risk for tobacco-related death and disease. However, we recognize that the availability of alternatives to traditional tobacco flavors in some products (*e.g.,* ENDS) may potentially help some adult users who are attempting to transition away from combusted products. Furthermore, at least some flavored combusted products are likely to be ''grandfathered'' and therefore would remain on the market regardless of the compliance period provided in the preamble. Taking into consideration all of the comments on the compliance period and flavors, we are establishing staggered compliance periods. This approach will enable FDA to balance concerns regarding the extended availability of all newly deemed, new tobacco products without scientific review, concerns regarding flavored tobacco products' appeal to youth, and emerging evidence that some adults may potentially use certain flavored tobacco products to transition away from combusted tobacco use. FDA is establishing staggered initial compliance periods based on the expected complexity of the applications to be submitted, followed by continued

[2] Although the NPRM did not explicitly include SE exemption requests as one of the marketing pathways that applicants could utilize within a compliance period, FDA did intend for its contemplated 24-month compliance period to be available for all marketing pathways.

compliance periods for FDA review such that our exercise of enforcement discretion will end twelve months after each initial compliance period. In other words, manufacturers of all newly deemed, new tobacco products will have a 12-, 18- or 24-month initial compliance period in which to prepare applications for marketing authorization, as well as a 12-month continued compliance period after those dates in which to obtain authorization from FDA (resulting in total compliance periods of 24, 30, or 36 months). After the close of the continued compliance period, products will be subject to enforcement unless they are grandfathered or are the subject of a marketing authorization order. FDA's revised compliance policy for premarket review—resulting in products remaining on the market while manufacturers seek review but also contemplating an end to the continued compliance policy—will balance the public health concerns raised in the comments, allow the Agency to more efficiently manage the flow of incoming applications, and encourage high-quality premarket submissions from applicants.

According to this revised compliance policy, for newly deemed products that are on the market on the effective date of this final rule and were not on the market on February 15, 2007, FDA is providing a 12-month initial compliance period for manufacturers to submit (and FDA to receive) an SE exemption request, an 18-month initial compliance period for manufacturers to submit (and FDA to receive) SE applications, and a 24-month initial compliance period for manufacturers to submit (and FDA to receive) a PMTA.

If manufacturers submit (and FDA receives) the applications during their respective compliance periods, FDA, for a certain period of time as discussed in the following paragraph, intends to continue the compliance policy and does not intend to initiate enforcement action for these products remaining on the market without FDA authorization.

For newly deemed tobacco products using the SE Exemption pathway, this continued compliance period (*i.e.,* the time during which FDA does not intend to enforce the premarket review requirements) will close 24 months after the effective date of part 1100 of this final deeming rule (*i.e.,*12 months after the 12-month initial compliance period closes for submission and receipt of SE exemption requests). The earlier submission period for the SE exemption pathway is intended to allow the manufacturer time to consider other pathways if the exemption request is denied or if FDA refuses to accept the request if, for example, the application is incomplete. For newly deemed tobacco products using the SE pathway, this continued compliance period will close 30 months after the effective date of part 1100 of this final deeming rule (*i.e.,* 12 months after the 18-month initial compliance period closes for submission and receipt of SE Reports). For newly deemed tobacco products using the PMTA pathway, this continued compliance period will close 36 months after the effective date (*i.e.,* 12 months after the 24-month compliance period closes for submission and receipt of PMTAs). Any such newly deemed tobacco product for which an application under one of the three marketing pathways has not been submitted within 24 months from the effective date of part 1100 of this final deeming rule will not benefit from this continued compliance policy and will be subject to enforcement as of that date. In addition, once the respective continued compliance period ends for products with applications submitted according to this policy, products remaining on the market without premarket authorizations in effect, even if the product has a pending application that was originally submitted by its respective initial compliance deadline set forth previously in this document, will be subject to enforcement. However, if at the time of the conclusion of the continued compliance period, the applicant has provided the needed information and review of a pending marketing application has made substantial progress toward completion, FDA may consider, on a case-by-case basis, whether to defer enforcement of the premarket authorization requirements for a reasonable time period.

Regarding concerns as to the inability to use the SE pathway for certain products, FDA notes that an applicant may use as a predicate any tobacco product commercially marketed in the United States as of February 15, 2007, or previously found substantially equivalent (note that we interpret the phrase ''as of'' February 15, 2007, as meaning that the tobacco product was commercially marketed (other than exclusively in test markets) in the United States on February 15, 2007. If your tobacco product had been commercially marketed in the United States before February 15, 2007, but was not commercially marketed on that date, it is not a grandfathered product and may not be commercially marketed unless you obtain a marketing authorization under section 910 of the FD&C Act).[3] This may possibly include a predicate that is in a different category or subcategory than the new product that is the subject of the SE report. While FDA currently does not have a policy that limits comparisons to the same category, we do see cross-category comparisons as more challenging for an applicant and we may express limitations on such comparisons in the future, if they become warranted as we gain experience regulating newly deemed products. FDA also is continuing to research e-cigarettes, other ENDS, and heated cigarette products that likely were on the market ''as of'' (*i.e.,* on) February 15, 2007. Additionally, FDA has determined that some e-cigarettes and other ENDS were manufactured in 2006 and commercially marketed in the United States in early 2007. In particular, we have identified an ENDS product that may have been on the market on February 15, 2007. This product may possibly be able to serve as a valid predicate for purposes of the SE pathway. The burden of demonstrating that a valid predicate exists rests with the manufacturer submitting a SE report. To facilitate the determination that a product is eligible to serve as a valid predicate, any individual who has evidence that an e-cigarette or other ENDS was commercially marketed in the United States on February 15, 2007, may submit a stand-alone grandfather submission to FDA (See final guidance, ''Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007'' (79 FR 58358, September 29, 2014)). (Based on FDA's experiences to date, and since stand-alone grandfather submissions are purely voluntary, FDA does not anticipate that many manufacturers will make such submissions, but this option is available.) Regardless of the predicate selected for comparison, manufacturers are responsible for providing scientific data adequate to demonstrate that, in the case of an SE report, the characteristics of the new product are the same as the predicate or, if the characteristics are different, that these differences do not cause the new product to raise different questions of public health. We encourage interested parties to review the applications FDA

[3] FDA Guidance states that ''[i]f you cannot provide documentation specifically dated on February 15, 2007, FDA suggests you provide documentation of commercial marketing for a reasonable period of time before and after February 15, 2007.'' Guidance for Industry entitled ''Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007 (79 FR 58358, Sept. 29, 2014), The guidance also provides examples of sources of evidence, *e.g.,* bills of lading.

posts on *http://www.fda.gov* for examples of products that do not raise different questions of public health when compared with the specified predicate product.

Vape Establishments Acting as Manufacturers—Several comments asked FDA to clarify whether e-cigarette retail stores and vape establishments are considered ''tobacco product manufacturers'' under the FD&C Act. In response, FDA has explained that establishments that mix or prepare e-liquids or create or modify aerosolizing apparatus for direct sale to consumers are tobacco product manufacturers under the definition set forth in the FD&C Act and, accordingly, are subject to the same legal requirements that apply to other tobacco product manufacturers.

Revisions to Health Warning Requirements—FDA is finalizing this deeming rule with a few changes to the proposed health warning requirements for newly deemed products. For example, FDA has slightly revised the nicotine warning statement to read: ''WARNING: This product contains nicotine. Nicotine is an addictive chemical.'' The alternative warning statement for products that do not contain nicotine (*i.e.,* no nicotine at detectable levels) is revised to read: ''This product is made from tobacco.'' We have also provided additional language explaining the process for self-certifying that the product does not contain nicotine, which must be submitted to FDA, and the recordkeeping recommendations for this self-certification. E-liquids that do not contain tobacco or nicotine or are not derived from tobacco or nicotine do not meet the definition of ''covered tobacco product,'' as described throughout this final rule, and will not be required to carry an addiction warning or to submit a self-certification. In addition, we have added language to clarify that the warning statements on packages must be printed in at least 12-point font size to be conspicuous and legible.

Further, we have added a provision to indicate that a product package too small or otherwise unable to accommodate a label with sufficient space to bear such information will be exempt from the requirements to place the warning statement directly on packages (as required in § 1143.3(a)(1)), as long as the warning requirements enumerated in § 1143.3(a)(2) and (d) are met. For instance, for small packages, the warning statement must appear on the two principal display panels on the outer carton or other outer container or wrapper or on a tag otherwise permanently affixed to the tobacco product package. This required warning must be printed using the same specifications in § 1143.3(a)(1) and (2) (which provide the specifications for the addiction warning). In such cases, the carton, outer container, wrapper, or tag would serve as one of the principal display panels.

Reproductive Health Warning for Cigars—In the proposed deeming rule, FDA proposed to require four of the five warnings already included on most cigar packages and in most cigar advertisements as a result of settlement agreements between the Federal Trade Commission (FTC) and the seven largest U.S. cigar manufacturers (hereinafter, ''FTC consent decrees''). (See, *e.g.,* In re Swisher International, Inc., Docket No. C–3964.) FDA did not propose to require the fifth warning (SURGEON GENERAL WARNING: Tobacco Use Increases the Risk of Infertility, Stillbirth and Low Birth Weight), but asked for comments regarding this decision. Upon further consideration, FDA has decided to require a fifth warning regarding reproductive health effects and cigar use specifically, which reads ''WARNING: Cigar use while pregnant can harm you and your baby.'' This requirement is supported by existing scientific evidence and is appropriate for the protection of the public health. However, because the general statement ''Tobacco smoke increases the risk of infertility, stillbirth and low birth weight'' is also a true statement, and because scientific evidence demonstrates that cigar smoke is similar in content and effects to cigarette smoke, FDA is allowing the use of the reproductive health warning required by the FTC consent decrees as an optional alternative to the fifth FDA warning. FDA expects that providing the optional alternative will benefit entities bound by the FTC consent decrees.

Nicotine Exposure Warning and Child-Resistant Packaging—After reviewing the comments, FDA recognizes the importance of alerting consumers to, and protecting children from, the hazards from ingestion of, and eye and skin exposure to, e-liquids containing nicotine. Toward that end, FDA issued an advance NPRM (ANPRM) prior to this deeming rule (80 FR 51146 (2015)), seeking comments, data, research, or other information that may inform regulatory actions FDA may take with respect to a nicotine exposure warning and child-resistant packaging. In addition, elsewhere in this issue of the **Federal Register,** FDA has made available draft guidance, which when final will describe FDA's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products, including recommendations for exposure warnings and child-resistant packaging that would help to support a showing that the marketing of a product is appropriate for the protection of public health.

Requests for Additional Regulations Applicable to Newly Deemed Products—In the NPRM, FDA noted that, once the products were deemed, the Agency could issue additional regulations applicable to newly deemed products, including product standards under section 907 of the FD&C Act (21 U.S.C. 387g). FDA received many suggestions for additional regulations that should apply to the newly deemed products. FDA is taking these comments under advisement and considering whether to issue NPRMs for such provisions.

Compliance Policy Regarding Certain Provisions and Small-Scale Tobacco Product Manufacturers—In the NPRM, FDA requested comment on the ability of small manufacturers of newly deemed tobacco products to fully comply with the requirements of the FD&C Act and how FDA might be able to address those concerns. Considering the comments and FDA's finite enforcement resources, the Agency's view is that those resources may not be best used in immediately enforcing certain provisions of this rule against certain manufacturers that are small-scale tobacco product manufacturers and that may need additional time to comply with certain requirements of the FD&C Act. Generally, for purposes of this new compliance policy in which FDA is specifying additional periods of time for such manufacturers to comply with certain provisions (*i.e.,* additional time to respond to SE deficiency letters, an additional six-month compliance period for the tobacco health document submission requirements, and additional time to submit ingredient listings, as discussed in Section IV.D). As with manufacturers generally, these small-scale tobacco manufacturers will also benefit from additional assistance with their marketing applications, including: a Regulatory Health Project Manager so that they have a single point of contact in FDA's Center for Tobacco Products (CTP's) Office of Science (OS) for questions about their marketing applications; an appeals process for denial of marketing applications (of which one small business has already taken advantage); and staff from CTP's Office of Compliance and Enforcement (OCE), who assist such businesses in helping them to identify documents that may be used to establish that their

predicate products were on the market on February 15, 2007. Further, CTP's OCE will continue to assist small-scale tobacco product manufacturers in their submission of rotational warning plans for FDA approval and to provide a system to assist such businesses in navigating the regulatory requirements of FDA. FDA considers a ''small-scale tobacco product manufacturer'' to be a manufacturer of any regulated tobacco product that employs 150 or fewer full-time equivalent employees and has annual total revenues of $5,000,000 or less. In formulating our thinking on what a small-scale tobacco product manufacturer is for purposes of this policy, FDA has considered all available data on employment, revenues, production volume and other details of operation for current manufacturers of newly deemed products. FDA considers a manufacturer to include each entity that it controls, is controlled by, or is under common control with. To help make FDA's individual enforcement decisions more efficient, a manufacturer may voluntarily submit information regarding employment and revenues.[4]

Policy for Certain Regulatory Requirements for All Manufacturers of Newly Deemed Products—Although FDA maintains that all of the automatic provisions are important given that all tobacco products have inherent risks, FDA recognizes that compliance with many of the automatic provisions may be challenging at first for entities that are new to Federal public health regulation. In addition, FDA expects that it will obtain necessary information from its regulation of finished tobacco products. As a result, FDA has established a compliance policy for premarket submission and for obtaining authorization with respect to certain components and parts of newly deemed tobacco products. We note that FDA also intends to issue a guidance regarding HPHC reporting under section 904(a)(3), and later a testing and reporting regulation as required by section 915, with enough time for manufacturers to report given the 3-year compliance period for HPHC reporting. Section 904(a)(3) requires the submission of a report listing all constituents, including smoke constituents identified as harmful or potentially harmful (HPHC) by the Secretary. Section 915 requires the testing and reporting of the constituents, ingredients, and additives the Secretary determines should be tested to protect the public health. The section 915 testing and reporting requirements apply only after FDA issues a regulation implementing that section, which it has not yet done. Until these testing and reporting requirements have been established, newly deemed tobacco products (and currently regulated tobacco products) are not subject to the testing and reporting provisions found under section 915. As noted elsewhere in this document, FDA does not intend to enforce the reporting requirements under section 904(a)(3) for newly deemed products before the close of the 3-year compliance period, even if the HPHC guidance and the section 915 regulation are issued well in advance of that time.

Severability—In accordance with section 5 of the Tobacco Control Act, FDA considers and intends the extension of its authorities over all tobacco products and the various requirements and prohibitions established by this rule to be severable. It is FDA's interpretation and position that the invalidity of any provision of this rule shall not affect the validity of any other part of this rule. In the event any court or other lawful authority were to temporarily or permanently invalidate, restrain, enjoin, or suspend any provision of this final rule, FDA would conclude that the remaining parts continue to be valid. As stated in section 5 of the Tobacco Control Act, if certain applications of this rule to persons or circumstances (discussed in the preamble or otherwise) are held to be invalid, application of such provisions to any other person or circumstance will not be affected and will continue to be enforced. Each provision of the rule is independently supported by data and analysis as described or referenced in this preamble and, if issued separately, would remain a proper exercise of FDA authority.

Costs and Benefits

This final rule deems all products meeting the statutory definition of ''tobacco product,'' except accessories of a newly deemed tobacco product, to be subject to chapter IX of the FD&C Act. This final rule also finalizes additional provisions that would apply to certain newly 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 will apply to newly deemed products include establishment registration and product listing, ingredient listing, HPHC testing and reporting, premarket submissions prior to the introduction of new products, and labeling requirements. Free samples of newly deemed tobacco products will also be prohibited. The additional provisions of this final rule include minimum age and identification requirements, vending machine restrictions, and required warning statements for packages and advertisements.

TABLE 1—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 of Private Sector Costs	517.7	783.7	1,109.8	450.4	670.9	939.8
Present Value of Government Costs [1]	204.6	204.6	204.6	145.7	145.7	145.7
Present Value of Total Costs	722.3	988.2	1,314.4	596.1	816.5	1,085.4
Annualized Value of Private Sector Costs	34.8	52.7	74.6	42.5	63.3	88.7
Annualized Value of Government Costs [1]	13.8	13.8	13.8	13.8	13.8	13.8
Annualized Value of Total Costs	48.5	66.4	88.3	56.3	77.1	102.5

[1] FDA costs represent an opportunity cost, but this rule will not result in changes to overall FDA accounting costs, the size of the Federal budget, or the total amount of tobacco industry user fees.

[4] FDA notes that our current thinking regarding ''small-scale tobacco product manufacturer'' for purposes of this compliance policy differs from definitions of ''small manufacturer'' or ''small tobacco product manufacturer'' that pertain in several other contexts, including definitions established by the Small Business Administration or the Tobacco Control Act's definition of a ''small tobacco product manufacturer.'' FDA notes that its current thinking reflects an evaluation of all available data regarding manufacturers of newly deemed tobacco products, as well as careful review of the potentially unique interests of the smallest tobacco product manufacturers as considered in light of the Agency's statutory obligations regarding the protection of public health.

The direct benefits of making each of the newly deemed tobacco products subject to the requirements of chapter IX of the FD&C Act are difficult to quantify, and we cannot predict the size of these benefits at this time. Table 1 summarizes the quantified costs of this final rule over 20 years. For the reasons provided in the preamble and analysis of impacts, FDA has concluded that the benefits of the final rule justify the costs. Among other effects, new products will be subject to an evaluation to ensure they meet the appropriate public health standard for the pathway before they can be marketed, labeling cannot contain misleading statements, and FDA will be made aware of the ingredients in newly deemed tobacco products. If, without the final rule, new products would pose substantially greater health risks than those already on the market, the premarket requirements made effective by this final rule would keep such products from appearing on the market and worsening the health effects of tobacco product use. The warning statements required by this final rule will help consumers better understand and appreciate the risks and characteristics of tobacco products.

I. Background

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 when the Tobacco Control Act went into effect. For other tobacco products, the statute authorized FDA to issue regulations ''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,'' if FDA determines the restrictions are appropriate for the protection of the public health (21 U.S.C. 387f(d)(1)).

The Surgeon General has long recognized that the addictive nature of tobacco products is due to the presence of highly addictive nicotine that can be absorbed into the bloodstream (see, *e.g.,* Ref. 1 at 6–9). While the amount of nicotine delivered and the means through which it is delivered can either reduce or enhance nicotine's potential for abuse and physiological effects (Ref. 2 at 113), nicotine is addictive. In general, the quicker the delivery, rate of absorption, and attainment of peak concentrations of nicotine, the greater the potential for addiction (id.).

The Surgeon General reported that ''most people begin to smoke in adolescence and develop characteristic patterns of nicotine dependence before adulthood'' (Ref. 3). 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. 4), and youth and young adults generally ''underestimate the tenacity of nicotine addiction and overestimate their ability to stop smoking when they choose'' (Ref. 5). For example, in a study of over 1,200 sixth grade students who inhaled tobacco products, 58.5 percent had lost autonomy over their tobacco use (*i.e.,* had difficulty trying to quit) (Ref. 6). One survey also revealed that ''nearly 60 percent of adolescents believed that they could smoke for a few years and then quit'' (Ref. 7). Research conducted in animal models has indicated that exposure to substances such as nicotine can disrupt prenatal brain development and may 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. 8), 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.).

The Surgeon General also emphasizes that ''nicotine addiction develops as a neurobiologic adaptation to chronic nicotine exposure,'' suggesting that the pattern of tobacco product use (*e.g.,* frequency of using the product) is a factor in the facilitation of nicotine addiction (Ref. 9 at 112). The Surgeon General also noted ''all forms of nicotine delivery do not pose an equal risk in establishing and maintaining addiction'' and this may be because the pharmacokinetics of various nicotine containing products differ (id.). The FDA-approved nicotine patch is an example of slow absorption and once-a-day dosing which results in minimal potential for addiction (Ref. 2 at 113). In 1988, the Surgeon General recognized that the ultimate levels of nicotine absorbed into the blood from tobacco products on the market at that time can be similar in magnitude regardless of the product forms used to deliver nicotine (Ref. 1). 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. 2 at 113).

FDA believes that the inhalation of nicotine (*i.e.,* nicotine without the products of combustion) is of less risk to the user than the inhalation of nicotine delivered by smoke from combusted tobacco products. However, limited data suggest that the pharmacokinetic properties of inhaled nicotine can be similar to nicotine delivered by combusted tobacco products. Thus, inhaled nicotine from a non-combustible product may be as addictive as inhaled nicotine delivered by combusted tobacco products. Researchers recognize that the effects from nicotine exposure by inhalation without combustion are likely not responsible for the high prevalence of tobacco-related death and disease in this country (Refs. 10, 11). Although nicotine itself has not been shown to cause the chronic disease associated with tobacco use, the 2014 Surgeon General's report noted that there are still risks associated with nicotine (Ref. 9 at 111). For example, nicotine at high enough doses has acute toxicity (id.). Research in animal models have demonstrated that nicotine exposure during fetal development may have lasting adverse consequences for brain development (id.). Nicotine also adversely affects maternal and fetal health during pregnancy, contributing to multiple adverse outcomes such as preterm delivery and stillbirth (id.; citing Refs. 12, 13). Further, data from studies of mice also suggest that nicotine exposure during adolescence may have lasting adverse consequences for brain development (id.). Some studies in animal models also have found that nicotine can have detrimental effects on the cardiovascular system and potentially disrupt the central nervous system (Refs. 14, 15).

''Since the 1964 Surgeon General's report, comprehensive tobacco control programs and policies have been proven effective for controlling tobacco use'' (Ref. 9 at 36). Accordingly, FDA is issuing this final rule to serve two purposes: (1) To deem products that meet the definition of ''tobacco product'' under the law, except accessories of newly deemed tobacco products, and subject them to the tobacco control authorities in the FD&C Act; and (2) to establish specific restrictions that are appropriate for the protection of the public health for the newly deemed tobacco products. To satisfy these purposes, FDA proposed two options (Option 1 and Option 2), which provided two alternatives for the scope of the deeming provisions and, consequently, the application of the additional specific provisions. Under Option 1, all products meeting the definition of a ''tobacco product,'' except accessories of newly deemed tobacco products, would be deemed. Option 2 was the same as Option 1,

except a subset of cigars known as ''premium cigars'' would be excluded.

Currently, tobacco products unregulated by FDA are widely available and come in many forms, including cigars, pipe tobacco, waterpipe tobacco, liquids (e-liquids) for ENDS (the most popular of which are electronic cigarettes, but also include e-hookah, e-cigars, vape pens, personal vaporizers, and electronic pipes), liquid nicotine that is made or derived from tobacco, nicotine gels, and certain dissolvable tobacco products (*i.e.,* 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). Upon implementation of this final rule, currently unregulated tobacco products and future products meeting the definition of ''tobacco product'' under section 201(rr) (except accessories of newly deemed tobacco products) will be subject to chapter IX of the FD&C Act.

FDA issued a proposed deeming rule on April 25, 2014 (79 FR 23142). We received over 135,000 comments on the NPRM. Comments were received from tobacco product manufacturers, retailers, academia, medical professionals, local governments, advocacy groups, and consumers. To make it easier to identify comments and our responses, the word ''Comment,'' in parentheses, will appear before each comment, and the word ''Response,'' in parentheses, will appear before each response. We have numbered the comments to make it easier to distinguish between comments; the numbers are for organizational purposes only and do not reflect the order in which we received the comments or any value associated with them. We have combined similar comments under one numbered comment. In addition to the comments specific to this rulemaking that we address in the following paragraphs, we received many general comments expressing support or opposition to the rule and separate provisions within the rule. These comments express broad policy views and do not address specific points related to this rulemaking. Therefore, these general comments do not require a response. Other comments outside the scope of this rulemaking also have not been addressed here. The remaining comments, as well as FDA's responses, are included in this document.

II. Legal Authority

A. Summary of Legal Authority

As set forth in the preamble to the NPRM (79 FR 23142 at 23145), the Tobacco Control Act provided FDA with the authority to regulate tobacco products by, among other things, adding chapter IX to the FD&C Act. Section 901 of the FD&C Act (21 U.S.C. 387a) provides that this new chapter (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. In accordance with section 901 of the FD&C Act, FDA issued a NPRM to 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,[5] except the accessories of these tobacco products, and provided two separate options as to the scope of cigar products that would be deemed subject to FDA's tobacco authorities. FDA is selecting Option 1 deeming all tobacco products, including premium cigars, except the accessories of the newly deemed products, with this final rule.

In addition, section 906(d)(1) of the FD&C Act authorizes FDA to 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.'' FDA has determined that the additional restrictions included with this final rule (*i.e.,* minimum age and identification requirements, vending machine restrictions, and health warning statements) are ''appropriate for the protection of the public health.''

These authorities are supplemented by section 903 of the FD&C Act (21 U.S.C. 387c), which provides, among other things, 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 a brief statement of the uses of the tobacco product and relevant warnings, precautions, side effects, and contraindications (section 903(a)(8)(B)(i) of the FD&C Act). Section 903(a)(7)(B) of the FD&C Act also provides that a tobacco product is misbranded if it is sold or distributed in violation of a regulation prescribed under section 906(d) of the FD&C Act.

In addition, section 701(a) of the FD&C Act (21 U.S.C. 371(a)) provides FDA with authority to issue regulations for the efficient enforcement of the FD&C Act.

B. Responses to Comments Regarding Legal Authority

FDA received comments on a wide range of legal issues, including FDA's authority to deem tobacco products subject to the FD&C Act and constitutional issues that may be implicated by the NPRM. FDA carefully considered these comments and concludes that the Agency has authority to deem the tobacco products covered under this final rule. FDA is not aware of other legal concerns from comments that prevent the Agency from taking the actions included in this final rule. A summary of comments regarding legal authority, and FDA's responses, follows.

1. Section 901 Authority

(Comment 1) Generally, the comments did not challenge FDA's authority under section 901 of the FD&C Act, but at least one comment argued that section 901 does not grant FDA the authority to deem, ''in a sweeping manner,'' all products (excluding accessories) that meet the statutory definition of ''tobacco product.'' The comment argued that Congress intended to grant FDA discretion to deem products only on a product-by-product basis, or at best, a category-by-category basis, and that FDA lacks authority to ''simply swallow all extant and future tobacco products up in its authority[.]''

(Response) FDA disagrees. Section 901 grants FDA the authority to deem ''any . . . tobacco products that the Secretary by regulation deems to be subject to [chapter IX of the FD&C Act].'' There is no provision in the statute that restricts FDA's authority to deem all tobacco products that meet the statutory definition or requires FDA to deem products on an individual or product category basis.

The comment did not provide a basis for the claim that Congress intended to restrict FDA's deeming authority to piecemeal deeming of specific categories of products and no such restrictions exist. FDA believes that deeming tobacco products on a product or category basis would create regulatory loopholes, substantial delay (at the risk to public health), and significantly impede FDA's ability to

[5] Section 201(rr) of the FD&C Act defines ''tobacco product,'' in relevant part, as 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). 21 U.S.C. 321(rr).

create a comprehensive regulatory scheme.

Even if there was ambiguity in the wording of section 901, which FDA does not believe there is, FDA would be entitled to deference on this interpretation of the statute (*Chevron U.S.A., Inc.* v. *Natural Res. Def. Council, Inc.,* 467 U.S. 837, 842–45 (1984), quoting *Morton* v. *Ruiz,* 415 U.S. 199, 231 (1974) (''We have long recognized that considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer, and the principle of deference to administrative interpretations . . .'')).

(Comment 2) At least one comment questioned whether section 901 of the FD&C Act provides authority to deem future tobacco products under the new rule. Specifically, the comment argued that a ''tobacco product'' must exist at the time the rule takes effect for it to be subject to ''deeming'' under the rule.

(Response) FDA disagrees. The term ''tobacco product'' is defined in section 201(rr) of the FD&C Act, 21 U.S.C. 321(rr), 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),'' and excluding drugs, devices, and combination products as defined under the FD&C Act. The definition has no temporal element, and nothing in the statute limits FDA's deeming authority to products or categories of products that are currently marketed. Contrary to Congress's intention in enacting the statute, the proposed interpretation would substantially impede FDA's ability to protect the public health. Indeed, FDA's ability to regulate new products would be further delayed by months or even years after the introduction of each new product, as the Agency would have to initiate a rulemaking to deem each new product before existing regulations would apply. Such an interpretation would frustrate the intent underlying the Tobacco Control Act and endanger the public health.

Moreover, we note that the Agency is not simply creating a rule to apply to theoretical products with completely unknown risks that will be developed in the future. Instead, FDA is finalizing this rule to include all ''tobacco products'' within the scope of its regulatory authority based on the potential harm posed by existing products and the Agency's experience with the regulation of such products (which have all been made or derived from tobacco). This experience has shown us that it would be easier for manufacturers and more protective for public health for a company to know (prior to development and marketing) that its product must be reviewed and authorized by FDA in order to be offered for sale in the United States.

(Comment 3) A number of comments contended that section 901(g) of the FD&C Act requires FDA to consult with other Federal Agencies before promulgating a new rule under chapter IX of the FD&C Act.

(Response) FDA agrees that section 901(g) requires FDA to ''endeavor to consult with other Federal Agencies, as appropriate.'' FDA consulted with other Federal Agencies during the Federal Agency review process required by Executive Order 12866, satisfying its requirement under section 901(g).

2. FDA's Exercise of Authority

(Comment 4) Some comments, largely from the ENDS industry, argued that FDA is required to establish that deeming will benefit public health, and that insufficient evidence exists to do so. Specifically, they argued that FDA is unable to quantify the health risks of certain products (namely, e-cigarettes)[6] without multiple long-term studies, and that currently such studies do not exist. A few comments cited the public health standard in section 906(d) of the FD&C Act as authority for these claims.

(Response) FDA disagrees. These comments attempted to impose a standard for the application of FDA's deeming authority that is not created by statute or otherwise. Under section 901(b), chapter IX of the FD&C Act shall apply to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to *any other tobacco products that the Secretary by regulation deems to be subject to this chapter* (emphasis added). The only pertinent limitations on the scope of FDA's deeming authority are the definition of ''tobacco product'' set forth in section 201(rr) of the FD&C Act and a provision regarding tobacco growers and similar entities and tobacco leaf that is not in the possession of a manufacturer of tobacco products in section 901(c)(2) of the FD&C Act.

FDA disagrees with the comments that argued that the standard set forth in section 906(d) of the FD&C Act applies to the act of deeming tobacco products. Sections 901 and 906(d)(1) provide FDA with separate authorities. Section 901 gives FDA the authority to deem additional products to be subject to chapter IX. Once products are subject to chapter IX, FDA can use other authorities in chapter IX, such as section 906(d), to take regulatory action with respect to such products. By its own language, section 906(d) applies to regulations FDA issues requiring restrictions on the sale and distribution, including restrictions on the access to, and the advertising and promotion of, a tobacco product; therefore, the standard in section 906(d)(1) applies only to the additional regulations issued by FDA under section 906(d) (such as the minimum age and identification requirements and vending machine restrictions this rule is promulgating in § 1140.14, and the health warning requirements in §§ 1143.3 and 1143.5) and not to deeming itself or the provisions in the statute that apply automatically to newly deemed products.

Although FDA is not required to meet a particular public health standard to deem tobacco products, regulation of the newly deemed products will be beneficial to public health. The Agency has concluded, based on scientific data, that the newly deemed products should be regulated due to their potential for public harm (*e.g.,* 79 FR at 23154–23158) and regulation is necessary to learn more about that potential. 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. Over time, since the ''appropriate for the protection of the public health'' standard involves comparison to the general tobacco product market, FDA believes the employment of the premarket authorities could create incentives for producers to develop products that 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 newly deemed products will

[6] FDA notes that most comments referred to ''e-cigarettes'' when discussing ENDS products. Therefore, FDA refers to ''e-cigarette'' in the comment summaries. Because FDA's responses generally apply to all ENDS products (the most popular of which are electronic cigarettes, but also includes e-hookah, e-cigars, vape pens, personal vaporizers, and electronic pipes), FDA's responses to the comments generally use the term ''ENDS.''

increase product consistency. For example, FDA's oversight of the constituents of e-cigarettes cartridges will 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 (*e.g.,* Refs. 16, 17, 18, 19, 20). 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. Implementation of the premarket review requirements also will allow FDA to monitor product development and changes and to prevent more harmful or addictive products from reaching the market.

In addition, as FDA discussed in the NPRM, deeming all tobacco products will provide FDA with critical information regarding the health risks of the products including information derived from ingredient listing submissions and reporting of HPHCs required under the FD&C Act (79 FR 23142 at 23148). Obtaining this information is particularly important given the addictiveness of nicotine and the toxicity associated with tobacco products. Given that ''[e]xposure to secondhand tobacco smoke has been causally linked to cancer, respiratory, and cardiovascular diseases, and to adverse effects on the health of infants and children,'' this information will be helpful in further assessing the toxicity of the newly deemed tobacco products (Ref. 9 at 7).[7]

Many of these comments also argued that FDA's acknowledgment that it does ''not currently have sufficient data . . . to determine what effects e-cigarettes have on the public health'' is an admission that FDA does not know, and cannot determine, whether *regulation* of these products will benefit public health. FDA disagrees. That language follows the statement, ''some have advanced views that certain new tobacco products that are noncombustible . . . may be less hazardous, at least in certain respects, than combustible products . . . ,'' and refers to the *lack* of evidence supporting such asserted benefits (79 FR 23142 at 23144). Whether ENDS generally may eventually be shown to have a net benefit on or harm to public health at the population level—and there have not yet been long-term studies conducted to support either claim at this time—*regulation* of ENDS will still benefit public health. The 2014 Surgeon General's Report also notes that ''[f]urther research with attention to their individual and population-level consequences will be helpful to fully address these questions. However, the promotion of noncombustible products is much more likely to provide public health benefits only in an environment where the appeal, accessibility, promotion, and use of cigarettes and other combusted tobacco products are being rapidly reduced'' (Ref. 9 at 874).

FDA noted in the NPRM that many public health benefits will flow from deeming tobacco products (including e-cigarettes and other ENDS). Even if a category of products were to prove generally beneficial, individual products within that category may raise concerns. For example, some products may be particularly attractive to youth or deliver unexpected high levels of toxicants. In addition, once all tobacco products are deemed, any manufacturer seeking to market its product as a modified risk tobacco product (MRTP) will be required to provide substantiation and obtain an order from FDA before making such claims, where it is currently not subject to such requirements under the FD&C Act. More generally, regulation and product review allows the Agency to help ensure the public health is protected. FDA's regulatory tools, including the adulteration and misbranding provisions in sections 902 (21 U.S.C. 387b) and 903 of the FD&C Act as applied to newly deemed products, will help to protect consumers by subjecting all tobacco products to certain basic requirements, such as that their labeling and advertising not be false or misleading. FDA will be able to take enforcement action against any tobacco products that do not meet these requirements. Further, implementation of the requirements regarding premarket applications, SE reports, and exemption requests (sections 905 and 910 of the FD&C Act (21 U.S.C. 387e and 387j, respectively)) will increase product consistency and help protect the public health from adverse impacts. For example, although there is currently variability in the concentrations of chemicals in e-liquids, FDA oversight of the constituents in e-liquids and ENDS will help to ensure quality control over the types and quantities of chemicals being aerosolized and inhaled (79 FR 23142 at 23149). Once deemed, the Tobacco Control Act authorizes FDA to impose certain types of restrictions that it has determined are appropriate to the protection of public health. Under this authority, FDA is imposing certain restrictions for ENDS and other products, such as minimum age requirements.

The need for deeming is further confirmed by the continued dramatic rise in youth and young adult use of tobacco products such as e-cigarettes and waterpipe tobacco, and continued youth and young adult use of cigars (mainly cigarillos). As discussed in the NPRM, e-cigarettes 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 which has been on the market far longer than e-cigarettes (Ref. 21).

Recent studies show a dramatic rise in the use of ENDS products. The Centers for Disease Control and Prevention (CDC) and FDA analyzed data from the 2011–2014 National Youth Tobacco Surveys (NYTS) and found that current (past 30 day) e-cigarette use among high school students increased nearly 800 percent from 1.5 percent in 2011 to 13.4 percent in 2014 (Ref. 22). In 2014, a total of 24.6 percent of high school students reported current use of a tobacco product (id.). Among all high school students, e-cigarettes (13.4 percent) were the most common tobacco products used (id.). This increase was not limited to any one demographic group; e-cigarettes were the most commonly used product among high school non-Hispanic whites, Hispanics, and persons of non-Hispanic other races (id.). E-cigarettes (3.9 percent) were also the tobacco product used most commonly by middle school students (id.). From 2011 to 2014, statistically significant nonlinear increases were observed among high school students for current e-cigarette use (1.5 percent to 13.4 percent) (id.). Among middle school students, statistically significant increases were observed from 2011 to 2014 (id.). In 2014, an estimated 4.6 million middle and high school students currently used any tobacco product (*i.e.,* cigarettes, cigars, smokeless tobacco, e-cigarettes, hookahs, tobacco pipes, snus, dissolvable tobacco, and bidis), of which an estimated 2.2 million students currently used two or more tobacco products. Overall, in 2014, 2.4 million middle and high school students reported current use of e-cigarettes (id.). The data also demonstrated that when use of all tobacco products was considered in aggregate, there was no

[7] As stated in the 2014 Surgeon General's Report, ''the burden of death and disease from tobacco use in the United States is overwhelmingly caused by cigarettes and other combusted tobacco products'' (Ref. 9 at 7).

change in overall current tobacco use among middle and high school students.

Another recently published study found that ninth grade students who reported having ever used e-cigarettes at the baseline assessment were approximately 2.7 times more likely than non-e-cigarette users to have started smoking combusted tobacco products (cigarettes, cigars, waterpipe tobacco) and 1.7 times more likely to have started smoking conventional cigarettes 6 to 12 months later (Ref. 23). While this study indicates that e-cigarette users are more likely than non-e-cigarette users to also use combusted tobacco products 12 months later, it cannot be determined by the research findings if such users would have used combusted tobacco products regardless of e-cigarette use. Researchers noted that some teens are more likely to use e-cigarettes prior to combustible tobacco products for several reasons including the availability of e-cigarettes in flavors attractive to youth (*id.*).

In terms of young adult and adult use of e-cigarettes, evidence from the most recent studies on ENDS use among young adults and adults indicates that among adults who had never smoked cigarettes, prevalence of ever e-cigarette use was highest among young adults aged 18 to 24 and decreased with increasing age (Ref. 24). However, current cigarette smokers and recent former smokers (*i.e.,* those who quit smoking within the past year) were more likely to use e-cigarettes than long-term former smokers (*i.e.,* those who quit smoking more than 1 year ago) and adults who had never smoked. Current cigarette smokers who had tried to quit in the past year were also more likely to use e-cigarettes than those who had not tried to quit (id.). It is noted that it cannot be determined by the research findings: (1) Whether former cigarette smokers who now exclusively use e-cigarettes would not have ceased smoking cigarettes regardless of e-cigarette use; and (2) whether the e-cigarette use preceded quitting or the quitting occurred first and then was followed by later e-cigarette use.

The data from the 2011 through 2014 NYTS also show that high school students' use of waterpipe tobacco more than doubled during this time period. In fact, researchers observed substantial increases in waterpipe tobacco use among both middle and high school students from 2011 through 2014 culminating in an estimated 1.6 million waterpipe tobacco youth users in 2014 (Ref. 22). From 2013 to 2014, prevalence almost doubled for high school students from 5.2 percent (770,000) to 9.4 percent (1.3 million) and more than doubled for middle school students from 1.1 percent (120,000) to 2.5 percent (280,000) (id.). These findings are consistent with earlier research on older youths and young adults discussed in the comments stating that waterpipe tobacco use continues to increase in popularity, particularly among college students, with as many as 40 percent reporting ever using waterpipe tobacco and 20 percent reporting current use (*i.e.,* use within the past 30 days) on some college campuses (Refs. 25, 26).

Likewise, youth continue to use cigars. Data from the 2014 NYTS indicate that 8.2 percent (1,200,000) of high school students and 1.9 percent (220,000) of middle school students had smoked cigars (including cigars, cigarillos, or little cigars) in the past 30 days (Ref. 22). Nineteen percent of students in 8th, 10th, and 12th grades participating in the Monitoring the Future study in 2014 also reported smoking small or little cigars (which represents a decrease from 23.1 percent in 2010, but it is unclear if subjects misidentified cigars as cigarettes during the study) (Ref. 27). In addition, the 2014 National Survey on Drug Use and Health (NSDUH) found that more than 2,500 youth under the age of 18 smoke their first cigar each day, nearly as many as those who smoke their first cigarette each day (more than 2,600) (Ref. 28). Nevertheless, data on youth cigar use from the Youth Risk Behavior Surveillance System (YRBSS) shows that current cigar use among youth (*i.e.,* use of a cigar, cigarillo, or little cigar on at least one day during the last 30 days) has declined between 1997 and 2013 (22 percent to 12.6 percent); however, no statistically significant change was observed between 2011 (13.1 percent) and 2013 (12.6 percent) (Ref. 29).

(Comment 5) At least one comment argued that the rule violates the APA, 5 U.S.C. 706, saying that it requires FDA to provide ''the specific basis for [its] conclusion and the data on which each of [its] critical assumptions is based'' (quoting *Ranchers Cattlemen Action Legal Fund United Stockgrowers of America,* No. 04–cv–51, 2004 WL 1047837 at *7 (D. Mont. Apr. 26, 2004), and FDA failed to do so.

(Response) FDA disagrees. The unpublished district court case quoted in the comment was reversed by the Ninth Circuit on exactly this point (415 F.3d 1078 (9th Cir. 2005)). The Ninth Circuit stated the correct standard: ''All that is required is that the agency have 'considered the relevant facts and articulated a rational connection between the facts found and the choices made' '' (id. at 1093). See *Citizens to Preserve Overton Park, Inc.* v. *Volpe,* 401 U.S. 402, 416 (1971); *Motor Vehicle Mfrs. Ass'n of U.S., Inc.* v. *State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 42–43 (1983).

In any event, the NPRM contains substantial explanation of FDA's reasoning in proposing this rule, including over 190 citations to scientific literature, and the NPRM and the final rule's supplementary information contain many pages explaining the data and comments considered, the conclusions drawn from the literature, and FDA's rationale for the final rule, fully satisfying the Administrative Procedure Act (APA).

(Comment 6) A few comments objected that FDA did not discuss the possibility of illicit markets in the proposed deeming rule, stating that FDA is required to consider the consequences of illicit markets under section 907(b)(2) of the FD&C Act.

(Response) FDA disagrees. Section 907(b)(2) does not apply to deeming, but rather applies only to the promulgation of regulations establishing tobacco product standards under section 907 of the FD&C Act. In any event, the Agency cannot refuse to act in furtherance of the public health because some individuals might violate the law. Nevertheless, FDA authority over the newly deemed tobacco products will give it means to determine which products are legally on the market and which are counterfeit or otherwise illegally marketed and to take enforcement action against manufacturers who sell and distribute illegal products. The Tobacco Control Act gives the Agency these and other authorities, such as section 920 of the FD&C Act (21 U.S.C. 387t), to help address illicit tobacco products.

3. Constitutional Issues

The Tobacco Control Act includes provisions restricting tobacco product marketing. As discussed in this document, some of these provisions apply to all products covered by the statute—including the newly deemed products—and others authorize FDA to impose additional restrictions. We received comments that argue that some of the restrictions this final rule imposes on newly deemed products violate the First Amendment.

a. Free Samples of Tobacco Products

(Comment 7) A few comments questioned the constitutionality of the ban on the distribution of free samples of tobacco products. (See § 1140.16(d)(1)).) First, the comments argued that distributing free samples is a form of commercial speech that is protected by the First Amendment and that the ban is unconstitutional as

applied to the newly deemed products. Citing *Central Hudson Gas and Electric Corp.* v. *Public Services Commission,* 447 U.S. 557, 566 (1980), the comments argued that, accordingly, FDA must show that the ban is narrowly tailored to directly and materially advance a substantial State interest and that FDA failed to do so. The comments stated that while the court in *Discount Tobacco City & Lottery* v. *United States,* 674 F.3d 509 (6th Cir. 2012), *cert. denied sub nom. Am. Snuff Co., LLC* v. *United States,* 133 S. Ct. 1996 (2013) (''*Discount Tobacco''*), upheld the Tobacco Control Act's sampling ban on cigarettes, the evidence the court used to uphold that ban does not support the same ban for the newly deemed tobacco products. They argued that FDA has presented no evidence that samples of these products lead to youth initiation and, therefore, the Agency would not be advancing a legitimate government interest with this ban. Additionally, they suggested that even if the ban did advance a legitimate government interest, FDA could achieve the same results through less restrictive means, such as by allowing samples in qualified adult-only facilities, as FDA does with smokeless tobacco.

(Response) FDA disagrees that the ban on free samples is unconstitutional. First, although FDA acknowledges that in *Discount Tobacco,* 674 F.3d at 538–39, the Sixth Circuit treated the distribution of free samples as a form of commercial speech, FDA continues to believe that distribution of free samples is conduct not speech. Provisions that regulate conduct without a significant expressive element do not implicate the First Amendment. See *Arcara* v. *Cloud Books, Inc.,* 478 U.S. 697, 706–07 (1986). Additionally, a free sample ban is akin to a price restriction (*i.e.,* tobacco products cannot be free)—a ''form[ ] of regulation that would not involve any restriction on speech.'' *44 Liquormart, Inc.* v. *Rhode Island,* 517 U.S. 484, 507 (1996) (opinion of Stevens, J.). Therefore, the free sample provision regulates the distribution of a product, and there is no First Amendment right to distribute free samples of a tobacco product.

Second, even if the distribution of free samples does implicate the First Amendment, as the Sixth Circuit concluded, the court went on to uphold the constitutionality of the restriction on free samples of tobacco products. *Discount Tobacco,* 674 F.3d at 541. In *Discount Tobacco,* as here, the manufacturers of tobacco products argued that the government failed to show that the ban would directly and materially advance the government interest of decreasing use of tobacco products by youth. The manufacturers further argued that even if the sampling ban were effective, there are less restrictive methods of preventing youth tobacco use (id. at 538, 541). The Sixth Circuit rejected both arguments, and held that the government ''presented extensive documentation that free samples of tobacco products are [an] 'easily accessible source of these products to young people,' . . . and freely obtainable, even with the tobacco industry's 'voluntary codes that supposedly restrict distribution of free samples to underage persons''' id. at 541 (quoting 61 FR 44396 at 44460, 45244–45 & nn. 1206–08 (August 28, 1996)). The Court further held that free samples ''may serve as the best advertisement of all for a product that is physiologically addictive, and socially attractive to youth'' (id.).

The comments do not attempt to distinguish *Discount Tobacco.* Here, where there is a substantial government interest in preventing youth access to all tobacco products, and the newly deemed products, like the products considered by the Sixth Circuit Court of Appeals, are also ''physiologically addictive, and socially attractive to youth,'' *Discount Tobacco* is directly on point. As we stated in the NPRM, the prohibition against free samples will eliminate a pathway for youth to access tobacco products, which can help in reducing youth initiation and therefore short-term and long-term morbidity and mortality resulting from these products.

Youth are uniquely susceptible to biological, social, and environmental influences to use and become addicted to tobacco products. See section X.A. As FDA recognized as early as 1995, ''[f]ree samples give young people a 'risk-free and cost-free way to satisfy their curiosity' about tobacco products, and, when distributed at cultural or social events, may increase social pressure on young people to accept and to use the free samples'' (60 FR 41314 at 41326 (quoting Ref. 30). For these reasons, we believe it is critical to prohibit the distribution of free samples of newly deemed tobacco products, which are highly addictive and can lead to a lifetime of tobacco use, with attendant adverse health consequences.

FDA received comments noting extensive sampling of some newly deemed products in venues that may attract youth, including:

- The major sellers of e-cigarettes distribute free samples in venues likely to attract large audiences.
- At least eight e-cigarette companies promote their products through sponsored or sampling events, many of which appear to be youth-oriented (Ref. 31).
- In 2012 and 2013 alone, 6 e-cigarette companies sponsored or provided free samples at 348 events, many of which were music festivals and motorsport events geared toward young people—including Grand Prix auto racing events (id.).
- Field research in Oregon found that e-cigarette retailers include the opportunity to sample the wide variety of flavored nicotine cartridges in their sales pitches with test stations for free sampling (Comments of Oregon Health Authority, FDA–2014–N–0189–76358).

As described above and in the NPRM, the free sample provision will address distribution of newly deemed tobacco products at venues such as these. Contrary to the assertions in the comments, FDA does not believe that it could achieve the same results by allowing samples of newly deemed products in qualified adult-only facilities, as FDA does with smokeless tobacco. In section 102(a)(2)(G) of the Tobacco Control Act (21 U.S.C. 387a–1(a)(2)(G)), Congress required FDA to reissue the final 1996 rule (published in the **Federal Register** of August 28, 1996, 61 FR 44396), with several changes, including the addition of a narrow exception to the free sample ban to allow for distribution of smokeless tobacco products in qualified, adult-only facilities (QAOFs). This exception is very prescriptive and operates only in very limited instances (*e.g.,* where the product is distributed in a specific type of temporary enclosed structure with age verification by a law enforcement officer or a security guard licensed by a governmental entity, and with the amount of smokeless tobacco per adult consumer subject to specific portion requirements). If FDA were to extend this exception, in whole or in part, to other tobacco products (when Congress explicitly extended the free sample ban to cigarettes and all ''other tobacco products,'' which would include all future deemed tobacco products and laid out the qualified adult-only facility exception only for smokeless), FDA would have to justify such an exception in light of the potential adverse public health impact of allowing free samples and determine the particular parameters of the exception as appropriate for newly deemed tobacco products. This would include, at a minimum, parameters relating to type of facility, means of access, type(s) of tobacco products distributed, and portion sizes for each type of tobacco product for which FDA is creating an exception. Newly deemed products have been largely unregulated and their markets,

particularly for novel noncombustible products such as ENDS, are dynamic. Comments did not provide evidence demonstrating that the distribution of free samples of newly deemed tobacco products would be consistent with protecting public health. While there is evidence suggesting that distribution of tobacco products is harmful (*e.g.,* courts have expressed concern that free samples can provide young people with easy access to tobacco products), FDA has not yet obtained product-specific evidence and, therefore, cannot set limits for the quantities or portion sizes of products taken away from a QAOF that are commensurate with the current exception for smokeless tobacco products. Therefore, QAOFs could still allow for access to tobacco products in a manner that will have a negative public health impact.

Prohibiting free samples is a minor restriction on distribution, and tobacco product manufacturers, distributors, and retailers remain free to inform consumers about their products. The free sample prohibition does not interfere with the ability of a manufacturer, distributor or retailer to communicate truthful and nonmisleading information to adult consumers. We further address this prohibition and respond to additional comments in section XI.F.

(Comment 8) Some comments recommended that FDA exempt e-cigarettes from the prohibition on free samples. In the alternative, the comments recommended that FDA restrict the circumstances in which free samples may be given to adult consumers. For example, comments suggested that FDA require age verification for each recipient of a free sample and limit the amount of free products that recipients may take away from an event in which samples are distributed.

(Response) We disagree for the reasons discussed in the response to the previous comment. As stated in the NPRM, prohibiting free samples eliminates a pathway to tobacco products for youth, which can help to reduce initiation and thus decrease morbidity caused by use of tobacco products (79 FR 23142 at 23149). 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 sub nom. Am. Snuff Co., LLC* v. *United States,* 133 S. Ct. 1966 (2013)). With the growth in the use of ENDS, particularly by youth (see section VIII.B), a free sample prohibition is necessary to reduce youth access to ENDS and possibly a transition to combusted tobacco products (see Ref. 23).

b. Modified Risk Tobacco Products

Section 911 of the FD&C Act (21 U.S.C. 387k) prohibits the introduction or delivery for introduction into interstate commerce of any MRTP without an FDA order in effect under section 911(g). An MRTP is a 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; this includes tobacco products, the product label, labeling, or advertising of which represents that it is less harmful or presents a lower risk of disease than other tobacco products.

(Comment 9) A comment from one tobacco company argued that section 911 is unconstitutional on its face. This comment argued, at length, that FDA's oversight of claims that a particular tobacco product is safer than others violates the First Amendment—even as applied to currently regulated products, such as cigarettes.

(Response) Comments addressed to the facial constitutionality of a statute are generally outside the scope of an agency's rulemaking authority. *Am. Meat Inst.* v. *U.S. Dep't of Agric.,* 760 F.3d 18, 25 (D.C. Cir. 2014) (*en banc*) (''We do not think the constitutionality of a statute should bobble up and down at an administration's discretion.''). That said, FDA disagrees with the challenges against section 911's constitutionality. The Sixth Circuit considered and unanimously rejected the same argument in *Discount Tobacco,* 674 F.3d at 531–37, and the Supreme Court denied the manufacturers' petition for a writ of certiorari (133 S. Ct. 1966 (2013)). As the Sixth Circuit explained, section 911 requires that a manufacturer establish health claims for particular tobacco products to FDA before marketing, rather than allow only post-market review of such claims (674 F.3d at 537 (''it would be a virtual impossibility to unring the bell of misinformation after it has been rung'')). This provision does not ''infringe significantly on noncommercial speech'' since it leaves ''untouched'' manufacturers' ''ability to make 'direct comments on public issues' '' (id. at 533 (citation omitted)). Instead, the court held, what section 911 restricts is commercial speech, since it applies to consumer-directed claims regarding a manufacturer's specific products (id.). That restriction on commercial speech, the court held, is constitutional under *Central Hudson Gas & Electric Corp.* v. *Public Service Commission,* 447 U.S. 557 (1980): It advances a substantial government interest in preventing inaccurate and harmful health claims about tobacco products of the sort that the industry has made for many decades, and it is sufficiently tailored because it concerns only consumer-targeted speech about tobacco products' health effects or contents and is no more extensive than warranted. *Discount Tobacco,* 674 F.3d at 534–37. FDA observes that this comment did not address *Discount Tobacco*'s holding or the Sixth Circuit's analysis.

(Comment 10) A few comments argued that section 911 may violate the First Amendment if it is applied to ban descriptions of e-cigarettes and other noncombustible products as ''smokeless'' or ''smoke-free.''

(Response) FDA has carefully considered the comments that argued that noncombusted products, including ENDS, should be permitted to use the terms ''smokeless'' and smoke-free'' to describe their products. We note that section 911 provides that ''No smokeless tobacco product shall be considered to be [an MRTP] solely because its label, labeling, or advertising uses the following phrases to describe such product and its use: 'smokeless tobacco,' 'smokeless tobacco product,' 'not consumed by smoking,' 'does not produce smoke,' 'smokefree' [and four more similar terms].'' However, this provision only applies to ''smokeless tobacco,'' which is explicitly defined in the FD&C Act as ''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'' (section 900(18) of the FD&C Act). ENDS do not fall within that definition. Moreover, in contrast to ENDS, consumption of ''smokeless tobacco products,'' as defined, does not require the use of heat, inhalation of the product into the lungs, or exhalation of constituents into the close environment. FDA is also aware that some e-cigarettes are heated to a high enough level to cause combustion of the e-liquid. For these reasons, and until FDA obtains product-specific evidence, the Agency will evaluate an ENDS manufacturer's use of ''smokeless'' or ''smoke-free'' (and similar descriptive terms) on a case-by-case basis, and the Agency will continue to apply the MRTP provisions in a manner consistent with the statute and Constitution. This case-by-case approach to ''smokeless,'' ''smoke-free,'' and similar terms is appropriate as

applied to ENDS, which encompasses a broad, heterogeneous, and evolving category of products.

4. Required Warning Labels

This final rule requires advertising and packaging warnings for newly deemed covered tobacco products and for cigarette tobacco and roll-your-own tobacco, as authorized by Section 906(d) of the FD&C Act, 21 U.S.C. 387f (d). Packaging and advertising for all newly deemed products other than cigars must display an addictiveness warning that states: ''WARNING: This product contains nicotine. Nicotine is an addictive chemical.'' (Subject to certain requirements, the manufacturer of a product that does not contain nicotine may use an alternative warning that states: ''This product is made from tobacco.'') Packaging and advertising for cigars must display either the addictiveness warning, or one of five others specified in the rule.

The final rule requires the warnings to appear on at least 30 percent of the two principal display panels of the package, and at least 20 percent of the area of advertisements. These are the same warning sizes Congress established for smokeless tobacco in the Tobacco Control Act: At least 30 percent of smokeless-tobacco packaging's two principal panels, and at least 20 percent of the area of each advertisement. 15 U.S.C. 4402(a)(2)(A), (b)(2)(B). In the same Act, Congress prescribed an even larger size for cigarette warnings: 50 percent of the front and rear panels of cigarette packaging (and the same 20 percent size for cigarette advertisements) (15 U.S.C. 1333(a)(2), (b)(2)). (The larger warning sizes required for cigarettes have not yet been implemented, because FDA's initial regulations implementing a graphics component for cigarette warnings were vacated by the DC Circuit Court of Appeals in *R.J. Reynolds Tobacco Co.* v. *FDA,* 696 F.3d 1205 (D.C. Cir. 2012), *overruled on other grounds by Am. Meat Inst.,* 760 F.3d at 22–23.)

A detailed discussion of the warning requirements appears in section XVI.

a. First Amendment Challenges

The required warnings are a form of compelled disclosure, and are thus subject to First Amendment scrutiny. *Milavetz, Gallop & Milavetz, P.A.* v. *United States,* 559 U.S. 229, 249 (2010); *Riley* v. *Nat'l Fed'n of the Blind of N.C., Inc.,* 487 U.S. 781, 797–98 (1988).

(Comment 11) Although the comments generally did not dispute the need for warning labels, some commenters questioned the accuracy of the addictiveness warning as applied to cigars, contending that cigar users do not always inhale.

(Response) Nicotine is ''one of the most addictive substances used by humans'' (Ref. 7). ''Because the extension of First Amendment protection to commercial speech is justified principally by the value to consumers of the information such speech provides,'' the manufacturers' ''constitutionally protected interest in *not* providing any particular factual information in his advertising is minimal.'' *Am. Meat Inst.,* 760 F.3d at 26 (quoting *Zauderer* v. *Office of Disciplinary Counsel,* 471 U.S. 626, 651 (1985)).

Cigar packaging and advertisements are required to display one of six warnings, one of which is the addictiveness warning. Research indicates that most cigar smokers do inhale some amount of smoke, even when they do not intend to inhale, and are not aware of doing so (Refs. 32, 33). Even when cigar smokers do not breathe smoke into their lungs, they are still subject to the addictive effects of nicotine through nicotine absorption (Refs. 32, 34). This is because cigar smoke dissolves in saliva, allowing the smoker to absorb sufficient nicotine to create dependence, even if the smoke is not inhaled (Refs. 34, 35).

(Comment 12) A few comments argued that the First Amendment prohibits a requirement for covered tobacco products to carry warning labels that cover 30 percent of the two principal display panels of the packaging. These comments argued that manufacturers have limited space on packaging to communicate information to consumers, including branding and marketing information, and that requiring manufacturers to dedicate 30 percent of that space for a warning is unduly burdensome, because it prevents manufacturers from using that space to convey their own messages. The comments argued that the warning label presents a simple message that could be relayed in a smaller space.

(Response) FDA disagrees. In *Discount Tobacco,* the Sixth Circuit considered and rejected the same First Amendment arguments against the size required by the Tobacco Control Act for cigarette and smokeless tobacco warnings. *Discount Tobacco,* 674 F.3d at 567. The court found ample evidence supporting the size requirements, and held that the manufacturers failed to show ''that the remaining portions of their packaging [were] insufficient for them to market their products'' (id. at 564–66, 567). The comments argued that the requirement that the warning cover 30 percent of the two principal display panels is unduly burdensome and would prevent manufacturers of newly deemed products from communicating information about their products. As in *Discount Tobacco,* the comments failed to substantiate that claim with evidence. Nor did the comments provide evidence that the same size requirements for smokeless tobacco—which have been in force since 2010—have unduly burdened the speech of smokeless tobacco manufacturers.

As the court explained in *Discount Tobacco,* Congress required larger warnings for smokeless tobacco and cigarettes in the wake of the Surgeon General's conclusion that existing warnings were '''given little attention or consideration by viewers''' and IOM's analysis showing that those warnings '''fail[ed] to convey relevant information in an effective way.''' *Discount Tobacco,* 674 F.3d at 562 (quoting Refs. 3, 7).

The comments contending that the warning label size is burdensome or unjustified are misplaced for the same reasons identified by the *Discount Tobacco* court. After emphasizing that the relevant First Amendment standard looks only to whether mandatory warnings are reasonably related to the government's interest, *Discount Tobacco,* 674 F.3d at 567 (citing *Zauderer* v. *Office of Disciplinary Counsel,* 471 U.S. 626, 651 (1985)), the Sixth Circuit held that the required cigarette warning labels, which were to cover 50 percent of the two primary panels of cigarette packs (far more than the 30 percent required here), did not violate the First Amendment because ''[a]mple evidence supports the size requirement for the new warnings . . . and Plaintiffs have not shown that the remaining portions of their packaging are insufficient for them to market their products.'' (674 F.3d at 567; see also id. at 530–31 (Clay, J., concurring in result) (finding that the government demonstrated that the Tobacco Control Act's size and placement requirements satisfied *Zauderer* scrutiny).)

Article 11 of the Framework Convention on Tobacco Control (FCTC), evidence of a strong worldwide consensus regarding a regulatory strategy for addressing the serious negative impacts of tobacco products,[8] recognized the importance of having warnings cover at least 30 percent of the area of the two principal display panels. The European Union (EU) requires that health warnings comprise 30 percent of the area on the front of the package and 40 percent on the back of the package

[8] There are 180 parties to the WHO's FCTC as of November 2015. At this time, the United States is a signatory but has not ratified this treaty.

(2001/37/EC). Users are more likely to recall warnings that are in a larger size and that appear on the front/major surfaces of the tobacco product package. (Ref. 7). Before a warning label can help a consumer better understand and appreciate the risks against which it warns, the consumer must notice and pay attention to the warning. The likelihood that a consumer will do so depends upon warning's size and position. (Refs. 36, 37, 38, 39, 40).

Some comments sought to support their First Amendment arguments against the warning label sizes by citing the D.C. Circuit's decision in *R.J. Reynolds* v. *FDA,* 696 F.3d 1205 (D.C. Cir. 2012), which vacated specific cigarette warnings previously issued by FDA. However, the decision in *Reynolds* was based on the graphics components of the cigarette warnings, not their size. Moreover, the reasoning of the *Reynolds* panel decision was overtaken by the D.C. Circuit's more recent *en banc* decision in *American Meat Institute,* 760 F.3d at 22–23.

FDA recognizes that the warning size requirement for covered tobacco products may present special difficulties for products in particularly small packages. To address this concern, FDA has added subsection (d) to § 1143.4. Under § 1143.4(d), a product that is too small or otherwise unable to accommodate a label with sufficient space to bear the required warning, printed in the required font size, may instead carry the warning on the carton or other outer container or wrapper. In cases where there is no carton or other outer container or wrapper that is large enough to carry the warning, the product may carry the warning on a tag firmly and permanently affixed to the package.

FDA agrees that other warnings on tobacco product packages, such as a warning regarding the risk of nicotine poisoning (as suggested by one particular comment), may also provide consumers with important health risk information. Therefore, elsewhere in this issue of the **Federal Register**, FDA has made available draft guidance, which when final will describe FDA's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products, including recommendations for exposure warnings that would help to support a showing that a product is appropriate for the protection of public health. FDA also has issued an ANPRM seeking comments, data, research, or other information that may inform regulatory actions FDA might take with respect to nicotine exposure warnings and child-resistant packaging for certain tobacco products. If FDA determines that it is appropriate for the protection of the public health to require such a warning (in addition to the addiction warning), FDA will consider at that time whether it is necessary to change the formatting requirements for the addiction warning to ensure that all warnings are clear and conspicuous.

b. Preemption of State Law Warning Requirements

(Comment 13) A number of comments sought an affirmative statement from FDA that the NPRM preempts State and local warning requirements. A few of the comments directly referenced California's reproductive health warning requirements for products containing nicotine (a notice mandated by Proposition 65). Many cited the explicit preemption provisions that apply to cigarettes and smokeless tobacco (see 15 U.S.C. 1334(b) and 4406(b)). One manufacturer argued that it would be arbitrary and capricious to subject the newly deemed products to a patchwork of Federal, State, and municipal requirements, while cigarettes and smokeless tobacco warning requirements are uniform across States and potentially less stringent. The comment further argued that it would be particularly unreasonable to subject noncombusted products to State and local labeling requirements because (according to the comment) noncombusted products are ''safer than cigarettes.''

Taking the other side of the issue were comments from public health groups and a joint comment from 29 State Attorneys General who advocated for an explicit statement that the NPRM does *not* preempt State and local warning requirements, including California's Proposition 65. At a minimum, they suggested that FDA change the heading of part 1143 from ''Required Warning Statement'' to ''Minimum Required Warning Statement'' to indicate that the deeming rule does not preclude other health warnings.

(Response) Section 916(a)(1) of the FD&C Act (21 U.S.C. 387p) expressly preserves the authority of State and local governments to, among other things, enact and enforce laws regarding tobacco products that are in addition to, or more stringent than, requirements established under chapter IX of the FD&C Act. The preservation of State and local governmental authority over tobacco products is limited by section 916(a)(2) of the FD&C Act, which expressly preempts any State or local requirement that 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 practices, or MRTPs.[9] However, section 916(a)(2)(B) of the FD&C Act states that the express preemption provision in section 916(a)(2)(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. A State or local statute is facially preempted only if no set of circumstances exists under which the statute would be valid. (See *Comm. of Dental Amalgam Mfrs. & Distribs.* v. *Stratton,* 92 F.3d 807, 810 (9th Cir. 1996).) FDA notified State and local jurisdictions about the potential impact this rule could have on their requirements. No State or local laws in effect at the close of the public comment period were identified that FDA determined would be preempted by this final rule.

With respect to the argument that it would be arbitrary and capricious to allow States and localities to subject newly deemed products to different warning requirements than cigarettes and smokeless tobacco products, we note that the preemptive effect depends on the relevant statutes. The preemption provisions of the Federal Cigarette Labeling and Advertising Act of 1965 (FCLAA) (15 U.S.C. 1334) and the Comprehensive Smokeless Tobacco Health Education Act of 1986 (CSTHEA) (15 U.S.C. 4406), which apply to cigarettes and smokeless products, respectively, are significantly different from section 916 of the FD&C Act. For example, the FCLAA and CSTHEA provisions expressly preempt State and local regulation of the content of cigarette and smokeless product advertisements, while section 916(a)(2)(B) of the FD&C Act exempts State and local advertising restrictions from preemption.

Separate and apart from the issue of preemption, elsewhere in this issue of the **Federal Register**, FDA has made available draft guidance, which when final will describe FDA's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products, including

[9] We note that while section 906(e) of the FD&C Act refers to ''good manufacturing practices,'' FDA refers to any regulations that could be issued under section 906(e) as tobacco product manufacturing practices.

recommendations for exposure warnings that would help support a showing that a product is appropriate for the protection of public health. Additionally, FDA notes that some ENDS product manufacturers have voluntarily included exposure warnings on their products. Accordingly, FDA has changed the heading of part 1143 from ''Required Warning Statements'' to ''Minimum Required Warning Statements'' in order to clarify that part 1143 is not intended to prevent tobacco product manufacturers from including truthful, non-misleading warnings on their products' packaging or advertisements voluntarily or as a result of FDA guidance.

III. Use of Premarket Pathways for Newly Deemed Products

As stated in the proposed deeming rule, manufacturers of newly deemed products that are ''new tobacco products'' as defined in section 910(a)(1) of the FD&C Act will be required to obtain premarket authorization of their products through one of three pathways—SE., exemption from SE., or premarket tobacco product application (PMTAs) (sections 905 and 910 of the FD&C Act). The substantive requirements of these provisions are set by statute and, thus, have not changed from the NPRM. However, FDA has revised the compliance periods for submitting premarket applications, as discussed in section V.A.

As an initial matter, with this final rule, we are also clarifying when FDA will consider a document to have been submitted for purposes of the compliance periods for submission of documents and data required by the automatic provisions of the statute. In the NPRM, we noted that the automatic provisions require companies to submit information to FDA, and we proposed various compliance periods to provide industry with time to make such submissions (*e.g.*, ''the manufacturer submits a 905(j) report for the product by [effective date of part 1100 plus 24 months]''). As previously discussed publically (see *http://www.fda.gov/tobaccoproducts/newsevents/ucm393894.htm*), FDA generally relies on the date of receipt of a submission by FDA's Document Control Center (DCC) as the date that the document was submitted (not the date that the submitter sent it). The DCC has been and will continue to be fully equipped to receive tobacco product submissions (including the number of submissions expected at the close of compliance periods). Therefore, regulated entities should ensure that FDA's DCC receives any submission by the due date or end of compliance period. The time it takes to review a premarket application is dependent upon the type of application and the complexity of the product. FDA has taken many steps to reduce the previous backlog and prevent further backlogs of marketing applications pending FDA review. FDA intends to act as expeditiously as possible with respect to all new applications, while ensuring that statutory standards are met. If an applicant wishes to discuss a product application, the applicant may request a meeting as set forth in FDA's final guidance entitled ''Meetings with Industry and Investigators on the Research and Development of Tobacco Products'' (announced May 25, 2012, 77 FR 31368).

In addition, we are clarifying that FDA distinguishes between a marketing application that has been ''filed,'' one that ''has been accepted,'' and one that has been ''submitted'' to FDA. A marketing application has been ''submitted'' when a complete application is delivered and received electronically, through the mail, or through a courier to CTP's Document Control Center (DCC). Once a complete PMTA application is submitted and received by CTP's DCC, FDA will have 180 days to consider the application as described in section 910(c)(A) of the Tobacco Control Act. A marketing application ''has been accepted'' after the Agency completes a preliminary review and determined that the application on its face contains information required by the statutory and/or regulatory provisions applicable to that type of application. A marketing application has been ''filed'' after the Agency completes a threshold review and has determined that a complete, substantive review is warranted. This filing review occurs only for a PMTA or a modified risk application and results in either a filing letter or a refusal to file letter.

A. Background: The Three Pathways To Market a New Tobacco Product

We received a large number of comments addressing the pathways to market a new tobacco product. Comments from industry argued that the review process for a new tobacco product is simply too difficult—that the standard is too high, and that the burden of submitting an application is too great. Many manufacturers of the newly deemed products argued that the two alternative pathways—SE and the SE exemption—are not available to them because there is no predicate to which they can claim SE. We address these comments in the following sections.

Under section 910 of the FD&C Act, manufacturers must receive FDA's permission to market new, including newly modified, tobacco products in the United States. The provision applies to all tobacco products covered by the FD&C Act, however, those that were commercially marketed in the United States on February 15, 2007 (the grandfather date) do not constitute new tobacco products and therefore do not require such premarket authorization. See section 910(a) of the FD&C Act (defining ''new tobacco product'' as any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007, or has been modified since that date).

Products that were introduced or modified after the grandfather date may seek permission to market under one of three pathways. The manufacturer may submit a PMTA, which is an application that requires the manufacturer to provide information about the product, including ingredients, additives, properties, manufacture, processing, labeling, and health risks, among other things (section 910(b) of the FD&C Act). FDA will grant permission to market the new product if the PMTA shows that it would be appropriate for the protection of the public health, among other things (section 910(c)(2) of the FD&C Act; see also section 910(c)(4) (requiring FDA to consider the risks and benefits to both users and nonusers, and explicitly requiring FDA to consider the effect of marketing the product on the likelihood that existing users of tobacco products will stop using them, and the likelihood that nonusers of tobacco products will start)). Whether the marketing of a product is appropriate for the protection of the public health will be evaluated on a case-by-case basis (in accordance with Section 910(c)(4) of the FD&C Act) and with consideration of the continuum of risk of nicotine-delivering products. The statute instructs FDA to base its findings regarding whether marketing the tobacco product would be appropriate for the protection of public health on well-controlled investigations, which may include one or more clinical investigations, where appropriate. However, it also allows FDA to authorize that its findings be made on the basis of valid scientific evidence other than controlled studies if FDA finds such other evidence sufficient to evaluate the tobacco product (section 910(c)(5) of the FD&C Act). We received several comments addressing the burden the PMTA application places on manufacturers, including the expense and time that clinical studies require.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a draft guidance, which when final will provide the Agency's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products, including specific recommendations concerning how to support a showing that the marketing of a new tobacco product is appropriate for the protection of the public health.

The second pathway to market is the SE pathway, which allows for a manufacturer to apply for permission to market a tobacco product that it demonstrates is ''substantially equivalent'' to a tobacco product that was marketed on the grandfather date or to a product previously found substantially equivalent (the ''predicate'') (section 910(a)(2)(A) and section 905(j) of the FD&C Act). To receive marketing authorization under the SE pathway, a manufacturer must submit an application that shows that the product to be marketed has the same characteristics as the predicate tobacco product or has different characteristics and the information submitted contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that it is not appropriate to regulate the product under section 910 because the product does not raise different questions of public health (section 910(a)(3)(A) of the FD&C Act). The statute defines ''characteristics,'' for this purpose, as the materials, ingredients, design, composition, heating source, or other features of a tobacco product (section 910(a)(3)(B) of the FD&C Act).

As new tobacco products continue to evolve from the cigarettes and smokeless tobacco that were on the market on the grandfather date, the SE pathway may not be available for some new products. The availability of the SE pathway for the newly deemed products was the subject of many comments, with some arguing that a different, later grandfather date should be adopted, and others arguing there should be no change in the grandfather date and that the newly deemed products should proceed through the PMTA pathway if no appropriate predicate is available.

Under the third pathway, a product may be exempted from the SE requirements if the only change to the product is a minor change and that change only involves a change to an additive in a tobacco product that can be sold under the FD&C Act, for which an SE report is not necessary and where the exemption is otherwise appropriate, as discussed in section 905(j)(3) of the FD&C Act.

B. Interpretation of Substantial Equivalence

(Comment 14) Some comments argued that FDA should interpret ''substantial equivalence'' broadly so that newly deemed products could avoid what the comments characterize as the more burdensome new tobacco product application (PMTA) pathway with a showing that the product has some similar characteristics to the predicate products.

(Response) FDA disagrees. SE is explicitly defined in section 910(a)(3) of the FD&C Act, which provides, in relevant part, that the term ''substantially equivalent'' or ''substantial equivalence'' means that the Secretary by order has found that the tobacco product: (1) Has the same characteristics as the predicate tobacco product or (2) has different characteristics and the information submitted contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that it is not appropriate to require a PMTA because the product does not raise different questions of public health. Section 910(a)(3)(B) provides that the term ''characteristics'' means the materials, ingredients, design, composition, heating source, or other features of a tobacco product. A product must have the same characteristics—all of the same characteristics—as the predicate product, to be found substantially equivalent under section 910(a)(3)(A)(i) of the FD&C Act or if the new product has different characteristics FDA must find that the new product does not raise different questions of public health under section 910(a)(3)(A)(ii).

FDA notes that for newly deemed products about which concerns have been raised with respect to the availability of an appropriate predicate—*e.g.*, e-cigarettes—many of these products have entirely different characteristics from traditional tobacco products. As such, a manufacturer would need to satisfy section 910(a)(3)(A)(ii) (*i.e.*, demonstrate that the new product does not raise different questions of public health as compared to the predicate). FDA is continuing to research e-cigarettes, other ENDS, and heated cigarette products that likely were on the market on February 15, 2007, and is working to determine the availability of such products for comparison. FDA determined that some e-cigarettes were manufactured in 2006 and introduced into the United States in early 2007. In particular, we have identified a non-flavored e-cigarette (also marketed as an ''e-cigar'') that may have been on the market on February 15, 2007. This product may possibly be able to serve as an appropriate predicate for purposes of the SE pathway. The burden of demonstrating that a valid predicate exists rests with the manufacturer submitting a SE report. To facilitate the determination that a product is eligible as a predicate for an SE application, any individual who has evidence that an e-cigarette or other tobacco product was commercially marketed in the United States on February 15, 2007, is encouraged to contact the Agency at 1–877–CTP–1373. Regardless of the predicate selected for comparison, manufacturers are responsible for providing scientific data adequate to demonstrate that, in the case of an SE Report, the characteristics are the same or, if the characteristics are different, these differences do not cause the new product to raise different questions of public health. It should also be noted that, where the predicate and new products are in a different category or subcategory, the evidence needed to obtain marketing authorization through the PMTA pathway may be similar to gather and submit than that needed for the SE pathway. For example, as stated in the NPRM, it is possible that an applicant may not need to conduct any new nonclinical or clinical studies for PMTA, while in other cases, such as where there is limited understanding of a product's potential impact, nonclinical and clinical studies may be required for market authorization. In cases where no new nonclinical or clinical studies are needed, the effort associated with gathering and submitting a PMTA may not be materially greater than that for an SE Report.

As stated earlier, the FD&C Act does not place limitations on which pathway manufacturers can use to seek market authorization for a new product. Thus, manufacturers may choose to submit applications under any of the three legal pathways. To obtain marketing authorization under the PMTA pathway, manufacturers are required to establish, among other things, that permitting their products to be marketed would be appropriate for the protection of public health. In establishing this, manufacturers should take into account, and FDA will consider, the ways in which the new product is likely to be used. For example, PMTAs for these products should contain information on whether the product is likely to be used alone or together with other legally

marketed tobacco products (such as available delivery systems), as well as the type and range of other products with which it is likely to be used.

For example, where a manufacturer seeks authorization of a new e-liquid to be used with ENDS, the manufacturer may need to provide evidence and analysis of the product's likely impact when used in the range of delivery systems available. Similarly, a manufacturer seeking authorization of a stand-alone apparatus component—such as a heating coil or cartridge—may need to provide evidence and analysis of the product's likely impact when used together with the range of other components and liquids available.

In the case of e-liquids, FDA expects that it may be possible for manufacturers to satisfy the statute by demonstrating that marketing of the liquid is appropriate for the protection of public health as it may be used in any of the legally available delivery systems. While FDA recognizes that there may remain some degree of uncertainty in any such analysis, FDA expects that the range of delivery system specifications authorized by FDA will provide a sufficiently specific spectrum of possibilities, such that a meaningful public health impact analysis can be done.

In the case of ENDS hardware/apparatus components, FDA expects that it may be difficult for manufacturers to make the showing necessary to meet the statutory standard, given the great extent of possible variations in combinations of hardware components, if all are considered and sold separately. Thus, with respect to apparatus, FDA expects that manufacturers will be most successful where authorization is sought for entire delivery systems, rather than individual components. In the case of these complete delivery systems—systems for which the application covers all potential parts, including customizable options as applicable, and where labeling, instructions for use and/or other measures are used to help ensure use as intended—FDA expects that the range of possible outcomes may be narrow enough for the manufacturer to demonstrate, and for FDA to assess, public health impact.

(Comment 15) Some comments asserted that under section 910(a)(3)(A)(ii) of the FD&C Act, certain categories of products should easily meet the SE standard because the products, overall, are beneficial to public health when compared to traditional, combustible cigarettes.

(Response) The issue of whether a product or certain categories of products may be beneficial to an individual is different than whether a category of products, overall, has a net positive benefit on population health. As explained in the NPRM, a category of products may benefit some individual tobacco users but may not have an overall net population health benefit if it leads to increased tobacco product initiation or dual use. In any event, this is a consideration relevant under the PMTA standard, not the SE standard.

Under section 910(a)(3)(A)(ii), a product can be found substantially equivalent to a predicate product even if it does not share all of the same characteristics of the predicate, if the information submitted contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that it is not appropriate to require a new product application because the product does not raise different questions of public health as compared to the predicate.

FDA will authorize the marketing of products through the SE pathway that meet the applicable standards in the FD&C Act. However, the SE pathway is a comparison between a new tobacco product and a predicate identified by the submitter, not an evaluation of whether the product is appropriate for the protection of the public health more generally as would be conducted under an application under section 910(b) (*i.e.*, a PMTA). Therefore, some differences between new and predicate products may not be appropriate for an SE Report, and the product instead is more suited to seeking authorization using a PMTA. Additionally, as the SE pathway is a specific comparison between a predicate and a new tobacco product, it does not necessarily provide a pathway to market for entire categories of products. Rather, under section 910(a)(3)(A)(ii), an application for SE must show that any differences in characteristics between the product and the predicate ''do not raise different questions of public health.''

(Comment 16) A small number of comments argued that newly deemed products should be permitted to be marketed under the SE pathway even if they do not share the same characteristics as the claimed predicate.

(Response) The statute does allow for applicants to use the SE pathway for new tobacco products that have different characteristics than the predicate product. To receive a marketing authorization under the SE pathway, these applicants must show that the new product has different characteristics and the information submitted contains information, including clinical data if necessary, to show that the product does not raise different questions of public health (section 910(a)(3)(A)(ii)).

(Comment 17) A few comments argued that section 910(a)(3)(A)(ii) allows for cross-category comparisons (*i.e.*, applicants may provide a comparison to predicate products from similar (but not identical) tobacco product categories).

(Response) It is up to the manufacturer to select an appropriate predicate tobacco product and provide the scientific evidence demonstrating SE. If the manufacturer provides scientific evidence and a rationale that demonstrates to FDA that the new product does not raise different questions of public health than the predicate (even though there are differences from the predicate product), FDA could issue an SE order. However, manufacturers of cigars or ENDS would have great difficulty showing that a product is substantially equivalent to a combusted cigarette or a smokeless tobacco product. For example, if FDA received an SE Report for a new product that is an ENDS closed aerosol generating apparatus and a predicate product that is a filtered combusted cigarette, then the product characteristics between the new and predicate products would be different. Because of the differences in characteristics in this example, a significant amount of scientific evidence would be needed to demonstrate that the new product does not raise different questions of public health. Such evidence, as discussed in FDA's 2011 Guidance titled ''Section 905(j) Reports: Demonstrating Substantial Equivalence,'' could include but would not be limited to the following: (1) Smoke yield data from HPHCs, (2) actual use data demonstrating how smoke topography compares between the new and predicate products, (3) actual use data demonstrating how the amount of product use varies between the new and predicate products (*e.g.*, number of puffs per day), and (4) marketing data indicating how consumer perception (product appeal) by youth differs between the new and predicate products. In these cases, it would be difficult to show that the differences between the product and the predicate product are such that the product ''does not raise a different question of public health.''

In addition, the evidence required to make such a showing may be as substantial or even greater than the evidence required under the PMTA pathway (section 910(b)), and the PMTA pathway allows for different effects on public health—as long as the applicant

provides a demonstration that the product is appropriate for the protection of the public health. Nevertheless, there is nothing in the statute to prohibit the attempted use of cross-category comparisons in an SE submission, but it is the responsibility of the manufacturer to provide appropriate and sufficient evidence to support a finding of SE.

(Comment 18) A few comments from industry argued that FDA should interpret ''substantial equivalence'' as the term is applied to medical devices under section 510(k) of the FD&C Act (21 U.S.C. 360(k)), which does not require premarket review for what the comments refer to as ''even the slightest change to a predicate.''

(Response) FDA's interpretation of SE with respect to medical devices is based on a different statutory section than is applicable to tobacco products. FDA has issued guidance interpreting SE within the meaning of section 910 of the FD&C Act.

C. Comments on the Grandfather Date

We received numerous comments on the February 15, 2007, grandfather date and the challenges it may present to certain categories of the newly deemed products. We address those comments as follows.

Lack of Authority To Change the Grandfather Date to a Later Date. As stated in the NPRM, FDA has determined that it lacks authority to change the grandfather date, which is set by statute (79 FR 23142 at 23174). FDA specifically asked for comments on our legal interpretation. We received a large number of comments in response to this statement, but none provided a legal theory that would support changing the date.

(Comment 19) A number of comments argued that adoption of a later grandfather date would be an acceptable exercise of FDA's discretion under section 701(a) of the FD&C Act, which provides FDA authority to issue regulations ''for the efficient enforcement'' of the statute. Others argued that an alternative date would be a permissible Agency interpretation of the statute, subject to deference under the *Chevron* doctrine. (See *Chevron U.S.A., Inc.* v. *NRDC,* 467 U.S. 837 (1984).)

(Response) After careful consideration of these comments, FDA concludes that it lacks authority to change the grandfather date for the newly deemed products. The grandfather date is prescribed in the statute. Section 910(a)(1)(A) of the FD&C Act states, in pertinent part, that the term ''new tobacco product'' means any tobacco product (including those products in test markets) that was not commercially marketed in the United States on February 15, 2007. For purposes of the SE pathway, the statute also clearly states that a predicate product must be commercially marketed (other than for test marketing) in the United States on February 15, 2007, in both section 910(a)(2)(A) and section 910(j)(1). FDA's authority is not so broad as to allow FDA to issue a regulation that contradicts a clear statutory provision.

Many comments cited examples of FDA's exercise of discretion to show that FDA can and should exercise discretion to change the grandfather date. For example, comments pointed to FDA's decision to extend compliance deadlines, as well as FDA's guidance informing industry that it does not intend to take enforcement action against manufacturers who make tobacco blending changes without a premarket submission for a new tobacco product when such tobacco blending changes are intended to address the natural variation of tobacco (*e.g.*, tobacco blending changes due to variation in growing conditions). However, the exercise of discretion reflected in these examples did not require FDA to contradict the clear language of the Tobacco Control Act, as changing the grandfather date would.

(Comment 20) A number of comments argued that the February 15, 2007, date in section 910 of the FD&C Act is simply an anachronism, that the date was only intended to apply to the initially regulated products, and the fact that the statutory language does not provide a different date is simply a drafting error.

(Response) FDA disagrees and is aware of no evidence supporting this view. Congress carefully distinguished those provisions of the statute that would apply to all tobacco products from those that would apply only to the initially regulated products or, in some cases, only to traditional cigarettes. (See, *e.g.*, section 102(a)(1) of the Tobacco Control Act (requiring FDA to issue a rule establishing restrictions on the sale and distribution of cigarettes and smokeless tobacco, with certain different provisions for the two categories of products).) If Congress had intended that there be a later grandfather date for tobacco products deemed subject to the statute after its date of enactment, it would have provided one.

(Comment 21) Some comments argued that application of the February 15, 2007, date is unfair to the manufacturers of the newly deemed tobacco products (particularly e-cigarettes) because they were not on notice of pending regulation and they contended that ''all newly deemed products will be forced from the market.'' Thus, they argue, decisions were made to invest in an industry that was presumed to be unregulated, and now the industry must bear unanticipated costs.

(Response) FDA disagrees with comments stating that all newly deemed products will be forced to be removed from the market as some newly deemed products will qualify as ''grandfathered'' products under the statute and any that are not grandfathered will be able to apply for premarket authorization. The Tobacco Control Act plainly provides for regulation of all tobacco products. FDA also clearly stated its intention to deem these products long before the NPRM was published (see Unified Agenda, Spring 2011, RIN 0910–AG38). Therefore, manufacturers of the newly deemed products have been on notice for more than 4 years that these products could and likely would be regulated.

The ENDS industry has acknowledged that it was aware of both FDA's intention to regulate ENDS and the applicability of the Tobacco Control Act to e-cigarettes and other ENDS, as evidenced by the litigation in *Smoking Everywhere, Inc.* v. *Food & Drug Administration,* 680 F. Supp.2d 62 (D.D.C. 2010), affirmed by *Sottera, Inc.* v. *Food & Drug Administration,* 627 F.3d 891 (D.C. Cir. 2010), which was pending during the passage of the Tobacco Control Act. When FDA attempted to regulate e-cigarettes as a drug-device combination, plaintiffs Sottera (doing business as NJOY) and Smoking Everywhere argued that Congress intended for tobacco products, including their own, to be subject to the Tobacco Control Act and not to the drug and device provisions of the FD&C Act. The district court described plaintiffs' position as follows: ''In *FDA* v. *Brown and Williamson Tobacco Corp.,* the Supreme Court held that tobacco products, like traditional cigarettes, are not subject to FDA regulation as a drug or device. [529 U.S. 120 (2000).] Because electronic cigarettes, as marketed by plaintiffs, are the functional equivalent of traditional cigarettes, plaintiffs contend that FDA cannot regulate their products [as combination drug-device products]. They further contend that Congress's recent enactment of the [Tobacco Control Act] supports their argument. Under the [Act], FDA may now regulate tobacco products, which the Act defines as ''any product made or derived from tobacco that is intended for human consumption,'' . . . but it cannot regulate those products as it would a

drug or device under the FDCA[.] There being no dispute that the nicotine in plaintiffs' electronic cigarettes is naturally distilled from actual tobacco and is intended for human consumption, . . . plaintiffs assert that their electronic cigarettes qualify as a tobacco product and are therefore exempt from regulation as a drug-device combination.'' (*Smoking Everywhere* v. *FDA,* 680 F. Supp. 2d 62, 66–67 (D.D.C. 2010).)

The district court found that, ''it is apparent from Congress's broad definition of 'tobacco product' that it intended the Tobacco Act's regulatory scheme to cover far more than the fixed array of traditional tobacco products[.]'' (Id. at 71.) ENDS manufacturers were made especially aware of FDA's authority to deem their products and subject them to the tobacco control authorities of the FD&C Act when the court noted that ''. . . now that FDA has regulatory power over electronic cigarettes through the Tobacco Act, any harm to the public interest or to third parties caused by an injunction that merely forbids FDA from regulating electronic cigarettes as a drug-device combination is greatly diminished.'' (Id. at 77–78.)

On appeal, the D.C. Circuit affirmed, commenting that ''the Tobacco Act provides the FDA with regulatory authority over tobacco products without requiring therapeutic claims. . . . [T]he act broadly defines tobacco products as extending to 'any product made or derived from tobacco.' '' Sottera, Inc. v. Food & Drug Administration, 627 F.3d 891, 897 (D.C. Cir. 2010) (quoting 21 U.S.C. 321(rr)(1); emphases added by the court). The D.C. Circuit went on to state that ''the [lower] court rightly found that the FDA has authority under the Tobacco Act to regulate electronic cigarettes''—authority that, it added, was ''unquestioned.'' *Id.* at 898.

(Comment 22) Some comments argued that FDA previously exercised enforcement discretion to amend the grandfather date of the reissued 1996 rule (published in the **Federal Register** of August 28, 1996, 61 FR 44396) with respect to use of a trade or brand name of a nontobacco product for cigarettes or smokeless tobacco products and argued that FDA has the authority to take similar action with respect to the SE grandfather date.

(Response) FDA disagrees. In section 102 of the Tobacco Control Act, Congress required FDA to reissue the 1996 final rule regarding cigarettes and smokeless tobacco identical to the original rule (61 FR 44396 at 44615 through 44618), with certain enumerated exceptions. Congress did not list the grandfather date for the use of nontobacco brand-names as one of the exceptions. Nonetheless, the Agency issued a compliance policy stating that it did not intend to enforce the January 1, 1995, grandfather date for the use of a nontobacco brand name while considering what changes to the regulation, if any, would be appropriate. Section 102(a)(4) also gave FDA authority to amend its own rule. On November 17, 2011, FDA issued the proposed brand name rule (76 FR 71281) seeking to exercise its authority to amend the January 1, 1995, date that was originally included in 21 CFR 897.16(a) to June 22, 2009, in recognition of the fact that 14 years elapsed since the publication of the 1996 final rule. Using the January 1995 date would have significantly changed the provision, from one that was intended to apply prospectively to one that applies retroactively. The statute does not give FDA similar authority to change the provisions in section 910 of the FD&C Act to amend the grandfather date.

D. Impact of Premarket Requirements

(Comment 23) Numerous comments argued that if the SE pathway is not available for some newly deemed products, manufacturers will have to use the PMTA pathway, will not have sufficient resources to complete PMTAs, and will be forced to remove their products from the market. Members of the e-cigarette industry further argued that removal of their products would be detrimental to public health. However, other comments expressed concern regarding any delay in implementing and enforcing the premarket review requirements given the data showing the growing use of the newly deemed products, particularly among youth and young adults.

(Response) As an initial matter, FDA notes that the primary premarket pathway for new tobacco products is the premarket tobacco product application pathway, and that the SE and SE exemption pathways are exceptions to that pathway, but manufacturers can choose to submit applications under any of the three pathways for which they think they can meet the criteria in the FD&C Act for marketing authorization for a new product. See section 910(a)(2)(A) of the FD&C Act stating that an order for a new tobacco product is required unless the Secretary has issued an order that the tobacco product is substantially equivalent to tobacco product commercially marketed. The SE pathway is not intended to be available to every product. Rather, by its terms, the SE pathway is limited to products that can be shown to be substantially equivalent to a product that was on the market on the grandfather date. If that showing cannot be made, the appropriate premarket pathway is the premarket tobacco product application pathway.

To obtain marketing authorization under the PMTA pathway, manufacturers are required to establish, among other things, that permitting their products to be marketed would be appropriate for the protection of public health. In establishing this, manufacturers should take into account, and FDA will consider, the ways in which the new product is likely to be used. We also note that, elsewhere in this issue of the **Federal Register**, FDA has made available draft guidance, which when final will describe FDA's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products. Should firms have specific questions regarding application content and information necessary to satisfy the filing criteria under section 910(b) or ways to reduce burden by reference to another submission, they may contact CTP's OS at 1–877–CTP–1373.

For example, where a manufacturer seeks authorization of a new e-liquid to be used with ENDS, the manufacturer may need to provide evidence and analysis of the product's likely impact when used in the range of delivery systems available. Similarly, a manufacturer seeking authorization of a stand-alone apparatus component—such as a heating coil or cartridge—may need to provide evidence and analysis of the product's likely impact when used together with the range of other components and liquids available.

In the case of e-liquids, FDA expects that it may be possible for manufacturers to satisfy the statute by demonstrating that marketing of the liquid is appropriate for the protection of public health as it may be used in any of the legally available delivery systems. While FDA recognizes that there may remain some degree of uncertainty in any such analysis, FDA expects that the range of delivery system specifications authorized by FDA will provide a sufficiently specific spectrum of possibilities, such that a meaningful public health impact analysis can be done.

In the case of ENDS hardware/apparatus components, FDA expects that it may be difficult for manufacturers to make the showing necessary to meet the statutory standard, given the great extent of possible variations in combinations of

hardware components, if all are considered and sold separately. Thus, with respect to apparatus, FDA expects that manufacturers will be most successful where authorization is sought for entire delivery systems, rather than individual components. In the case of these complete delivery systems—systems for which the application covers all potential parts, including customizable options as applicable, and where labeling, instructions for use and/or other measures are used to help ensure use as intended—FDA expects that the range of possible outcomes may be narrow enough for the manufacturer to demonstrate, and for FDA to assess, public health impact.

FDA also notes that many comments from the ENDS industry emphasized the potential public health benefits of these products in their comments on the NPRM. For example, numerous industry comments argued that restrictions on access to the newly deemed products would be detrimental to public health, as the products may be less toxic than conventional cigarettes and may be successfully used as a cessation product. FDA's consideration of public health benefits of products will be included in FDA's review of PMTAs based on the evidence.

(Comment 24) A few comments expressed concern that if manufacturers would be forced to submit PMTAs rather than SE applications, they would need to conduct more animal studies to meet PMTA requirements.

(Response) FDA shares an interest in reducing the reliance on animal-based studies, and the Agency is committed to the three ''Rs'' of reduction, refinement, and replacement in animal testing. Although we are hopeful that in vitro assays and computer models can ultimately help to replace much of the need for animal testing, there are still many areas for which non-animal testing is not yet a scientifically valid and available option. FDA is committed to addressing concerns raised regarding use of animal testing methods, while still ensuring that the Agency satisfies its public health and patient safety responsibilities and acts in accordance with its governing statutes.

(Comment 25) One comment stated that e-cigarettes have two variables—the ratio of the propylene glycol to vegetable glycerin and the level of nicotine in the product—which would result in many combinations and, therefore, require submission of numerous, very costly PMTAs for products that have very minor variations. In contrast, one comment noted that the lower number of ingredients in e-cigarettes means that less information will be required in PMTAs for e-cigarettes than for other products.

(Response) The requirements and costs of a PMTA may vary based on the type and complexity of the product. Variations in the ratio of ingredients, such as propylene glycol and glycerin, would indicate that products have different levels of each of these ingredients. As stated in section 910(a)(1)(B) of the FD&C Act, any change in an ingredient level, as with additions or removal of ingredients, yields a new tobacco product.

We also note that the statute requires FDA to review PMTAs based on well-controlled investigations, ''when appropriate,'' or other valid scientific evidence sufficient to evaluate the tobacco product. In addition, elsewhere in this issue of the **Federal Register**, FDA has made available draft guidance, which when final will describe FDA's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products. Should firms have specific questions regarding application content and information necessary to satisfy the filing criteria under section 910(b) or ways to reduce burden by reference to another submission, they may contact CTP's OS at 1–877–CTP–1373.

(Comment 26) Many comments stated that a requirement to prepare PMTAs for all of the many parts and components that go into some of the newly deemed tobacco products would create an effective ban of these products.

(Response) The definition of a tobacco product includes components and parts, and these products are subject to the automatic provisions of the FD&C Act, including premarket authorization requirements. However, at this time, FDA intends to limit enforcement of the premarket authorization provisions to finished tobacco products. In this context, a finished tobacco product refers to a tobacco product, including all components and parts, sealed in final packaging intended for consumer use (*e.g.*, filters or filter tubes sold separately to consumers or as part of kits). For example, an e-liquid sealed in final packaging that is to be sold or distributed to a consumer for use in a finished tobacco product will be subject to enforcement if it is on the market without authorization. In contrast, an e-liquid that is sold or distributed for further manufacturing into a finished ENDS product is not itself a finished tobacco product. At this time, FDA does not intend to enforce the premarket authorization requirements against such e-liquids or other components and parts of newly deemed products that are sold or distributed solely for further manufacturing without a marketing order.

(Comment 27) Many expressed concern that requiring cigars to comply with the PMTA requirements would either force cigars off the market or require them to mimic cigarettes in uniformity of size, shape, and taste, which would change the fundamental nature of the cigar industry. At least one comment stated that FDA should eliminate the premarket and SE application requirements for cigars and instead implement a system by which cigar manufacturers could introduce new products to the market after providing 90 days' notice to FDA of their intentions to do so.

(Response) FDA disagrees. Sections 905 and 910 of the FD&C Act establish specific requirements that apply to new tobacco products before they may be marketed. Some cigars may be grandfathered and other products may have valid predicate products and may be able to avail themselves of the SE pathway to market. FDA generally expects that cigars with blending changes (other than blending changes to address the natural variation of tobacco, FDA's policy for which is discussed in the response to Comment 28) will be able to successfully use the SE pathway so long as the blending change does not significantly raise levels of HPHCs in the product (*i.e.*, raising different questions of public health). If a product is unable to utilize the SE pathway and is not eligible for an SE exemption, the statute requires the product (including limited or seasonal blends) to obtain a marketing authorization through the PMTA pathway. As explained previously, the requirements of a particular PMTA may also vary based on the type and complexity of the product. If an applicant wishes to discuss a product application, the applicant may request a meeting as set forth in FDA's final guidance entitled ''Meetings with Industry and Investigators on the Research and Development of Tobacco Products'' (announced May 25, 2012, 77 FR 31368).

(Comment 28) A number of comments discussed the natural variability in the tobacco used for cigars and pipe tobacco, stating that because the characteristics of tobacco used for each of these products can vary from year to year, manufacturers must use different blends to create a consistent product. Some comments expressed concerns that each blending change could result in a new product for which manufacturers and importers would be

required to submit a PMTA. They also stated that this would be economically unfeasible for limited editions and special releases for cigars and pipe tobacco. Others expressed concerns that tobacco blending changes and natural variations of the tobacco used in the product, such as the number of ribs or perforations in a cigar wrapper, may produce different results for HPHC testing of the same product. These comments advocated that cigars and pipe tobacco should be either excluded from the ingredient listing, HPHC listing, and premarket review requirements or manufacturers should be allowed to make tobacco blending changes without being required to submit a marketing application or comply with HPHC testing and reporting requirements.

(Response) FDA is aware that the tobacco used to produce some of the newly deemed products can naturally vary from year to year. As stated in section IV.C.1, FDA does not intend to enforce the premarket authorization requirements where manufacturers make tobacco blending changes without premarket authorization for tobacco blending changes to address the natural variation of tobacco (*e.g.*, tobacco blending changes due to variation in growing conditions) in order to maintain a consistent product. However, FDA does intend to enforce the premarket authorization requirement for tobacco blending changes that are intended to alter the chemical or perception properties of the new product (*e.g.*, nicotine level, pH, smoothness, harshness, etc.) compared to the predicate product, and such changes should be reported under 910 or 905(j). In addition, FDA intends to issue a guidance regarding HPHC reporting under section 904(a)(3), and later a testing and reporting regulation as required by section 915, with enough time for manufacturers to report given the 3-year compliance period for HPHC reporting. As noted elsewhere in this document, FDA does not intend to enforce the reporting requirements under section 904(a)(3) for newly deemed products before the close of the 3-year compliance period, even if the HPHC guidance is issued well in advance of that time. Additionally, changes made to the number of ribs or perforations in a cigar wrapper as well as any changes to ingredients or additives, would result in a new tobacco product (as stated in section 910(a)(1)(B)) and would require a marketing application and authorization under section 910 or 905(j). FDA intends to enforce other applicable requirements (*e.g.*, ingredient listing) against manufacturers making blending changes to address the natural variation of tobacco.

(Comment 29) Some comments stated that small companies are at a competitive disadvantage compared to larger companies because they do not have the resources to complete PMTAs. They feared that FDA's premarket requirements would force many companies to remove their products from the market and that, as a result, cigarette use would increase. To address these concerns, comments suggested that FDA stagger requirements based on the size of the business to protect small businesses and spur innovation. They stated that staggered compliance periods could be based on the number of employees in the business, number of products the business has, and/or the product's placement on the continuum of risk. In addition, some comments stated that such staggered dates could be based on FDA's issuance of final PMTA guidance for each product category, which would allow for more meaningful and complete submissions. They also stated that, because such guidance likely would include issues of first impression, the Agency is required to first issue the guidance in draft form before issuing a final guidance. Some comments stated that staggered PMTA compliance periods may not be sufficient to address the competitive disadvantage of small companies because they still would not have the resources to complete a PMTA for each of their new tobacco products.

Other comments believed that premarket requirements should apply equally to all manufacturers, regardless of size, for several reasons. First, they explained that the FD&C Act states that the purpose of a PMTA is to ensure that permitting marketing of a tobacco product would be ''appropriate for the protection of the public health'' (section 910(c)(2)(A)) and that this public health purpose should outweigh concerns regarding small businesses. The comments noted that the public health purpose of the Tobacco Control Act does not differentiate between large and small businesses. Second, they stated that the public health concerns presented by products of small manufacturers are no less significant than the public health concerns presented by products of large manufacturers. They also noted that small manufacturers may lack the quality control processes that they believed large manufacturers already have in place. They also noted that many small businesses are e-cigarette retail establishments that mix their own e-liquids, which can be accessible to children and potentially subject to tampering and, therefore, should not receive additional time to comply with critical automatic requirements. Third, they stated that Congress did not intend for small manufacturers to have additional time to comply with all of the automatic provisions under the law once they are deemed. Instead, Congress only intended that small manufacturers receive additional time to comply with good manufacturing practices under section 906(e)(1)(B) of the FD&C Act and testing requirements under section 915(d) (21 U.S.C. 387o). If Congress had intended for small manufacturers to receive additional time to comply with other provisions, it would have explicitly said so. Fourth, they stated that FDA already provides adequate assistance to small businesses with the small business center (included as part of CTP's OCE) and frequent Webinar programs, but other comments stated that the small business center was not properly organized and staffed.

(Response) FDA is announcing multiple policies with this final rule including a policy for ''small-scale tobacco product manufacturers'' discussed in section IV.D. FDA is announcing this policy, because ''small-scale tobacco product manufacturers'' do not have the same business capabilities of larger businesses. Moreover, FDA did not receive any comments from large manufacturers suggesting that they are in need of the relief that is being provided for small-scale tobacco product manufacturers. Congress also acknowledged the potential disparity by requiring FDA to establish the Office of Small Business Assistance (OSBA) within CTP to assist small tobacco product manufacturers and retailers in complying with the law. OSBA is available to assist manufacturers with any questions regarding statutory and regulatory requirements and will continue to provide support with respect to these newly finalized regulations. Small business owners may contact the OSBA by calling 1–877–CTP–1373 or sending a message to *SmallBiz.Tobacco@fda.hhs.gov*. FDA intends to expand the staffing for the OSBA to provide support for manufacturers who are newly regulated by FDA.

As discussed in the earlier section of this final rule describing the purpose of this rule, FDA will be able to obtain critical information regarding the health risks of newly deemed tobacco products, including information derived from ingredient listing submissions and reporting of HPHCs. Because FDA did not previously have regulatory authority

over these products, it does not have access to commercial confidential information on materials, ingredients, design, composition, heating source and other features of these products. As FDA gains experience regulating these newly deemed tobacco products, the Agency expects there will be more information to aid manufacturers seeking premarket determination that a tobacco product is ''appropriate for the protection of public health.'' However, it would negatively impact public health if FDA were to significantly delay implementation of its premarket requirement authorities after issuance of this deeming rule. Such delay could result in more youth becoming addicted to nicotine. FDA recognized that ENDS are different than conventional tobacco products, and that more specific guidance would be useful to manufacturers in preparing premarket applications. Therefore, FDA has made available draft guidance, which when final, will describe FDA's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products, including recommendations that would help to support a showing that the marketing of a product is appropriate for the protection of public health. FDA intends to issue additional guidance in the future.

E. Clinical Studies and PMTAs

(Comment 30) Comments expressed concern about the need for costly clinical studies to develop PMTAs that satisfy the requirements under section 910 of the FD&C Act. They indicated that FDA's previous statements, including language from draft guidance that recommends the collection of numerous types of data ranging from chemistry to in vivo toxicology and possible clinical trials, suggest the need for costly studies that are redundant and unnecessary. They also noted the Government Accountability Office's (GAO's) summary of this issue, which stated ''CTP's guidance document for the PMTA pathway states that PMTA submissions should include data from well-controlled studies demonstrating that the tobacco product is appropriate for the protection of the public health. [According to CTP,] '[d]ata from such studies must address, for example, the health risks associated with the product in comparison to the health risks of other products on the market and the product's effect on the likelihood that current tobacco users will stop using tobacco products''' (Ref. 41 at 18–19).

(Response) In the NPRM, FDA included discussion intended to supplement and clarify its earlier statements regarding clinical studies needed for PMTAs (79 FR 23142 at 23176 and 23177). As we noted, FDA expects that, in some cases, it may be possible for an applicant to obtain a PMTA marketing authorization order without conducting any new nonclinical or clinical studies where there is an established body of evidence regarding the public health impact of the product. However, in cases where there have been few or no scientific studies of a product's potential impact on the public health, new nonclinical and clinical studies may be required for market authorization. In addition, elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a draft guidance, which when final will provide the Agency's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products, including the need for ''clinical studies'' for the purposes of preparing PMTAs for ENDS.

(Comment 31) Several comments suggested that section 910(c)(5)(B) provides FDA with authority to develop a flexible framework for PMTAs that would not require well-controlled investigations. They suggested the following alternatives to the requirement of well-controlled investigations:

- Create a user registry for e-cigarette users to input baseline demographic, cessation and initiation, adverse experiences, and followup data for collection of real-world data;
- Identify clinical studies that will constitute ''valid scientific data'' and identify historical controls and published literature suitable for comparative purposes;
- Adopt a process similar to FDA's process for new medical devices, where the product can undergo de novo review to obtain a lower risk classification and be subject to general controls and specific controls (rather than the premarket requirements under sections 905 and 910(d));
- Use a process similar to the accelerated approval process for new drugs for serious or life-threatening illnesses, which bases approval on the effect of the drug on a surrogate endpoint; and
- Adopt a method similar to the dietary supplement process, based on registration, ingredient disclosures, and good manufacturing practice (GMP) compliance checks.

(Response) FDA is not implementing these changes. Most of the approaches in the comments are all implemented under different statutory authorities that do not apply to tobacco products. FDA's responses to these individual suggestions are discussed in the following paragraphs.

- Create a user registry for e-cigarette users to input baseline demographic, cessation and initiation, adverse experiences, and follow-up data for collection of real-world data—

The data and information in a PMTA must be sufficient to show that the marketing of the *specific* new tobacco product is ''appropriate for the protection of the public health'' (section 910(c)(4) of the FD&C Act). This information from a user registry would not be sufficient on its own to support a marketing application, but it could provide additional real-time information (*e.g.*, adverse experiences that may otherwise be gathered in more long-term studies). If an applicant wishes to use a registry or other alternatives, we encourage it to request a meeting with FDA to discuss these and other issues *before* it prepares and submits an application.

- Identify clinical studies that will constitute ''valid scientific data'' and identify historical controls and published literature deemed suitable for comparative purposes—

FDA does not have enough information at this time to do this in a manner that would be generally applicable. It may be possible for an applicant to submit information (*e.g.*, published literature, marketing information) with appropriate information or data that would be adequate scientific data for parts of the application. This will likely be limited to specific aspects of the PMTA requirements (*e.g.*, nonclinical work, shelf life/stability, health risks based on consumer information). If an applicant wishes to use this or other alternatives, we encourage them to request a meeting with FDA to discuss these and other issues in the context of a particular product before they prepare and submit an application.

- Adopt a process similar to FDA's process for new medical devices, where the product can undergo de novo review to obtain a lower risk classification and be subject to general controls and specific controls (rather than the premarket requirements under sections 905 and 910(d))—

FDA is not authorized to deviate from the premarket requirements of chapter IX of the FD&C Act. The medical device requirements in chapter V of the FD&C Act apply to medical devices only, not tobacco products as defined in section 201(rr) of the FD&C Act.

- Use a process similar to the accelerated approval process for new

drugs for serious or life-threatening illnesses, which bases approval on the effect of the drug on a surrogate endpoint—

The purpose of the accelerated drug approval process was to establish procedures designed to expedite the development, evaluation, and marketing of new therapies intended to treat persons with life-threatening and severely debilitating illnesses, especially where no satisfactory alternative therapy exists. This is not the case with a tobacco product. Section 910(b) of the FD&C Act requires that specific contents be contained in a PMTA. In addition, as stated in section 910(c)(4) of the FD&C Act, the data and information in a PMTA must be sufficient to show that the marketing of a new tobacco product is ''appropriate for the protection of the public health.'' FDA believes that an accelerated premarket review process is neither feasible nor appropriate for these products at this time. However, if an applicant believes it can demonstrate that its new product is ''appropriate for the protection of public health'' in an accelerated fashion, we encourage it to request a meeting with FDA to discuss these and other issues before they prepare and submit an application.

- Adopt a method similar to the dietary supplement process, based on registration, ingredient disclosures, and GMP compliance checks—

As stated in section 910(c)(4) of the FD&C Act, the data and information in a PMTA must be sufficient to show that the marketing of a new tobacco product is ''appropriate for the protection of the public health.'' The method suggested in this comment would differ from the process and standard outlined in sections 905 and 910 of the FD&C Act and, therefore, is inapplicable to tobacco products.

The FD&C Act states that determining whether a new product is appropriate for the protection of the public health shall be determined ''when appropriate . . . on the basis of well-controlled investigations.'' (section 910(c)(5)(A)). However, section 910(c)(5)(B) of the FD&C Act also allows the Agency to consider other ''valid scientific evidence'' if found sufficient to evaluate the tobacco product. Thus, if an application includes, for example, information (*e.g.*, published literature, marketing information) with appropriate bridging studies, FDA will review that information to determine whether it is valid scientific evidence sufficient to demonstrate that the product is appropriate for the protection of the public health. If an applicant has questions or other alternatives to well-controlled investigations it would like to utilize, we recommend that it meet with FDA to discuss the approach prior to preparing and submitting an application (see FDA guidance entitled ''Meetings with Industry and Investigators on the Research and Development of Tobacco Products''). We also note that, elsewhere in the **Federal Register**, FDA is announcing the availability of a draft guidance, which when final will provide the Agency's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products.

F. Premarket Pathways and Continuum of Risk

(Comment 32) We received many comments requesting that FDA provide an expedited or abbreviated pathway for those products that are on the less harmful end of the continuum of risk spectrum. Some comments stated that noncombusted and nicotine delivery products derived from, but not containing, tobacco should be treated differently than combusted products for the purposes of premarket review and that less harmful products need an accelerated pathway to ensure continued innovation. They also stated that the different risks and benefits associated with tobacco derived nicotine delivery products make the PMTA process and FDA's draft PMTA guidance inapplicable. Other comments claimed that e-cigarettes and other tobacco derived nicotine delivery products are not tobacco products at all and do not fit into the strict tobacco product regulatory framework. The comments also stated that an abbreviated pathway should be based on public participation to decide what information is sufficient to determine that the product is appropriate for the protection of the public health without impeding innovation.

Some comments also suggested that FDA require a premarket notification or report, similar to EU's Tobacco Products Directive, where the notification certifies that the product has met specific product standards, and the Agency could approve the product based on the certification.

At least one comment disagreed with the idea of providing an expedited or abbreviated pathway for some products, stating that FDA will not know if the products are less harmful until it reviews the applications.

(Response) An ENDS is a tobacco product as long as it meets the definition of ''tobacco product'' under section 201(rr) of the FD&C Act. Regardless of the type of tobacco product (and its potential risks and benefits), *all* tobacco products going through the PMTA pathway must meet all the requirements for a premarket authorization in section 910 of the FD&C Act before FDA can issue such an authorization. In addition, we note that, at this time, while there is general evidence of harm for all classes of newly deemed products, FDA has not yet obtained product-specific evidence regarding the various ENDS on the market. Since ENDS products contain nicotine, it is possible that such products may result in overall public health harm if individuals who would not have initiated tobacco use in the absence of ENDS ultimately graduate to combusted products (though scientific data regarding this hypothesis is unclear) or use them in conjunction with combusted products or if the users would never have initiated tobacco use absent the availability of ENDS. In addition, nicotine use in any form is of particular concern for youth and pregnant women. On the other hand, if ENDS promote transition from combustible tobacco use among current users, there could be a public health benefit. The 2014 Surgeon General Report notes that ''[f]urther research with attention to their individual and population-level consequences will be helpful to fully address these questions. However, the promotion of noncombustible products is much more likely to provide public health benefits only in an environment where the appeal, accessibility, promotion, and use of cigarettes and other combusted tobacco products are being rapidly reduced'' (Ref. 9 at 873). FDA believes that regulation of all tobacco products will help to address these questions and provide public health benefits.

(Comment 33) Many comments expressed concern regarding the cost of PMTAs for newly deemed products and the effect that this requirement will have on cigarette smokers who are attempting to quit. They also disagreed with FDA's assertion that premarket review will enhance innovation (79 FR 23142 at 23149), stating that the cost of submitting PMTAs is more of a business concern than competition with lower quality products. They claimed that the PMTA process would have the largest negative impact on open system apparatus, which some comments believed are the most popular with people who have achieved complete substitution from conventional cigarettes to e-cigarettes. The comment suggests that the result would be that newer e-cigarettes would not make it onto the market, driving up prices, and

driving adult consumers back to conventional cigarettes.

(Response) The Tobacco Control Act provides for three specific marketing pathways for new tobacco products—SE., SE exemption, and PMTA; it does not provide alternative pathways. Through the PMTA pathway, FDA will ensure that only products that are shown to be appropriate for the protection of public health are permitted to be marketed. Use of the PMTA pathway also will allow FDA to monitor product development and changes and to prevent more harmful or addictive products from reaching the market. The PMTA pathway will incentivize development of tobacco products that pose less risk to human health by limiting market access for more-risky competitor products. Furthermore, since the ''appropriate for the protection of the public health'' standard involves comparison to the general tobacco product market existing at the time of an application, FDA believes that, over time, the premarket authorities will move the market toward less-risky tobacco products.

A recently published paper by Friedman (Ref. 42) looked at youth smoking rates in states that enacted early bans on sales of e-cigarettes to minors. The author concluded, based on state-level combusted cigarette smoking data available through 2013, that the decline in adolescent smoking rates slowed in states that enacted restrictions on access to ENDS by minors before January 2013, relative to states that did not. Some have interpreted the results of the study as providing evidence that any policies that restrict access to e-cigarettes or regulate e-cigarettes could increase consumption of combusted tobacco products. However, the research has several limitations that are acknowledged in the study. First, the survey data used in the study, from the NSDUH, track changes in the prevalence of cigarette smoking but lack information available on e-cigarette use. As such, the study does not establish that youth switched directly from using ENDS to smoking combusted cigarettes after restrictions on sales of e-cigarettes to minors were enacted, only that the decline in prevalence of cigarette smoking slowed in states where such restrictions were enacted relative to states that did not. Second, the fact that the study examines a period very early on in the development of the market for ENDS products may also limit the inferences that can be drawn for substitution and dual usage patterns that will emerge as the market matures. Third, the ''increase'' in the prevalence of youth smoking is relative to what would have been predicted from ongoing trends; in both states that did and states that did not enact restrictions, the prevalence of youth smoking continued to decline, just at a slower rate in the states that enacted bans. Finally, given these issues, FDA acknowledges this paper as a first attempt to study potential impacts of youth ENDS access restrictions, but more research will be necessary to explore the potential effects of this rule on product switching or dual usage.

(Comment 34) Some comments suggested that FDA should establish a monograph-like system to allow e-cigarettes seeking to enter the market to be compared to a baseline or ''model'' e-cigarette. In addition, a few comments suggested that combustible product manufacturers should also be able to compare their products to a reference product to ease SE burdens.

(Response) FDA disagrees as these suggested alternatives are not consistent with the Tobacco Control Act. Under the SE pathway, FDA must determine if the new tobacco product raises different questions of public health than an identified, and valid, predicate product. To be an eligible predicate product under section 910 of the FD&C Act, the product must have been commercially marketed in the United States on February 15, 2007, or been previously found substantially equivalent.

Moreover, elsewhere in this issue of the **Federal Register**, FDA has made available a final guidance to provide information for manufacturers on how to establish and reference a Tobacco Product Master File (TPMF). We expect reliance on TPMFs to increase efficiency and reduce any burdens on manufacturers. As discussed in section IX, because of the nature of upstream supply of many components for ENDS products, especially e-liquids, FDA anticipates that commercial incentives will be sufficient to drive manufacturer reliance on the system of master files. We note that, at present, FDA understands that, based on the Agency's review of publically available data, the number of entities engaged in upstream production of liquid nicotine and flavors specifically developed for use with e-liquids is small. Specifically, based on internet searches and information provided on firm Web sites, FDA estimates that there are roughly five to ten major pure liquid nicotine suppliers, most of which claim to have a significant market share.[10] Several of these companies already have master files with FDA for their nicotine products or report that they are ready to file submissions to meet U.S. and EU regulatory requirements. An online search of flavor manufacturers revealed many suppliers of flavorings that can be added to food or other consumer products; any of these products potentially could be used as e-liquid flavoring. However, FDA searches identified only two to three flavor houses that make flavoring specifically for e-liquids.[11] Given these realities of the marketplace, FDA expects that the master file system will be widely appealing and widely utilized by the ENDS industry.

(Comment 35) Comments suggested that the ''appropriate for the protection of the public health'' standard for PMTAs was meant for those products with well-established risks to consumers and should not apply to e-cigarettes. They suggested that FDA establish a different standard for issuing PMTA orders for e-cigarettes (*i.e.,* that the product is no more hazardous than currently marketed tobacco products).

(Response) FDA disagrees with comments suggesting the use of a different standard for e-cigarettes and other ENDS. Section 910(c)(4) specifies the standard FDA is to apply in deciding whether to issue a PMTA marketing authorization order. That section states that the product must be ''appropriate for the protection of the public health'' which ''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.'' FDA is not authorized to deviate from this statutory standard.

(Comment 36) Some comments recommended that FDA deem products currently on the market without subjecting those products to the statute's premarketing requirements. Similarly, some comments argued that the premarket requirements should not apply to specific categories of products (specifically, e-cigarettes and other novel tobacco products), including those that are introduced after the enactment of the rule. They stated that

[10] See, *e.g.,* Ref. 43. FDA Internet searches included review of Web sites identifying product suppliers, such as *www.thomasnet.com* and *www.alibaba.com*, as well as manufacturer Web sites and news reports on the market.

[11] FDA Internet searches included review of Web sites identifying product suppliers, such as *www.thomasnet.com* and *www.alibaba.com*, as well as manufacturer Web sites and news reports on the market.

this large burden does not have a clear benefit to public health.

(Response) The statute automatically subjects deemed products to the statutory requirements for ''tobacco products'' in chapter IX of the FD&C Act. Once deemed, the products are subject to all statutory provisions that apply to all tobacco products covered by the FD&C Act. See section 901(b) of the FD&C Act (''This subchapter shall apply to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Secretary by regulation deems to be subject to this subchapter.''). Section 910, which establishes the procedures that must be followed before a new tobacco product can be authorized for marketing, is one of the statutory provisions that apply automatically to all tobacco products, including newly deemed products. FDA believes that the premarket review requirements will, in fact, benefit public health, as discussed in the NPRM (79 FR 23142 at 23148 and 23149).

(Comment 37) Some comments stated that FDA must get a better scientific understanding of e-cigarettes before finalizing the compliance period for premarket review of these products. One comment also proposed a system in which FDA could create product standards under section 907 of the FD&C Act for the entire category of e-cigarettes and then approve or reject PMTAs for individual e-cigarettes based upon whether they meet the standards.

(Response) FDA disagrees with comments suggesting that the Agency needs additional time before determining an appropriate compliance period for the premarket review requirements for ENDS. As we have stated throughout the document, FDA has data regarding health harms generally associated with all of the categories of tobacco products regulated under this rule (including ENDS). FDA is regulating these products in accordance with this knowledge. FDA also disagrees with comments suggesting that FDA can change the statutory requirements and standards for issuing PMTA orders. FDA's revised compliance policy for submission of PMTAs and other premarket submissions is discussed in section V.A.

(Comment 38) At least one comment suggested that applicants be able to utilize publications regarding scientific understanding of e-cigarettes as harm reduction products to support their PMTAs.

(Response) FDA agrees that applicants can include scientific literature as part of their PMTA submission pursuant to section 910(b)(1). In addition, elsewhere in this issue of the **Federal Register**, FDA has made available draft guidance, which when final will describe FDA's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products, including the use of scientific literature.

(Comment 39) Comments recommended that FDA issue PMTA orders based only on HPHC data and appeal to children, as well as a manufacturer's postmarketing commitments to conduct long-term studies regarding effects of e-cigarette use (similar to the supplemental application processes for new drug applications (NDA) and device premarket approval supplement regimes codified in 21 CFR 314.70 and 814.39, respectively). Comments also suggested that FDA create a supplemental PMTA for modifications and minor modifications to tobacco products so each product would not require a full PMTA.

(Response) FDA disagrees. The statutory authorities for FDA's regulation of drugs, devices, and tobacco products are different. Section 506A of the FD&C Act (21 U.S.C. 356a) authorizes FDA to utilize a supplemental NDA process allowing manufacturers to make manufacturing changes to approved drugs and section 515 (21 U.S.C. 360e) allows device manufacturers to supplement their premarket approval applications for modifications to products. Although FDA does not have the same ability to allow an applicant to obtain an authorization and later supplement the application (given the different statutory scheme for tobacco products), FDA is actively considering other opportunities for efficiency and streamlining in the PMTA process, consistent with its mission to protect the public health.

(Comment 40) One comment suggested that FDA publish guidance on how the Agency will determine whether an e-cigarette is substantially equivalent to a predicate product. According to this comment, the SE review should focus on the aerosol delivered to the consumer to determine whether a new e-cigarette raises different questions of public health.

(Response) FDA may issue guidances for specific product categories at a later date. However, FDA finds that the available guidance for SE reports should be sufficient to assist manufacturers in preparing reports and to advise them of the factors FDA considers when assessing SE reports, as evidenced by the fact that the agency has issued many orders regarding SE to applicants that have utilized the available guidance (for the most recent SE actions, see *http://www.fda.gov/TobaccoProducts/Labeling/MarketingandAdvertising/ucm435693.htm*). Previously issued SE orders were for products whose applications may differ substantially from those for the newly deemed tobacco products. As required by section 910(a)(3)(A) of the FD&C Act and as stated in FDA's guidance documents, the Agency must consider product characteristics when evaluating SE reports. The constituents found in e-cigarette aerosol are just some of the characteristics that FDA will consider when reviewing SE reports for e-cigarettes. Other characteristics include the materials, other ingredients, design, composition, heating source, and other features of the e-cigarette (see section 910(a)(3)(B)). We also encourage prospective applicants to review the applications FDA posts on *www.fda.gov* for examples of products that have different characteristics but do not raise different questions of public health when compared with the specified predicate product.

(Comment 41) Some comments provided several suggestions as to how FDA can craft the PMTA process to acknowledge the position of e-cigarettes on the continuum of nicotine-delivering products. For example, they indicated that e-cigarettes should not need to undergo a rigorous, comprehensive premarket review process and, instead, should be given an abbreviated pathway that would allow FDA to achieve the same objectives. For example, some comments suggested that, in order to streamline the process, a PMTA for an e-cigarette should be required to contain only the following: (1) A sample of the product; (2) specimens of proposed labeling; (3) a description of the product's principles of operation; (4) ingredient listing for e-liquids; (5) a description of methods of manufacturing and processing; and (6) a description of quality control and product testing systems. They suggested that FDA could require e-cigarettes to comply with product standards once they are established.

Other comments urged FDA to impose strict regulations on the sale of e-cigarettes, including extensive premarket review, to ensure that future generations are not burdened by nicotine addiction. While some of these comments noted that there may be potential benefits to some individuals, they believed the Agency cannot lower its scientific standards, weaken its requirements for rigorous science, or change its requirements for evaluating the public health impact of e-cigarettes. To determine eligibility for expedited

review or an abbreviated pathway, these comments stated that FDA must recognize that: (1) The use of any tobacco product, including a well-regulated e-cigarette, poses a greater risk than using no tobacco product; and (2) the scientific evidence does not demonstrate substantial reduction in harm to an individual from e-cigarette use if the consumer dual uses with cigarettes, except when dual use is a short-term pathway to quitting smoking cigarettes.

(Response) Section 910(b) of the FD&C Act lays out the specific elements to be submitted in a PMTA and 910(c)(2)(A) specifies that FDA cannot authorize the marketing of a product where there is a lack of showing that the marketing of a new tobacco product is ''appropriate for the protection of the public health.'' The FD&C Act states that this finding will be determined, when appropriate, on the basis of well-controlled investigations (section 910(c)(5)(A)). However, section 910(c)(5)(B) of the FD&C Act also allows the Agency to consider other ''valid scientific evidence'' if found sufficient to evaluate the tobacco product. Thus, if an application includes, for example, information (*e.g.,* published literature, marketing information) with appropriate bridging studies, FDA will review that information to determine whether it is valid scientific evidence sufficient to demonstrate that a product is appropriate for the protection of the public health. If an applicant has questions or other alternatives to well-controlled investigations it would like to utilize, we recommend that the applicant meet with FDA to discuss the approach prior to preparing and submitting an application (see FDA guidance ''Meetings with Industry and Investigators on the Research and Development of Tobacco Products''). In addition, elsewhere in this issue of the **Federal Register**, FDA has made available ENDS PMTA draft guidance which, when final, will describe FDA's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products.

(Comment 42) Given the differences among newly deemed product categories and the potential benefits from these products, some comments said that FDA should develop clear guidance regarding the scientific evidence the Agency will need to review the safety and health impact of these products and to accelerate the review of marketing applications where necessary.

(Response) To help provide clarity regarding submission requirements for marketing applications, FDA has issued several guidance documents, and is finalizing other guidance documents, regarding the evidence needed for SE reports, including FDA draft guidance entitled ''Substantial Equivalence Reports: Manufacturer Requests for Extensions or to Change the Predicate Tobacco Product'' (79 FR 41292, July 15, 2014), and FDA guidance entitled ''Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007,'' among others. FDA also has issued a draft guidance entitled ''Applications for Premarket Review of New Tobacco Products'' (76 FR 60055, September 28, 2011). In addition, elsewhere in this issue of the **Federal Register**, FDA has made available draft guidance, which when final will describe FDA's current thinking on some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products. If FDA determines that additional guidance is necessary to help manufacturers prepare marketing applications, FDA will issue additional guidance and publish a notice of availability in the **Federal Register**.

(Comment 43) One comment stated that, because there is a lack of scientific evidence to show the health impact of vapor products, applying the premarket requirements to this category of products is premature. Therefore, the comment suggested that FDA exercise enforcement discretion to delay implementation of this requirement until more evidence is available.

(Response) FDA has established a compliance policy regarding the premarket review requirements. This is described in section V.A. As discussed elsewhere in this document, we believe the compliance period is appropriate, and it takes into account the time for firms to generate and submit the information for a PMTA. The requirements and costs of a PMTA may vary based on the type and complexity of the product. For example, where there is limited understanding of a product's potential impact on public health, nonclinical and clinical studies may be required for market authorization. In such case, the requirements and cost of the PMTA likely would be higher (and the review time longer) than for a product in which there is already substantial scientific data on the potential public health impact. This information provided as part of premarket review (design, ingredients, levels of HPHCs) will provide critical information on these products.

(Comment 44) One comment suggested that FDA regulate e-cigarettes as an adult consumer product without providing additional details.

(Response) It is unclear what this comment envisioned by suggesting that FDA regulate e-cigarettes as an adult consumer product. Nevertheless, FDA must regulate tobacco products in accordance with the Tobacco Control Act, including section 910 of the FD&C Act, which states that in reviewing PMTAs for new tobacco products, FDA must consider whether the marketing of such product is appropriate for the protection of the public health, and that this finding is to be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the product, taking into account—the increased or decreased likelihood that existing users of tobacco products will stop using such products; and the increased or decreased likelihood that those who do not use tobacco products will start using such products (section 910(c)(4) of the FD&C Act). This public health standard requires the Agency to consider the impact of the products on the ''population as a whole,'' not simply the adult population that may be using such products.

(Comment 45) Some comments stated that FDA regulations should support manufacturers' efforts to invest in alternative tobacco products with the potential to reduce harm.

(Response) The Agency continues to support development of alternative tobacco products with the potential to reduce harm, and believes that the PMTA, MRTP, and other regulatory provisions will help foster the development of tobacco products that pose less risk to human health. In addition, as a practical effect of the Agency's compliance policy for premarket review of newly deemed tobacco products, FDA expects that many manufacturers, including those with alternative tobacco products, will continue to market their products during preparation of submissions and for the continued compliance period afterward. The time it takes to review premarket applications is dependent upon the type of application and the complexity of the product.

G. Other Comments

(Comment 46) A few comments suggested that FDA review and authorize marketing of products at the ingredient level. For example, if a tobacco product contained only preauthorized ingredients, the product could be marketed, possibly through self-certification. If the product used unapproved ingredients, the manufacturer would be required to

submit a PMTA containing information on only those ingredients or meet established testing guidelines. The comments suggested that standards that could be used to assess the ingredients may include the U.S. Pharmacopeial Convention (USP), FDA's Generally Recognized as Safe (GRAS) standards, the New Drug Products Q3B(R2) guidance; and the Food Chemicals Codex or FDA Redbook of Foods.

(Response) FDA disagrees. Section 910 of the FD&C Act requires FDA to evaluate the new tobacco product as a whole to determine whether the authorization of marketing of the product is appropriate for the protection of the public health. In addition, we note that GRAS status for a food additive does not mean that the substance is GRAS when inhaled, since GRAS status does not take inhalation toxicity into account and applies only to intended uses that may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (section 201(s) of the FD&C Act.).

(Comment 47) A few comments expressed concern as to the contemplated compliance periods for HPHC testing (with a proposed compliance period of 3 years following the effective date of the final rule) and the contemplated 24-month compliance period for marketing applications, because applicants will need to submit HPHC data with their PMTAs. They requested that FDA delay its enforcement of PMTA and SE application requirements until it has established an HPHC list and validated methodology for individual products.

(Response) While applicants should submit certain information about HPHCs as part of their applications, the requirement to submit HPHC listings under section 904 of the FD&C Act (21 U.S.C. 387d) is separate and distinct from the premarket review requirements under section 910. HPHC information submitted under section 904 will assist FDA in assessing potential health risks and determining if future regulations to address a product's health risks are warranted. For PMTAs, FDA expects that applicants will report the levels of HPHCs as appropriate for each product, so the reported HPHCs will differ among different product categories. Elsewhere in this issue of the **Federal Register**, FDA has made available draft guidance, which when final will describe FDA's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products, including information regarding HPHCs. The Agency recommends that manufacturers consult with CTP's OS about what is appropriate in the context of a specific application.

FDA recognizes, however, that it could be difficult for certain manufacturers of the newly deemed products (*e.g.,* small businesses) to comply with the section 904 HPHC requirements for all of their currently marketed products. For example, contract laboratories may not be prepared for the large volume of requests for the testing of quantities of the HPHCs for all brands and subbrands of tobacco products marketed prior to the effective date. Thus, we have established a compliance period of 3 years for submission of this data under section 904 for products on the market as of the effective date. In addition, in the context of all newly deemed products considered in total, many products may be grandfathered and will thus not be required to obtain premarket authorization through one of three pathways—SE, exemption from SE, or premarket tobacco product applications (sections 905 and 910 of the FD&C Act). Given that the number of newly deemed products in total seeking PMTA orders likely will be much smaller than the total number of such tobacco products on the market as of the effective date (given that many products will be grandfathered and that some products may exit without submission of an application), FDA expects that the HPHC information submitted as part of these PMTA applications can be obtained within the 2-year submission period for newly deemed tobacco products. (FDA notes that the proportion of products that may qualify as grandfathered is likely to vary for different product categories. For example, the ENDS product category, for which the market has changed dramatically since 2007, is likely to have a smaller proportion of grandfathered products than some other product categories.)

Moreover, elsewhere in this issue of the **Federal Register**, FDA has made available a final guidance to provide information on how to establish and reference a Tobacco Product Master File (TPMF). FDA notes that we expect reliance, to the extent applicable, on TPMFs to increase efficiency and reduce any burdens on manufacturers. As discussed in section IX, because of the nature of upstream supply of many components for ENDS products, especially e-liquids, FDA anticipates that commercial incentives will be sufficient to drive manufacturer reliance on the system of master files. We note that, at present, FDA understands, based on publically available information, that the number of entities engaged in upstream production of liquid nicotine and flavors specifically developed for use with e-liquids is in the range of seven to thirteen entities (see earlier discussion in response to comment 34). Given the nature of the marketplace, FDA expects that the master file system will be widely appealing and widely utilized by the ENDS industry.

(Comment 48) Several comments noted that large numbers of tobacco product manufacturers waited until March 22, 2011 (the date that provisional SE reports were due for the original tobacco products subject to the FD&C Act) to submit their SE reports. They considered this an abuse of the process and expressed concern that manufacturers of newly deemed products would act similarly, particularly with a 24-month compliance period. They suggested that FDA expressly require companies to meet all other requirements, including ingredient reporting and quality controls, to be able to avail themselves of this extended compliance period. Other comments stated that any compliance period should be contingent on FDA issuing orders on all pending SE reports already submitted to the Agency.

(Response) FDA understands concerns about the Agency's timely review of applications given the influx of SE reports that FDA received at the close of the SE provisional period (March 22, 2011). However, FDA has taken several steps to address the resulting backlog and to provide helpful feedback to industry to encourage more complete, streamlined submissions and reviews, including: (1) Encouraging teleconferences between the assigned regulatory health project manager and the applicant; (2) streamlining the SE report review process by modifying the preliminary review so that it focuses only on administrative issues and allowing submission deficiencies to be communicated to the applicant more quickly; (3) providing information on FDA's Web site about the three pathways available to market products (including SE) and developing public Webinars to explain the Agency's processes; and (4) publishing guidance documents. On March 24, 2014, FDA announced that the Agency no longer has a backlog of regular SE reports awaiting review. The Agency is now reviewing regular SE reports as they are received. FDA expects that these steps will help reduce the time it will take FDA to review submissions for newly deemed products. In addition, FDA has specified end dates for the compliance

periods for such products, after which such products on the market without authorization (even if applications submitted during the relevant compliance periods are still under review) will be subject to enforcement. We note that these staggered compliance dates will help to manage the flow of applications into FDA. If an applicant wishes to discuss a product application, the applicant may request a meeting as set forth in FDA's final guidance entitled ''Meetings with Industry and Investigators on the Research and Development of Tobacco Products'' (announced May 25, 2012, 77 FR 31368).

(Comment 49) At least one comment suggested that FDA should require manufacturers that have not received their marketing authorizations within 1 year after the effective date of the final deeming to include a statement on their packaging and labeling indicating that the product is pending FDA evaluation under the Tobacco Control Act.

(Response) FDA declines to issue such a labeling requirement at this time. We do not have evidence that the statement will be appropriate for the protection of the public health, as determined with respect to the risks and benefits to the population as a whole (which is the standard for such a requirement under section 906(d) of the FD&C Act). FDA also is concerned about consumer confusion or misconceptions that could result from such a requirement.

(Comment 50) At least one comment suggested that application of premarket review requirements to the newly deemed products (namely, e-cigarettes) is unnecessary, because the benefits that would accrue as a result of deeming are independent of the premarket review provisions.

(Response) FDA disagrees. The premarket provisions of the statute apply automatically to deemed products. While FDA outlined in the NPRM a number of public health benefits that would accrue as a result of deeming products subject to chapter IX as a whole (79 FR 23142 at 23148 and 23149), as explained in this document, FDA believes that the public health benefits that will accrue from the premarket review provisions are substantial. Implementation of these provisions will allow FDA to monitor product development and to prevent potentially more harmful or addictive products from reaching the market. Premarket review is especially critical given the changing nature of the ENDS technology and industry and the increasing interest in these products from youth and young adults. FDA's premarket review also will increase product consistency. For example, FDA's oversight of the constituents of e-cigarette and other ENDS cartridges will 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 among some products—including variability between labeled content and concentration and actual content and concentration (see section VIII.D). Without a regulatory framework, users will be subject to significant variability among products, raising potential public health and safety issues.

IV. Implementation

FDA's proposal stated that part 1100, deeming additional tobacco products to be subject to chapter IX of the FD&C Act, and the minimum age and identification and vending machine restrictions in part 1140 would be effective 30 days after publication of the final rule and listed compliance periods for different requirements. FDA received many comments regarding the proposed effective date, compliance periods, and other enforcement issues. A summary of these comments and FDA's responses are included as follows.

A. Effective Date for Rule

FDA proposed that part 1100, deeming products to be subject to the chapter IX automatic provisions, and the minimum age and identification and vending machine restrictions in part 1140 be effective 30 days from the publication date of the final rule. Based on our review of comments, FDA is finalizing this rule so that the automatic provisions, minimum age provisions, and vending machine restrictions will be effective 90 days from the date of the final rule's publication, as explained in this document. The compliance periods for other sections are discussed in this section.

(Comment 51) A few comments expressed concern regarding the effective date of the deeming provisions in part 1100, which is also the effective date of the minimum age and identification regulations. They stated that a 30-day effective date for the minimum age and identification regulations provides too small a window of time for retailers to adjust employee training curricula, train and educate employees, raise awareness of the new requirements, and adjust in-store or point-of-sale job aids to ensure compliance. These comments requested a 6-month compliance period for both the youth access and vending machine provisions.

(Response) FDA recognizes that certain retailers may need more than 30 days to begin compliance with the youth access and vending machine restrictions included in this rule. For example, ENDS retail establishments or cigar retailers that have not previously been subject to similar restrictions for cigarettes and smokeless tobacco may need additional time to implement these regulations. To address these situations, FDA is establishing a 90-day effective date for this deeming provision and the accompanying automatic provisions in the FD&C Act, as well as the minimum age and identification requirements and vending machine restrictions. FDA does not believe that a 6-month compliance period is necessary to educate retailers on these requirements given that many retailers also sell products that are currently subject to Federal and/or State and local regulations regarding minimum age and identification.

(Comment 52) Some comments suggested that FDA delay the effective dates of all deeming provisions until the Agency can issue product standards (under section 907) and good manufacturing practice regulations (under section 906(e)), as these are the most important requirements for the newly deemed products. They stated, however, that all rulemaking on e-cigarettes should be delayed until the science is firmly established to allow for more informed FDA decisionmaking.

(Response) FDA disagrees. As we have stated throughout the document, FDA has data regarding health harms generally associated with all of the categories of tobacco products regulated under this rule (including ENDS). FDA is regulating these products in accordance with this knowledge. We will continue to build upon our product-specific knowledge through the information we receive as a result of the application of the FD&C Act's automatic provisions, such as ingredient reporting and the reporting of HPHCs, to newly deemed tobacco products. In addition, as discussed in the NPRM, FDA believes that many public health benefits will accrue as a result of deeming these products (79 FR 23142 at 23148 and 23149). It would not protect the public health to forego implementation of these provisions until FDA can issue final product standards and tobacco product manufacturing practice regulations. It is also important to note that this final deeming rule is a foundational rule that enables FDA to issue future regulations if FDA determines that they would be appropriate for the protection of public health.

(Comment 53) Comments stated the NPRM is a ''major rule'' according to the

Office of Information and Regulatory Affairs, 5 U.S.C. 804(2) (1996), and the Congressional Review Act mandates that the rule cannot take effect until 60 days after the final rule is published in the **Federal Register** (5 U.S.C. 801(a)(3) (1996)). Therefore, they requested that FDA change the effective date for this rule and the compliance periods for parts 1100 and 1140 to at least 60 days following publication of the final rule.

(Response) FDA is providing a 90-day effective date for parts 1100 and 1140 with this final rule.

B. Compliance Periods for Certain Provisions

To avoid confusion about existing dates in the FD&C Act that are based on the date of enactment of the law and to provide time for firms to comply with provisions that require labeling changes or information submissions to the Agency, FDA proposed compliance timeframes for certain provisions. The final compliance dates are included in tables 2 and 3.

(Comment 54) Comments requested that FDA impose the same requirements on the newly deemed products that apply to currently regulated products, including the same compliance periods for all provisions and the same marketing and advertising restrictions. In addition, they stated that establishing exemptions would create a significant administrative burden for FDA, and that a single, comprehensive plan would be easier for industry to understand and for the Agency to implement.

(Response) With this final rule, FDA is deeming additional tobacco products subject to its chapter IX tobacco authorities. This means that newly deemed products will be subject to all provisions in the FD&C Act applicable to ''tobacco products'' in the same way that currently regulated tobacco products are also subject to those provisions. Under section 901, FDA is authorized to deem products subject to ''chapter IX,'' not to particular provisions of chapter IX. Thus, there are no exemptions from particular requirements for any product category (although FDA is announcing enforcement policies for certain requirements and for small-scale tobacco product manufacturers as discussed throughout this document). FDA is subjecting covered tobacco products to the additional provisions (*i.e.,* age and identification requirements, vending machine restrictions, and health warning requirements) discussed in this final rule. If FDA later determines that further marketing and advertising restrictions for newly deemed products are appropriate and meet the applicable standard in section 906(d), FDA will follow the requirements of the APA to implement such restrictions.

With respect to compliance periods, FDA is providing different compliance periods for certain automatic requirements of the FD&C Act that are generally similar to the timeframes provided in the statute for currently regulated products to meet certain requirements after the law's date of enactment.

1. HPHC Reporting Requirements (Section 904)

As of the effective date of this rule, the ingredient listing and HPHC reporting requirements of section 904 will apply to the newly deemed products. To provide manufacturers sufficient time to comply with these requirements, FDA is providing compliance periods for these requirements as stated in table 3.

(Comment 55) Most comments agreed with the compliance timeframes included in table 1B of the NPRM, aside from the HPHC requirements under section 904(a)(3) (79 FR 23142 at 23172 through 23174). They argued that the compliance period for testing and listing of HPHCs was not sufficient for several reasons, including: The costs associated with compliance; the lack of clear product-specific guidance; and the lack of available independent laboratories to complete the testing for the many small businesses that would be affected by the requirements.

(Response) The compliance period for HPHC reporting under section 904(a)(3) is the effective date of this rule plus 3 years. FDA intends to issue guidance regarding HPHC reporting, and later a testing and reporting regulation as required by section 915, with enough time for manufacturers to report given this compliance period. Section 904(a)(3) requires the submission of a report listing all constituents, including smoke constituents, identified as harmful or potentially harmful (HPHC) by the Secretary. Section 915 requires the testing and reporting of the constituents, ingredients, and additives the Secretary determines should be tested to protect the public health. The section 915 testing and reporting requirements apply only after FDA issues a regulation implementing that section, which it has not yet done. Until these testing and reporting requirements have been established, newly deemed tobacco products (and currently regulated tobacco products) are not subject to the testing and reporting provisions found under section 915. As noted elsewhere in this document, FDA does not intend to enforce the reporting requirements under section 904(a)(3) for newly deemed products before the close of the 3-year compliance period, even if the HPHC guidance is issued well in advance of that time. In addition, at this time, FDA also does not intend to enforce this requirement in relation to manufacturers of components and parts used for incorporation into finished tobacco products. In this context, a finished tobacco product refers to a tobacco product, including all components and parts, sealed in final packaging intended for consumer use (*e.g.,* filters or filter tubes sold separately to consumers or as part of kits). FDA considers an e-liquid to be a finished tobacco product if sold separately and not as part of an ENDS.

The Agency is committed to helping industry better understand the tobacco product review process and the requirements of the law and will continue holding public Webinars and meetings with industry. FDA has also published guidance on meetings with industry; this has enabled FDA to have many productive meetings to address companies' specific questions on their development of tobacco products. In addition, FDA intends to issue guidance regarding HPHC reporting, and later a testing and reporting regulation as required by section 915, with enough time for manufacturers to report given the 3-year compliance period for HPHC reporting. As noted elsewhere in this document, FDA does not intend to enforce the reporting requirements under section 904(a)(3) for newly deemed products before the close of the 3-year compliance period, even if the HPHC guidance is issued well in advance of that time.

2. Registration and Listing (Section 905)

As of the effective date of this rule, those persons who own or operate domestic manufacturing establishments engaged in manufacturing newly deemed tobacco products (including those that engage in the blending of pipe tobacco and the mixing of e-liquids as discussed in section IX.C) will be required to register with FDA and submit product listings under section 905. This deeming rule will not require foreign manufacturing establishments to register their establishments or to list their tobacco products in order to sell them in the United States. However, foreign manufacturing establishments will be required to comply with the registration and listing requirements of section 905 of the FD&C Act after a registration and listing rule is final and effective. Because the compliance period for registration and listing

depends on the date of publication of this final rule, FDA intends to revise the current guidance (''Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments''), which FDA expects to issue within six months following the effective date of the final deeming rule, to clarify the compliance periods for manufacturers of newly deemed tobacco products.

(Comment 56) Most of those comments regarding the registration and listing requirements stated that the contemplated compliance period was sufficient, because these requirements are not costly or time-consuming for manufacturers, provided FDA's electronic submission system is working effectively. A minority of comments asked for a longer compliance period that would be based on FDA published guidance for individual product categories that includes examples of completed registration and listing forms.

Most of the comments also stated that foreign and domestic companies should be required to comply with registration and listing requirements at the same time to ensure fair and equal treatment among each product category. They stated that this was especially important given that many of the novel products are manufactured outside the United States and that comprehensive registration requirements will promote equitable assessment and collection of user fees.

(Response) FDA agrees with comments stating that the contemplated compliance period for registration and listing is sufficient. To provide additional assistance to newly deemed product manufacturers, FDA intends to provide examples of completed registration and listing forms for each major category of newly deemed products at least 6 months before the end of the compliance period. In addition, in 2013, CTP adopted a new electronic system, FDA Unified Registration and Listing System (FURLS), with capacity to accept registration and listing submissions for all FDA-regulated products, which has and will continue to simplify the process of submitting registration and listing information, making it more efficient for industry and providing faster access to this information by both FDA and industry. Unlike the previous eSubmitter process, FURLS is an online application that allows users to access multiple databases simply by going to the FURLS Web site and viewing and updating their data at any time. Questions regarding registration and listing requirements can be directed to CTP's call center at 1–877–CTP–1373 and to CTP's Office of Small Business Assistance, which is part of OCE.

Further, section 905 of the FD&C Act requires FDA to issue a rule through the notice and comment rulemaking process in order to apply the registration and product listing requirements to foreign manufacturers—the requirements for domestic manufacturers are immediately implemented and do not require a regulation. (Section 905(h) of the FD&C Act.) FDA has announced its intent to issue a rule regarding registration and listing, including application of the requirements to foreign manufacturers, in the Unified Agenda (RIN No. 0910–AG89).

3. Modified Risk (Section 911)

As of the effective date of this rule, section 911 will automatically apply to the newly deemed products. Among other requirements, this section prohibits the introduction or delivery for introduction into interstate commerce of MRTPs, including those with certain specified descriptors (''light,'' ''low,'' ''mild,'' or similar descriptors) in the label, labeling, and advertising of such products, unless manufacturers submit a MRTP application and receive FDA authorization before marketing. The basic requirement for premarket review of MRTPs will apply immediately upon the effective date. To provide manufacturers sufficient time to comply with the prohibition on products with specified descriptors, FDA is providing a compliance period for this requirement, as stated in table 3.

(Comment 57) The comments generally stated the 1-year compliance period for section 911(b)(2)(A)(ii) was sufficient, but some stated that it was unnecessary for FDA to provide any compliance period and that manufacturers should begin complying with these provisions upon the final rule's effective date.

(Response) FDA believes that the 12-month period to comply with the restrictions set forth in section 911(b)(2)(A)(ii) (after which a manufacturer may not manufacture, without an order in the effect, any tobacco product which contains ''light,'' ''low,'' or ''mild,'' or similar descriptors on label, labeling, or advertising), and the additional 30-day period where manufacturers may continue to distribute products into domestic commerce, are consistent with the effective dates originally included in the Tobacco Control Act. Under section 911(b)(3), the prohibition on the manufacture and distribution of tobacco products containing ''light,'' ''low,'' or ''mild,'' or similar descriptors appearing on labeling, labels, or advertising (unless an order was issued authorizing their marketing) took effect 12 months after the date of enactment of the Tobacco Control Act, and manufacturers also had an additional 30 days after the effective date to continue to introduce these products with these descriptors into domestic commerce. Additionally, this compliance policy balances the need to help consumers better understand and appreciate the health risks of these newly deemed tobacco products while providing manufacturers with sufficient time to revise the label, labeling, and advertising as appropriate.

This compliance policy does not extend to other MRTPs as defined in the remaining sections of 911(b) (*e.g.,* tobacco products of which the label, labeling, or advertising explicitly or implicitly represents that the product presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products, the product or its smoke contains a reduced level/presents a reduced exposure to a substance, or the product or its smoke does not contain/is free of a substance; or action taken by a manufacturer directed to consumers through media or otherwise, other than through the product's label, labeling, or advertising that would be reasonably expected to result in consumers believing that the tobacco product or its smoke may present a lower risk of disease or is less harmful than one or more commercially marketed tobacco products, or presents a reduced level/exposure to substance(s), or does not contain/is free of a substance(s)). Just as these provisions took effect immediately upon the enactment of the Tobacco Control Act for currently regulated products, newly deemed products will be expected to comply with these provisions on the effective date of part 1100. The agency believes this is necessary in order to ensure that consumers better understand and appreciate the health risks of newly deemed products, particularly where a product's label, labeling, or advertising makes express or implied claims of reduced risk or less harm or that a product has reduced levels of or is free of a substance(s).

4. Required Warnings

(Comment 58) A few comments suggested that manufacturers should be required to implement the proposed health warnings within 6 months following the effective date of this rule. One comment stated that the health warnings should take effect no later than 12 months from publication of the

final rule. They stated that the delay in implementing the health warnings has the potential to continue to foster the perception, particularly on the part of youth, that e-cigarettes are safe products and the misunderstanding that they have been found to be safe and effective cessation products. They also stated that the shorter compliance period is necessary to quickly make consumers aware of the possibility of becoming addicted to e-cigarettes.

(Response) FDA has considered the comments and the time and resources it will take for manufacturers to comply with the health warnings requirements and the need to provide these messages to consumers and has determined that the proposed effective date of 24 months after publication of this rule for the warning requirements in part 1143 is appropriate.

5. Compliance Period Tables

The final compliance period table for various provisions is included in this document. (The compliance policy for submission of premarketing applications is discussed in section V.A.) To clarify, effective dates differ from compliance periods. While a requirement is effective on a certain date (here, the ''effective date''), for many provisions, FDA is providing a compliance period with additional time during which FDA does not intend to enforce compliance with the regulation. We note that the compliance periods and provisions for sections 904(a)(3) and 904(a)(4) have been consistent with FDA's approach for currently marketed tobacco products and FDA's final guidance entitled ''Tobacco Health Document Submission'' (75 FR 20606, April 20, 2010). In addition, FDA has revised the compliance period for section 903(a)(8) of the FD&C Act from ''effective date of part 1100 PLUS 1 year'' to ''24 months after the publication of this final regulation'' so that it is consistent with the effective dates for the health warning requirements in part 1143 of this final rule.

TABLE 2—COMPLIANCE WITH VARIOUS AUTOMATIC PROVISIONS

FD&C Act citation	Compliance period
902(1)–(5), (8)	Effective date of part 1100.
903(a)(1)	Effective date of part 1100.
903(a)(6)–(7)	Effective date of part 1100.
904(c)(2), (3)	Effective date of part 1100.
905(i)(3)	Effective date of part 1100.
911(a), 911(b) [with the exception of products sold or distributed using the descriptors set forth in 911(b)(2)(A)(ii)].	Effective date of part 1100.
919(a)	See FDA's final rule revising the current user fee regulations published concurrently with this final deeming rule.

TABLE 3—COMPLIANCE PERIODS FOR OTHER PROVISIONS

FD&C Act citation	Compliance period
903(a)(2)	24 months after the publication of this final regulation. * This is designed to match the 24 month effective date of the health warnings.
903(a)(3)	Effective date of part 1100 PLUS 1 year. * This is designed to match the 1 year deadline in the FD&C Act for currently regulated products.
903(a)(4)	24 months after the publication of this final regulation. * This is designed to match the 24 month effective date of the health warnings.
903(a)(8)	24 months after the publication of this final regulation. * This is designed to match the 24 month effective date of the health warnings.
904(a)(1), 904(c)(1)	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). * This matches the timeframes provided in this section.
904(a)(3)	Effective date of part 1100 PLUS 3 years or, for products delivered for introduction into interstate commerce later than 3 years after the effective date, 90 days before delivery for introduction into interstate commerce (products entering the market after the effective date). * This matches the timeframes provided in this section.
904(a)(4)	Effective date of part 1100 PLUS 6 months. * This matches the timeframes provided in this section.
905(b), (c), (d), (h)	If the final rule publishes in the second half of the calendar year, FDA intends to issue a compliance policy with a compliance period for registration that is no later than 6 months into the subsequent calendar year. * This matches the timeframes provided in this section.
905(i)(1)	Same compliance period as that for initial registration; see date specified for 905(b).
907(a)(1)(B)	Effective date of part 1100 PLUS 2 years. * This matches the timeframe provided in this section.
911(a), (b)(1), (b)(2)(A)(ii), (b)(3)	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). * This matches the timeframes provided in this section.
920(a)(1)	24 months after the publication of this final regulation. * This is designed to match the 24 month effective date of the health warnings.

6. Other Enforcement Issues

(Comment 59) A few comments expressed concern that this rule will result in the growth of an illicit market for certain newly deemed tobacco products, particularly e-cigarettes and e-liquids. They suggested that such an illicit market could make products more available and more attractive to youth and young adults. They also feared that this illicit market would worsen if FDA were to ban certain e-liquid flavorings, stating that the deeming rule (and/or a ban on certain flavorings) would result in consumers mixing their own e-liquids, even though the comments stated that most consumers are not adept at handling or mixing chemicals. These ''do-it-yourself manufacturers,'' as the comments referred to them, would increase health risks, because more individuals possessing pure nicotine could lead to more accidental poisonings and the possibility of overdoses. Comments pointed to a survey from an e-cigarette forum which stated that ''[a]bout 79 percent of respondents said they would 'look to the black market' if products they use 'were banned tomorrow,' while 14 percent said they would return to smoking analog cigarettes'' (*e.g.,* Ref. 44).

Comments also expressed concern that regulation will increase prices of the newly deemed tobacco products and consumers will turn to an illicit market to obtain products for lower prices. For example, they stated that some markets for cigarettes (*e.g.,* New York) experience smuggling rates of beyond 50 percent, as consumers seek products for lower costs. These comments expected a similar result to occur after the deeming rule becomes effective (see Ref. 45).

Further, they stated that this illicit market would cause additional problems like stifling innovation for regulated companies, because companies operating in the illicit market would not be complying with costly regulations and would be able to take advantage of innovations elsewhere in the world. They theorized that this illicit market would favor very small domestic producers over existing medium-sized domestic manufacturers with better quality control and safety mechanisms.

In addition to concerns about e-cigarettes, comments expressed concerns about the potential for illicit markets for other newly deemed products. For example, they stated that a final deeming regulation (without an exemption for premium cigars) would exacerbate the black market that already exists for premium Cuban cigars. The comments also noted that those involved in the waterpipe tobacco industry already operate more informally (*e.g.,* without local regulation) and, therefore, the deeming regulation would cause more business to be transacted in illicit markets. They also expressed concern about the development of a flourishing illicit market if flavors were not permitted in the deemed products.

(Response) FDA understands these concerns, but believes that this rule will not increase current illicit practices or create new illicit markets, because FDA is not banning any tobacco product with this deeming rule. Even if some illicit trade were to develop in an attempt to evade the requirements of this rule, FDA does not believe it would result in a volume sufficient to outweigh the public health benefits of the rule. FDA authority over the newly deemed tobacco products will give it means to determine which products are legally on the market and which are counterfeit or otherwise illegally marketed. The Tobacco Control Act gives the Agency these and other authorities, such as section 920 of the FD&C Act (21 U.S.C. 387t), to help address illicit tobacco products.

In addition, FDA recently commissioned a report from the National Research Council and Institute of Medicine Panel to help us better understand and consider all aspects of illicit tobacco markets (Ref. 46). This report focused mainly on combustible products, especially cigarettes, as they are the subject of most illicit tobacco trade. The relevance of those findings to an assessment of the potential for illicit trade in tobacco products more generally in the United States, such as ENDS products, is open to question. Overall, illicit trade in cigarettes is under 10 percent. It is not clear if illicit trade in any of the newly deemed products will be greater or less than that observed for cigarettes. Evidence from Canada shows the development of an illicit market in ENDS products in that particular context where the government currently regulates all nicotine-containing electronic smoking products as medical devices under the Food and Drugs Act, regardless of the products' health claims.[12] Canada does, however, have a legal market for the sale of non-nicotine containing ENDS products. Despite the fact that Health Canada has not approved any nicotine-containing ENDS products for sale or importation in the country a 2015 e-cigarette usage study (Ref. 48) showed usage rates among Canadian populations that were similar to those among U.S. populations.

Despite the potential for some illicit ENDS market activity to occur, FDA emphasizes that the presence of an illicit market does not affect its legal authority to regulate such products and that there is evidence that many ENDS manufacturers will likely submit premarket applications in the United States.

Moreover, as stated previously, FDA expects that the public health benefits that likely will accrue as a result of this final rule will be greater than the negative effects that could result if there were an increase in illicit markets. This final deeming rule will afford FDA additional tools to reduce the number of illnesses and premature deaths associated with tobacco product use. For example, FDA will be able to obtain critical information regarding the health risks of newly deemed tobacco products, including information derived from ingredient listing submissions and reporting of HPHCs required under the FD&C Act. FDA will also receive information on the location and number of manufacturing establishments, which will allow the Agency to establish effective compliance programs. In addition, because of this rule, FDA will be able to take enforcement action against manufacturers of newly deemed products who make unsubstantiated MRTP claims or false or misleading claims about their products, thus allowing for better-informed consumers and helping to prevent the use of misleading campaigns targeted to youth populations. It will also prevent from entering the market new products that are not appropriate for the protection of public health, are not substantially equivalent to a valid predicate product, or are not exempt from SE. Finally, the newly deemed tobacco products may be subject to future regulations that FDA determines are appropriate.

FDA believes that this rule will not stifle innovation but could, instead, encourage it. The greater regulatory certainty created by the premarket review process may encourage companies to invest in creating potentially beneficial novel products, with greater confidence that improved products will not be competing against equally novel, but more dangerous, products. For example, a company may be more willing to invest the additional resources needed to ensure that its product is designed and manufactured with appropriate methods and controls.

[12] ENDS and e-liquids that do not contain nicotine can be legally sold in Canada. Health Canada issued a Notice in 2009 regarding electronic cigarette products that contain nicotine (Ref. 47).

The PMTA pathway will incentivize development of tobacco products that pose less risk to human health by limiting market access by riskier competitor products. Furthermore, since the ''appropriate for the protection of the public health'' standard involves comparison to the general tobacco product market, FDA believes that, over time, the premarket authorities will move the market toward less risky tobacco products.

C. Policy for Certain Regulatory Requirements for All Manufacturers of Newly Deemed Products

FDA received many comments expressing concern regarding the regulatory and financial burdens associated with certain automatic provisions that will apply to newly deemed products once this rule becomes effective. In response to comments, FDA has considered instances in which the Agency has implemented compliance policies for currently regulated products. Accordingly, the Agency is announcing the following compliance policy with respect to newly deemed products. As with any such policy, the Agency will review and revise this policy as appropriate. If FDA were to change this policy, the Agency would provide notice to affected entities.

1. Substantial Equivalence

As provided in guidance for currently regulated products (''Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Edition 2)'' (80 FR 53810, September 8, 2015)), FDA does not intend to enforce against manufacturers who make tobacco blending changes without a marketing authorization if the tobacco blending changes are intended to address the natural variation of tobacco (*e.g.,* due to variation in growing conditions) in order to maintain a consistent product. However, FDA does intend to enforce the premarket authorization requirements for tobacco blending changes that are intended to alter the chemical or perception properties of the new product (*e.g.,* nicotine level, pH, smoothness, harshness).

FDA does not intend to take enforcement action for at least 30 calendar days from the date the not substantially equivalent (NSE) order issues for those products that are in a retailer's current inventory at a specific retail location on the date FDA issues the NSE order. This policy extends only to tobacco products that are already in a retail store that offers the products for sale directly to adult consumers.

FDA has provided guidance (''Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Edition 2)'') on currently regulated tobacco products stating that a change in supplier, where the new supplier is used for the same ingredient, additive, component, part, or material, with identical specifications, would not render a new tobacco product. This guidance also will apply to newly deemed products.

2. Reporting of HPHCs

FDA intends to issue guidance regarding HPHC reporting, and later a testing and reporting regulation as required by section 915, with enough time for manufacturers to report given the 3-year compliance period for HPHC reporting. Section 904 (a)(3) requires the submission of a report listing all constituents, including smoke constituents, identified as harmful or potentially harmful (HPHC) by the Secretary. Section 915 requires the testing and reporting of the constituents, ingredients, and additives the Secretary determines should be tested to protect the public health. The section 915 testing and reporting requirements apply only after FDA issues a regulation implementing that section, which it has not yet done. Until these testing and reporting requirements have been established, newly deemed tobacco products (and currently regulated tobacco products) are not subject to the testing and reporting provisions found under section 915. As noted elsewhere in this document, FDA does not intend to enforce the reporting requirements under section 904(a)(3) for newly deemed products before the close of the 3-year compliance period, even if the guidance is issued well in advance of that time. At this time, FDA also does not intend to enforce this requirement in relation to manufacturers of components and parts used for incorporation into finished tobacco products. In the future, we intend to evaluate if there are additional constituents that are present in newly deemed products and should be included in the HPHC list for reporting. FDA also intends to issue guidance to further refine the list of reportable HPHCs based on product class.

3. Tobacco Health Document Submission

Although section 904(a)(4) sets out an ongoing requirement to submit tobacco health documents developed after June 22, 2009 (the date of enactment of the Tobacco Control Act), FDA generally does not intend to enforce the requirement with respect to all such documents at this time, so long as a specified set of documents is submitted by the effective date plus 6 months. FDA intends to publish additional guidance that specifies the scope of such health documents within three to six months of the publication date of this final rule, with sufficient advance time for manufacturers and importers to prepare their submissions.

FDA does intend to collect other tobacco health documents developed after June 22, 2009, but before doing so the Agency will publish additional guidance specifying the timing of subsequent submissions. Note that, despite this compliance policy with respect to timeliness of submissions, manufacturers and importers are still to preserve all tobacco health documents developed after June 22, 2009, for future submissions to FDA. Failure to submit tobacco health documents developed after June 22, 2009, because of a failure to preserve them after publication of this rule will constitute a violation of section 904(a)(4).

4. Compliance Policy for Components and Parts

As discussed in section VI.B, at this time FDA does not intend to enforce certain requirements for components and parts of newly deemed products that are sold or distributed for further manufacturing into finished tobacco products.

D. Compliance Policy Regarding Certain Provisions and Small-Scale Tobacco Product Manufacturers

In the NPRM, FDA requested comment on the ability of smaller manufacturers of newly deemed tobacco products to fully comply with the requirements of the FD&C Act and how FDA might be able to address those concerns. Considering the comments and FDA's finite enforcement resources, the Agency's view is that those resources may not be best used in immediately enforcing the provisions of this rule against certain manufacturers that are small-scale tobacco product manufacturers and that fail to comply with certain requirements of the FD&C Act. Therefore, FDA generally intends to grant small-scale tobacco manufacturers additional time to respond to SE deficiency letters and to not bring enforcement action against those small-scale tobacco product manufacturers who submit ingredient listings within 12 months of the effective date of this rule, and is granting small-scale tobacco product manufacturers an additional six-month compliance period for the tobacco health document submission

requirements. As with any such policy, FDA will review and revise these policies as appropriate. If FDA were to change these policies, FDA would do so consistent with its Good Guidance Practices regulations.

For purposes of this compliance policy, FDA generally considers a ''small-scale tobacco product manufacturer'' to be a manufacturer of any regulated tobacco product that employs 150 or fewer full-time equivalent employees and has annual total revenues of $5,000,000 or less. FDA considers a manufacturer to include each entity that it controls, is controlled by, or is under common control with. To help make FDA's individual enforcement decisions more efficient, a manufacturer may voluntarily submit information regarding all relevant factors, including information regarding employment and revenues. Interested manufacturers may contact CTP's call center at 1–877–CTP–1373 for questions regarding this compliance policy. We note that FDA's thinking regarding ''small-scale tobacco product manufacturer'' differs from the definition of ''small tobacco product manufacturer'' in section 900(16) of the FD&C Act.

FDA notes that our thinking regarding what a ''small-scale tobacco product manufacturer'' is for purposes of this policy is designed to align with the nature of the specific relief provided. That is, the relief provided (as described throughout this document) relates generally to requirements for entities to compile or report information. These activities may require an investment of employee time and/or financial resources that is more challenging for the smallest entities to achieve. For these reasons, the threshold takes note of both employee resources (FTEs) and financial resources (annual revenues), ensuring that those entities with the most limited human and financial resources are uniquely considered in FDA's decisions about enforcement of these provisions, precisely because the provisions may require resources not as readily available to these entities. Further, as stated elsewhere in this document, in formulating its thinking, FDA has considered all available data on employment, revenues, production volume and other details of operation for current manufacturers of newly deemed products. In addition, FDA notes that its current approach reflects a careful review of the potentially unique interests of the smallest tobacco product manufacturers as considered in light of the Agency's statutory obligations regarding the protection of public health.

1. SE Extension Requests (Section 905(j))

Although information adequate to make submissions should be available to all manufacturers, we expect small manufacturers to have more difficulty in putting this information together in an SE Report. FDA presently intends, for the first 30 months following the effective date of this rule, to grant extensions to small-scale tobacco product manufacturers for SE reports that need additional time to respond to SE deficiency letters. Extensions are not automatically granted. Requests will be considered on a case-by-case basis. Any extensions granted are likely to be limited in time—for example, where a manufacturer normally might have 90 days to respond to a deficiency letter, FDA will, for small-scale tobacco product manufacturers, grant an additional 30 days for such a response. FDA encourages all small-scale tobacco product manufacturers, especially those with limited or no experience with the SE pathway, to submit SE reports as early as possible. FDA is not instituting a similar policy for extension requests related to PMTAs (nor is it providing additional time for small-scale tobacco product manufacturers to prepare PMTAs) given the already-extended compliance period for PMTAs, which provides an additional 6 months to submit a PMTA, discussed in section V.A.

2. Tobacco Health Document Submissions (Section 904(a)(4))

To address concerns of small-scale tobacco product manufacturers regarding the submission of certain health documents, and in recognition of FDA's current enforcement priorities, FDA, for an additional 6 months following the end of the generally applicable compliance period, intends not to bring enforcement action against those small-scale tobacco product manufacturers who submit the required information.

3. Ingredient Listing Submissions (Section 904(a)(1))

FDA understands concerns that small-scale tobacco product manufacturers may need additional time to comply with section 904(a)(1)'s requirement that manufacturers submit ingredient lists. FDA presently intends not to bring enforcement action against those small-scale tobacco product manufacturers who submit section 904(a)(1)'s required information within 12 months of the effective date of this final rule.

4. Assistance With Marketing Applications

As with manufacturers in general, these small-scale tobacco manufacturers will also benefit from additional assistance with their marketing applications, including the designation of a Regulatory Health Project Manager so that they have a single point of contact in CTP's OS for questions about their marketing applications. They will also have access to an appeals process in the event that FDA denies their marketing applications (of which one small business has already taken advantage). Staff from CTP's OCE also will assist small-scale tobacco product manufacturers with identifying the types of documents that may be used to establish that their predicate products were on the market on February 15, 2007. This may include several calls or correspondence with the manufacturer as it submits different documents to the Agency.

5. Assistance in Navigating Other Regulatory Requirements

CTP's OCE will continue to assist small-scale tobacco product manufacturers in submitting rotational warning plans for FDA approval. These plans provide the firm's plan for how the required warnings will be displayed on the packaging and advertising for their product, as required by 21 CFR 1143.5. This may include several calls or correspondence with the small business as it seeks approval from the Agency.

CTP also has a system to assist small businesses in navigating the regulatory requirements of FDA. For example, the Center has a Call Center that triages all calls received from regulated industry. The Center's Office of Small Business responds to hundreds of calls, emails and correspondences from small businesses every year to assist them in answering their specific questions on how to comply with the law.

V. Premarket Review Requirements and Compliance Policy

Section 910 of the FD&C Act requires FDA authorization in order to market a new tobacco product. As described elsewhere, the FD&C Act contains three pathways for obtaining premarket authorization: SE exemptions, SE reports, and PMTAs.

Tobacco products that were on the market on February 15, 2007, are grandfathered and do not require premarket authorization. However, as described throughout this preamble, these products are subject to the other requirements of the statute.

A. Compliance Policy for Premarket Review Requirements

In the NPRM, FDA contemplated a compliance period of 24 months following the effective date for submitting a premarket application (SE exemption request, SE report, or PMTA), with a continued compliance period pending review of those applications (79 FR 23142 at 23144). In essence, the products would remain on the market during this indefinite compliance period until the agency rendered a decision on an application or the application was withdrawn.

Agency compliance/enforcement policies are not subject to the requirements that govern notice-and-comment rulemaking. *Prof'ls & Patients for Customized Care* v. *Shalala,* 56 F.3d 592 (5th Cir. 1995) (a compliance policy guide is not a substantive rule and not subject to APA's notice-and-comment rulemaking); *Takhar* v. *Kessler,* 76 F.3d 995, 1002 (9th Cir. 1996) (FDA compliance policy guides were not required to go through notice-and-comment procedures). But because the relevant time periods are of obvious interest, FDA laid out its anticipated compliance policy in the NPRM, and for similar reasons, is announcing its revised compliance policy here in the preamble to the final rule, rather than in a separate guidance document.

FDA has considered the comments and data submitted in response to the compliance policy in the NPRM. Some comments expressed concern about the extended availability of newly deemed, new tobacco products without scientific review. Others provided additional data regarding youth and young adult use of flavored tobacco products. In addition, others comments discussed the potential public health benefits from the availability of certain flavored newly deemed products (as discussed in section VIII.F). Taking the diverse comments on these issues, as well as the uncertainty regarding the positive or negative impact on public health from products like ENDS, into account, FDA has decided to implement the compliance policy with staggered initial compliance periods based on the expected complexity of the applications, followed by continued compliance periods for FDA review, such that our enforcement discretion will end twelve months after each initial compliance period. Under the policy described here for the staggered compliance periods, and while FDA is conducting its review of marketing applications during the continued compliance period, the Agency does not intend to take enforcement action against products remaining on the market for failure to have a premarket authorization order.

The compliance periods are staggered to improve efficiency for both FDA and regulated entities given that the time it takes to prepare premarket applications is dependent upon the type of application and complexity of the product. FDA intends to act as expeditiously as possible with respect to all new applications, while ensuring that statutory standards are met. Further, if at the time of the conclusion of the continued compliance period, the applicant has provided the needed information and review of a pending marketing application has made substantial progress toward completion, FDA may consider, on a case-by-case basis, whether to defer enforcement of the premarket authorization requirements for a reasonable time period.

FDA's revised compliance policy for premarket review aims to balance the public health concerns raised in the comments, allow the Agency to more efficiently manage the flow of incoming applications, and encourage high-quality premarket submissions from applicants.

In accordance with the Tobacco Control Act (sections 905 and 910 of the FD&C Act), a new tobacco product may be legally marketed only if FDA has authorized its marketing under one of the three premarket pathways described throughout this document. As a result of the compliance policy being announced, we expect that manufacturers of certain newly deemed, new tobacco products will continue to market their products without FDA authorization for certain time periods.

1. FDA's Revised Compliance Policy Is Informed by Comments Submitted in Response to the NPRM

FDA received many comments responding to its detailed requests for comment on possible compliance approaches. 79 FR at 23175–77. Some comments expressed concern that the compliance policy for premarket review described in the NPRM would permit the continued marketing of tobacco products that have not been reviewed under the public health standards of the Tobacco Control Act. For example, comments jointly submitted by 24 health and medical organizations stated that the contemplated 24-month compliance period and indefinite period of continued marketing during FDA's review included in the NPRM would prolong the public's exposure to products that contain nicotine, a highly addictive substance, and that do not meet the statutory standard for the grant of a marketing order (Comment No. FDA–2014–N–0189–79772.).

They also stated that this approach would allow manufacturers to continue to market the newly deemed products in ways that appeal to youth and to manipulate the content of these products in uncontrolled ways for an indefinite period (id.). They urged FDA to forego its contemplated compliance policy unless proper precautions are taken to limit the time period these products are allowed to remain on the market pending FDA review and authorization. In addition, they expressed concern that manufacturers, knowing that submission of an application will permit them to market products for years, have incentive to submit numerous applications (regardless of how incomplete or deficient the applications).

A network of tobacco control policy and legal specialists also expressed concern regarding the effect of continued marketing of new tobacco products that have not been reviewed under the applicable public health standards of the Tobacco Control Act (Comment No. FDA–2014–N–0189–81044). This organization noted the thousands of provisional SE reports submitted in the last five days before the statutory deadline, where such applications pending FDA review are ''being used as placeholders that will allow the tobacco industry to continue to introduce new products at will, rather than following the proper legal procedures established by the Tobacco Control Act.'' They proposed a staggered timeline to submit applications under the three marketing pathways and a definite time period in which FDA would no longer exercise enforcement discretion with respect to premarket review of these products, noting that such an approach would incentivize industry to generate high-quality, complete applications within the initial compliance period.

In addition, two large organizations dedicated to the health of youth and young adults urged FDA not to implement a compliance period of any length for products sold in characterizing flavors other than tobacco or any covered tobacco products that use marketing practices known to appeal to children and youth (Comment No. FDA–2014–N–0189–67268; Comment No. FDA–2014–N–0189–79413.). Ranking minority members of the Energy and Commerce Committee, Health Subcommittee, and Oversight and Investigations Subcommittee, U.S. House of Representatives also called for a more protective compliance period than the one contemplated in the

NPRM, arguing that the proposed compliance period ''puts the nation's youth at risk'' (Comment No. FDA–2014–N–0189–80119). These comments, among others, all stressed the attractiveness of these newly deemed tobacco products to youth and young adults and the need for a more restrictive compliance policy to ensure that FDA limits the continued marketing of new tobacco products that have not been reviewed under the public health standards of the Tobacco Control Act.

Further, in response to FDA's requests for comments and data in the NPRM, numerous comments included data, research, and personal stories regarding the impact of candy and fruit flavors in tobacco products, including their appeal to youth and young adults, youth perceptions of flavored tobacco products, and their potential effect on transition from combusted tobacco product use (particularly, comments noted, in the case of adults using flavored ENDS to attempt to switch completely away from cigarette smoking). In addition, many comments urged FDA to take immediate action regarding flavored tobacco products as a result of increasing prevalence of flavored product use, and new data show continued growth in youth and young adult usage of flavored tobacco products.

In deciding upon a compliance policy to announce with this final rule, FDA considered all these comments and sought to balance the Agency's concern about the continued marketing of new tobacco products that have not been reviewed by FDA, the potential harmful impact of flavored tobacco products on youth, and the possibility that some of those products are playing a role in helping some tobacco users transition away from what is likely the most harmful form of nicotine delivery for an individual user, combusted tobacco products. FDA considered adopting the compliance policy as described in the preamble to the NPRM or a compliance policy that would provide different compliance periods for flavored and non-flavored tobacco products. FDA also considered providing different compliance periods for different product categories. For example, certain industry comments urged FDA to stagger compliance dates for different product categories, to delay compliance until FDA publishes a final guidance for each product category and to provide ENDS manufacturers a lengthier compliance period based on where they purport to fit within the risk continuum for nicotine-delivering products (*e.g.,* Comment No. FDA–2014–N–0189–81859; Comment No. FDA–2014–N–0189–10852).

In response to these comments, we note that nicotine use in any form is of particular concern for youth and pregnant women. On the other hand, some evidence suggests that ENDS may potentially promote transition away from combusted tobacco use among some current users and it is possible that there could be a public health benefit. See also section III.F for additional discussion of premarket pathways and the continuum of nicotine-delivering products. Based on currently available scientific evidence, this revised compliance policy strikes an appropriate balance among various, often competing, considerations.

2. FDA Is Announcing a Revised Compliance Policy With Staggered Timeframes and Continued Compliance Periods

In the interest of public health and taking into account the fact that there are products already on the market that will now be subject to premarket review, and in light of the considerations discussed in section 1 above, we have established the following compliance policy for newly deemed tobacco products. For those newly deemed products that were on the market on the effective date of this final rule, but that were not on the market on February 15, 2007, FDA is providing two compliance periods: One for submission and FDA receipt of applications and one for obtaining premarket authorization. Although such products are subject to the premarket review requirements of the FD&C Act, FDA does not intend to initiate enforcement action for failure to have premarket authorization during the respective compliance periods.

The compliance period for submission and FDA receipt of applications for newly deemed tobacco products under the three premarket pathways is as follows:

SE Exemption Requests—12 months from the effective date of this final rule

SE Reports—18 months from the effective date of this final rule

PMTAs—24 months from the effective date of this final rule

FDA is adopting the staggered timelines in this policy to account for the possibility that applicants may need additional time to gather information for certain premarket submissions that may require additional data. For example, if a manufacturer plans to submit an SE Exemption Request, the firm may only need to identify the product, provide certification statements, and gather scientific information on the additive change itself and any supporting information demonstrating that the change to the product is minor and an SE Report is not necessary. This is less information than that likely required for a PMTA. We expect this policy will also create a more manageable flow of premarket applications for newly deemed products. FDA expects that this staggering of deadlines also will benefit regulated industry, since it will allow for greater efficiency of FDA review and incentivize higher quality applications, which will reduce review times for all products. New products for which no application has been submitted by 24 months from the effective date of this rule will no longer be subject to this compliance policy and will be subject to enforcement.

Unless FDA has issued an order denying or refusing to accept the submission, products for which timely premarket submissions have been submitted will be subject to a continued compliance period for 12 months after the initial compliance period described previously. For such products, FDA does not intend to initiate enforcement for failure to have premarket authorization during this continued compliance period, which is as follows:

SE Exemption Requests—24 months from the effective date of this final rule (12 months after the compliance period for submission of such requests)

SE Reports—30 months from the effective date of this final rule (12 months after the compliance period for submission of such reports)

PMTAs—36 months from the effective date of this final rule (12 months after the compliance period for submission of such requests).[13]

Once the continued compliance period ends, new tobacco products on the market without authorization will be subject to enforcement. FDA will act as expeditiously as possible with respect to all new applications, while ensuring that statutory standards are met. FDA expects that this revised compliance policy will encourage the submission of high quality applications. By providing a date in which the continued compliance period ends, manufacturers will have an incentive to submit a complete application and respond substantively and expeditiously to questions raised during the review process instead of an incomplete or deficient application just to stay on the market indefinitely. This staggered

[13] In addition, we note that any new tobacco product that was not on the market on the effective date of the rule (*i.e.,* 90 days after the publication date) is not covered by this compliance policy and will be subject to enforcement if marketed without authorization after the effective date.

compliance policy also will provide FDA with a more manageable flow of incoming applications to be reviewed, allowing the agency to more quickly make decisions on applications.

FDA believes the staggered compliance periods will be sufficient for manufacturers to provide high quality applications. To help provide clarity regarding submission requirements for marketing applications, FDA has issued several guidance documents, and is finalizing other guidance documents, regarding the evidence needed for SE reports, including FDA draft guidance entitled ''Substantial Equivalence Reports: Manufacturer Requests for Extensions or to Change the Predicate Tobacco Product'' (79 FR 41292, July 15, 2014), and FDA guidance entitled ''Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007,'' among others. FDA also has issued a draft guidance entitled ''Applications for Premarket Review of New Tobacco Products'' (76 FR 60055, September 28, 2011). In addition, elsewhere in this issue of the **Federal Register**, FDA has made available draft guidance, which when final will describe FDA's current thinking on some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products. If FDA determines that additional guidance is necessary to help manufacturers prepare marketing applications, FDA will issue additional guidance and publish a notice of availability in the **Federal Register**.

Further, if at the time of the conclusion of the continued compliance period, the applicant has provided the needed information and review of a pending marketing application has made substantial progress toward completion, FDA may consider, on a case-by-case basis, whether to defer enforcement of the premarket authorization requirements for a reasonable time period.

B. Responses to Comments Regarding Compliance Periods for Premarket Review Requirements

(Comment 60) FDA received many comments suggesting that we change the proposed compliance period for submitting marketing applications. Some comments suggested that the compliance period should be 24 months from the date FDA either announces its intent to no longer exercise enforcement discretion regarding premarket requirements or issues product-specific guidance on the preparation of PMTAs and the submission of HPHC testing results. They suggested that the issuance of the guidance documents be based upon the continuum of risk presented by nicotine-delivering products. Other comments suggested that we extend the PMTA compliance period to 5 years following the effective date of the final rule to give manufacturers sufficient time to complete the required testing.

(Response) FDA has already published for public comment draft guidance for industry regarding the submission of PMTAs, which when final will represent FDA's current thinking on this topic. In addition, elsewhere in this issue of the **Federal Register**, FDA has made available draft guidance, which when final will describe FDA's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products. FDA is committed to helping industry better understand the tobacco product premarket review process and will continue to hold public Webinars and meetings with industry. FDA has also published guidance on meetings with industry, and FDA has had many productive meetings to address companies' specific questions on the development of tobacco products. As FDA reviews product applications for currently regulated and newly deemed categories of products, we intend to identify topics for which rulemaking or more product specific guidance is appropriate.

Moreover, along with finalizing this rule, FDA is setting forth an initial 2-year compliance period for the submission of a PMTA for newly deemed, new tobacco products, followed by a continued compliance period of up to 12 months for FDA to review the application. FDA believes that this will give sufficient time for manufacturers of such products to prepare high quality applications, and for FDA to review new applications as expeditiously as possible, while ensuring that the statutory standards are met. FDA's compliance policy is further described in section V.A of.

(Comment 61) Comments were split as to whether the NPRM's contemplated premarket review compliance timeframes (*i.e.,* 24 months for manufacturers to submit and for FDA to receive a marketing application) should apply to manufacturers of newly deemed products. While many industry comments sought additional time to comply with these requirements, many other comments suggested that the reason Congress delayed application of certain requirements to the currently regulated products (*e.g.,* cigarettes and smokeless tobacco) was to account for the creation, staffing, and training for a new FDA center. In addition, they stated that manufacturers of the newly deemed products cannot argue that they did not have adequate notice that they would need to comply with premarket requirements given that the Unified Agenda entry for the deeming proposal published on July 7, 2011, and was continually updated in subsequent Unified Agenda entries. They argued that establishing similar timeframes for the newly deemed products only benefits industry and is detrimental to the public health.

(Response) FDA has considered these comments and concludes that the staggered compliance periods included with this final rule are sufficient to allow manufacturers of previously unregulated tobacco products to submit applications without unduly delaying compliance. As stated elsewhere in this document, FDA has taken several steps to provide helpful feedback to industry to encourage more complete, streamlined submissions and reviews, including: (1) Encouraging teleconferences between the assigned regulatory health project manager and the applicant; (2) streamlining the SE report review process by modifying the preliminary review so that it focuses only on administrative issues and allowing submission deficiencies to be communicated to the applicant more quickly; (3) providing information on FDA's Web site about the three pathways available to market products (including SE) and developing public Webinars to explain the Agency's processes; and (4) publishing guidance documents. FDA intends to act as expeditiously as possible with respect to all new applications, ensuring that statutory standards are met.

(Comment 62) One comment suggested FDA allow for submission of a confidential e-cigarette product report in order to satisfy premarket review requirements. Similarly, another comment encouraged FDA to establish a ''Tobacco Product Master File'' (TPMF) system similar to the Agency's Drug Master File (DMF) and Food Additive Master File (FAMF) systems to allow for e-cigarette/personal vaporizer and e-liquid suppliers to submit confidential product information (including information on formulations, facilities, processes, and articles used in the manufacturing, processing, packaging, and storing of ingredients used).

(Response) FDA does allow for the submission and use of information to be incorporated by reference similar to master file programs for other FDA-regulated products. In addition, elsewhere in this issue of the **Federal Register**, FDA has made available a final guidance to provide information on how

to establish and reference a TPMF. TPMFs are expected to help applicants of newly deemed products prepare premarket and other regulatory submissions because they can reference information in TPMFs rather than develop the information on their own.

Such a system would be especially helpful in the area of newly deemed tobacco products. Because of the nature of upstream supply of many components for ENDS products, especially e-liquids, FDA anticipates that commercial incentives will be sufficient to drive manufacturer reliance on the system of master files. We note that, at present, FDA understands that, based on publically available information, the number of entities engaged in upstream production of liquid nicotine and flavors specifically developed for use with e-liquids is small, in the range of seven to thirteen entities (see earlier discussion in response to comment 34). Given the nature of the marketplace, FDA expects that the master file system will be widely appealing and widely utilized by the ENDS industry.

(Comment 63) At least one comment stated that FDA should prioritize review of applications for products currently on the market over those seeking to enter the market and that FDA should establish clear review deadlines. Another comment suggested that priority should be given to those products whose marketing is unlikely to be seen by youth or is limited to existing adult users of the product.

(Response) During the initial implementation of the Tobacco Control Act, FDA received a large number of applications for currently marketed tobacco products. For these provisional products being reviewed through the SE pathway, in order to appropriately prioritize review, FDA performed a public health impact evaluation of the product's potential to raise different questions of public health. Currently marketed products with the highest potential to raise different questions of public health were placed in the tier to be reviewed first. If appropriate, FDA may consider using a prioritization method for newly deemed products.

FDA understands the value of establishing timelines for review of applications. For products not on the market on the effective date, FDA intends to establish review performance goals in the future as it did with currently regulated products.

(Comment 64) Some comments suggested that FDA continue to employ measures to ensure that completed SE reports and PMTAs are submitted as expeditiously as possible during the compliance period. They noted that FDA currently employs a ''refuse-to-accept'' policy for SE applications that allows FDA to make a threshold determination as to whether an SE application is sufficiently complete for the Agency to review. They stated that this policy will help to ensure that manufacturers of the newly deemed products do not try to unduly extend the time that products are marketed without FDA review of their applications.

(Response) FDA agrees. FDA plans to take all reasonable measures to ensure that applications are reviewed in a timely manner. FDA intends to continue employing its ''refuse-to-accept'' policy for SE Reports and other marketing applications (including SE Exemption Requests and PMTAs).

(Comment 65) Many comments suggested that FDA should develop a product category specific framework for submission of PMTAs in light of the large number of products for which PMTAs will be required, the size and cost of PMTAs, and FDA's available resources. The comments suggested that the compliance period should be based on the date FDA issues a category specific guidance document. The comments stated that, without category specific guidance, the PMTA process will effectively eliminate certain tobacco product categories, including the premium cigar industry. These comments asserted that it was Congress' intent to treat categories of tobacco products differently, as shown by the provisions banning flavored cigarettes, providing special considerations regarding menthol, establishing MRTP provisions, and creating baseline standards under sections 910 and 907.

(Response) As stated previously, the statute specifies the premarket pathways for tobacco products. Congress subjected all new tobacco products to the same premarket review requirements in sections 905 and 910. FDA has taken many steps to reduce and prevent backlogs of marketing applications pending FDA review and intends to act as expeditiously as possible with respect to all new applications, while ensuring that statutory standards are met. Elsewhere in this issue of the **Federal Register**, FDA has made available draft guidance, which when final will describe FDA's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products. FDA may issue additional category specific guidance as appropriate. FDA is committed to helping industry better understand the tobacco product premarket review process and will continue to hold public Webinars and meetings with industry. In the category of cigars, and for premium cigars in particular, we expect that some products will remain on the market due to their status as grandfathered products, and that others will be able to make use of the SE pathway.

(Comment 66) While many comments stated that they needed additional time to comply with premarketing requirements, many other comments stated that the contemplated 2-year compliance period was too long. For example, comments jointly submitted by 24 health and medical organizations stating that the contemplated 24-month compliance period included in the NPRM would prolong the public's exposure to products that contain nicotine, a highly addictive substance, and that, in their view, do not meet the statutory standard for the grant of a marketing order (Comment No. FDA–2014–N–0189–79772.). They stated that it would allow manufacturers to continue to market the newly deemed products in ways that appeal to youth and to manipulate the content of these products in uncontrolled ways for an indefinite period (id.). These comments also argued that a 2-year compliance period will result in large numbers of adolescents experimenting with newly deemed products and becoming established e-cigarette users or users of other tobacco products. Some suggested that FDA reduce the compliance period to 6 months or 12 months and others suggested different compliance periods for SE reports, SE exemption requests, and PMTAs. One comment stated that FDA's burden estimates show that the PMTA process should take 18 months, so the compliance period should not extend beyond 18 months. Alternatively, other comments stated that there should not be any compliance period for products because the PMTA process was created to provide a higher scrutiny of review for new products with unknown health risks and a compliance period is contrary to this purpose. They also stated that a compliance period would allow the industry to flood the market place with products and manufacturers would not have an incentive to quickly develop high-quality applications. In addition, some comments suggested that FDA should not provide a compliance period for combusted products, such as pipe tobacco or cigars, because there is no parallel provision in the current statute for such products.

Some comments also suggested that manufacturers that sell flavored tobacco products or that market tobacco

products to children should not be afforded any compliance period to satisfy the premarket review requirements of the FD&C Act (79 FR at 23176). For example, two large organizations dedicated to the health of youth and young adults urged FDA not to grant a compliance period of any length for products sold in characterizing flavors other than tobacco or any covered tobacco products that use marketing practices known to appeal to children and youth (Comment No. FDA–2014–N–0189–67268; Comment No. FDA–2014–N–0189–79413.).

Many comments also stated that manufacturers should not be able to avail themselves of the compliance period unless they agree to restrict their marketing to adults. However, some comments expressed concern as to how such a restriction could be administered in accordance with the First Amendment. In addition, Ranking minority members of the Energy and Commerce Committee, Health Subcommittee, and Oversight and Investigations Subcommittee, U.S. House of Representatives called for a more protective compliance period than the one contemplated in the NPRM, arguing that a 24-month compliance period ''puts the nation's youth at risk'' (Comment No. FDA–2014–N–0189–80119).

(Response) Once this rule takes effect, it will be illegal to sell these tobacco products to anyone under the age of 18. This final deeming rule is foundational, affording FDA with the authority to issue other regulations restricting sales and distribution, including advertising and promotion, under section 906(d).

FDA struck a balance by revising the initial compliance period for SE exemption requests and SE reports to 12 and 18 months, respectively, and is setting forth a 2-year compliance period for manufacturers of newly deemed, new tobacco products to submit (and FDA to receive) a PMTA. FDA believes that these time periods are sufficient for manufacturers to prepare high quality applications addressing the requirements in the statute.

FDA has given extensive consideration to having different compliance periods for flavored and non-flavored products. There is some evidence suggesting that flavored products pose a greater public-health risk than non-flavored products. FDA understands that the appeal of flavors and use of flavored tobacco products have an important role in the initiation and continued use of tobacco products, and in the health risks associated with use of these products. Many comments and studies provided data and information regarding youth and young adult use of flavored tobacco products in recent years. (*E.g.,* Refs. 49, 50, 51, 52, 53, 54, 55, 56). And flavors appear to encourage greater use. (*E.g.,* Ref. 57; Refs. 58, 59). The availability of appealing flavors is a commonly cited reason for use of non-combusted products among young tobacco users. (*E.g.,* Refs. 60, 61)

However, several considerations weigh against a shorter compliance period for flavored products. There are potential countervailing health concerns. At least some flavored combusted products (which are of particular concern because they are known to present similar risks to cigarettes and are youth appealing) are likely to be ''grandfathered'' and, therefore, would remain on the market regardless of the compliance period or enforcement policy for newly deemed, noncombusted flavored products. And, in any event, comments suggested that the availability of flavors in non-combusted tobacco products, such as ENDS, are appealing to current smokers of combusted products and may entice smokers to consider switching to e-cigarettes. (*e.g.,* Comment No. FDA–2014–N–0189–75088; Comment No. FDA–2014–N–0189–79096). And FDA is aware of emerging self-reports from current and former cigarette smokers supporting this claim. (*See* Refs. 62, 63.) Section VIII.F below discusses the preliminary evidence available to date regarding effectiveness of ENDS to help smokers transition from, or reduce their consumption of, combusted tobacco products. But at least some think that flavor variety is very important. (*See, e.g.,* Ref. 63). More research, especially longitudinal research, is needed to understand how flavoring impacts tobacco use over time (Ref. 64).

Finally, as with other tobacco products that will be regulated under this rule, FDA is cognizant of the transition that will be required for regulated entities. Several comments expressed concern that even the proposed 24-month compliance period was not sufficient to submit complete applications for all of their products. For example, one comment noted that most of the e-cigarette market ''are small and medium-sized businesses owned and operated by individuals and families [and] most, if not all of these smaller enterprises lack the resources to tackle such a high administrative burden'' associated with submitting multiple PMTAs within the time period (Comment No. FDA–2014–N–0189–80496). Several comments also expressed concern that the 24-month proposed compliance period would benefit larger companies with more resources to complete product applications at the expense of small and mid-size companies (*e.g.,* Comment No. FDA–2014–N–0189–76162). FDA notes that a shorter period would have an even greater impact on these businesses.

In light of these considerations, FDA believes that a two-year compliance period for flavored products, as with other tobacco products, represents the exercise of its enforcement discretion in a way that strikes an appropriate balance between providing industry time to transition and protecting the public health. Over time, FDA expects to see additional data on the role of certain flavored products in supporting reduction in or abstinence from the use of combusted products, as well as further data on the role of flavored products in youth initiation, use, and dual use. Such data will help inform FDA's regulation of, and product standards for, these and other tobacco products.

In developing this compliance period, FDA balanced three important public health considerations: Concern about the extended availability of newly deemed, new tobacco products without scientific review; concern about flavored products' youth appeal; and preliminary data that some individuals may potentially use such products to transition away from combusted tobacco use. Taking these factors into account, and based on currently available scientific evidence, FDA determined that the compliance periods described in Section V.A. strikes an appropriate balance to protect public health. FDA is establishing staggered compliance periods based on the expected complexity of the applications and continued compliance periods for FDA review such that our exercise of enforcement discretion will end twelve months after each initial compliance period. In addition, FDA is announcing that it intends in the future to issue a proposed product standard that would, if finalized, eliminate characterizing flavors in all cigars including cigarillos and little cigars.

Elsewhere in this issue of the **Federal Register**, FDA has made available draft guidance, which when final will describe FDA's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products. FDA recognizes that flavored e-liquids are especially attractive to youth and young adults. Attractiveness to youth and young adults is an important factor in evaluating whether the marketing of a product is

appropriate for the protection of the public health. Manufacturers should provide information on possible toxicity, addictiveness, and appeal of flavored tobacco products with their premarket review applications.

VI. Components, Parts, and Accessories

In the preamble to the NPRM, we asked for comments, including supporting facts, research, and other evidence, regarding FDA's proposal to include components and parts of the newly deemed products (but not accessories) under the scope of this rule. We also asked for comments as to whether FDA should define components and parts of tobacco products and how those items might be distinguished from accessories (79 FR 23142 at 23152 and 23153). After reviewing the comments, FDA is finalizing this rule to include components and parts of the newly deemed products (but excluding accessories of such products) within the scope of this rule. FDA is also explaining its current compliance policy with respect to components and parts and certain requirements that will become effective with this deeming rule.

A. Definitions

In response to comments, FDA is including definitions of ''accessory'' and ''component or part'' in parts 1100, 1140, and 1143. As stated in this final rule, an ''accessory'' means any product that is intended or reasonably expected to be used with or for the human consumption of a tobacco product; does not contain tobacco and is not made or derived from tobacco; and meets either of the following:

(1) Is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product, or

(2) Is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a tobacco product but (i) solely controls moisture and/or temperature of a stored product; or (ii) solely provides an external heat source to initiate but not maintain combustion of a tobacco product.

FDA has structured paragraph (2)(ii) to ensure that coils and charcoal are not encompassed by the definition of ''accessory.''

''Composition,'' as used in this definition, means the manner in which the materials, including, for example, ingredients, additives, and biological organisms, are arranged and integrated. Examples of accessories are ashtrays, spittoons, hookah tongs, cigar clips and stands, and pipe pouches, because they do not contain tobacco and are not derived from tobacco and do not affect or alter the performance, composition, constituents, or characteristics of a tobacco product. Accessory examples also include humidors that solely control the moisture and/or temperature of a stored product and a burner that solely provides an external heat source to initiate but not maintain combustion of a tobacco product. As stated in the NPRM, accessories of newly deemed products are not deemed with this final rule.

In addition, FDA is defining ''component or part'' to mean any software or assembly of materials intended or reasonably expected: (1) To alter or affect the tobacco product's performance, composition, constituents, or characteristics; or (2) to be used with or for the human consumption of a tobacco product. The definition excludes anything that is an accessory of a tobacco product.

We note that the term ''material'' means an assembly of ingredients, including additives. Materials are assembled to form components and parts. For example, material could be considered the glue or paper pulp for a cigarette where the paper pulp includes multiple ingredients (*e.g.,* multiple types of tobacco, water, and flavors) assembled into the paper (or pulp depending on the water content). A material could be considered the plastic in the mouthpiece of an ENDS containing multiple ingredients and additives assembled together to create a product.

In determining whether software or an assembly of materials might be ''intended or reasonably expected'' to alter or affect the tobacco product's performance, composition, constituents, or characteristics or to be used with or for the human consumption of a tobacco product (and, therefore, whether it is a component or part), FDA is not bound by the manufacturer or distributor's subjective claims of intent. Rather, FDA can consider the totality of the circumstances, including direct and circumstantial objective evidence, which encompasses a variety of factors such as circumstances surrounding the distribution of the product or the context in which it is sold (see, *e.g.,* 21 CFR 201.128 (drugs), 21 CFR 801.4 (devices); see also *U.S.* v. *Travia,* 180 F.Supp.2d 115, 119 (D.D.C. 2001)) and sales data.

Some examples of materials intended or reasonably expected to be used with or for the human consumption of a tobacco product are:

- Atomizers and cartomizers used with ENDS;
- water filtration base additives (including those which are flavored) used with waterpipe tobacco; and
- pouches or flavorings used with any of the newly deemed products (whether or not the pouch or flavoring contains nicotine or tobacco).

Some examples of materials intended or reasonably expected to alter or affect the tobacco product's performance, composition, constituents, or characteristics are:

- The cellophane wrapping or plastic tube for a single cigar;
- a plastic bag or tin holding loose pipe tobacco; and
- a glass or plastic vial container of e-liquid.

Although these examples are materials that are generally intended to prevent unintended changes to the characteristics of the tobacco product, they are also intended or reasonably expected to alter or affect the performance, composition, constituents, or characteristics of a tobacco product. For example, these materials often leach ingredients into the consumed product. As some comments noted, with ENDS, there is the potential for substances to leach from the containing vial into the e-liquid and these leachates may be inhaled when the e-liquids are used as intended, posing additional health risks for consumers. They often can also impact the moisture level or shelf life of a tobacco product (*e.g.,* whether a cigar is in a hard pack or soft pack, and whether pipe tobacco is in a plastic or metal container). The moisture level of a tobacco product, and changes to that moisture level, can, for example, significantly impact consumers' exposure to nicotine and other constituents. In some cases, menthol or other ingredients may have been applied to these materials in order to have them become incorporated into the consumed product.

FDA recognizes that in some circumstances some assemblies of materials can operate as both an aspect of the package and a component or part of the tobacco product. In such situations, the Agency is only examining a distinct subset of packaging materials that function as a component or part of a tobacco product by having the potential to alter or affect the tobacco product's performance, composition, constituents, or characteristics. Packaging materials that do not alter or affect, and are not reasonably expected to alter or affect, the tobacco product's performance, composition, constituents, or characteristics are not components or parts of a tobacco product. For example,

a glass vial containing an e-liquid is a component or part of the tobacco product, whereas a hard plastic blister pack in which the glass vial of e-liquid is distributed and sold to consumers is not.

FDA intends to seek additional public comment and issue a rule or guidance to provide further clarification on assemblies of materials that are a ''component or part'' of a tobacco product because they are intended or reasonably expected to alter or affect the tobacco product's performance, composition, constituents, or characteristics or are intended or reasonably expected to be used with or for the human consumption of a tobacco product.

Many comments specifically asked for clarification and examples of which objects used with waterpipe tobacco would be considered components, parts, and accessories. The following is a nonexhaustive list of examples of components and parts used with waterpipe tobacco: Flavor enhancers; hose cooling attachments; water filtration base additives (including those which are flavored); flavored hookah charcoals; and bowls, valves, hoses, and heads. The following is a nonexhaustive list of objects used with waterpipe tobacco that would likely be considered accessories: Hookah glow balls, foil pokers, shisha oyster forks, tongs, and bags.

Many comments also sought clarification and examples as to which objects used with e-cigarettes would be considered components, parts, and accessories. The following is a nonexhaustive list of examples of components and parts of ENDS (including e-cigarettes): Atomizers, flavors used or intended to be used with ENDS (with or without nicotine), e-liquid solvents, tanks and tank systems, batteries (with or without variable voltage), coils, cartomizers, digital display/lights to adjust settings, clearomisers, and programmable software. The following is a nonexhaustive list of examples of objects used with e-cigarettes or other ENDS that would likely be considered accessories: Screwdrivers and lanyards.

A summary of comments regarding these issues, and FDA's responses, is included as follows.

(Comment 67) Many comments urged FDA to define components, parts, and accessories (particularly for e-cigarettes) to standardize enforcement nationally, prevent confusion in the marketplace (including among retailers), close any potential loopholes to circumvent compliance, increase transparency, and ensure inspectors are enforcing regulations, while also taking into account retailers who are making a good faith effort to comply with the law. Many comments provided suggested definitions for ''component or part'' and ''accessory.'' Other comments stated that FDA should not define these categories of products, because it is too difficult to properly define such large categories of products and any definitions quickly would become outdated.

(Response) FDA agrees that definitions of component or part and accessory would be appropriate and has included definitions consistent with factors noted in the proposal and consideration of comments. Although we indicated in the NPRM that accessories are not expected to be used with or for consumption of a tobacco product, we also indicated our expectation that accessories will have little impact on the public health. While the definition of accessory is different than the description in the NPRM, based on consideration of the comments, it captures our original intent and the classes of products that the Agency views as accessories. The definitions of component, part, and accessory, which are discussed at the beginning of this section VI.A of the document, are included in §§ 1100.3, 1140.3, and 1143.1.

(Comment 68) Several comments expressed concern about FDA's statement in the NPRM that the Agency may consider rule revisions if FDA later decides to extend its regulatory authority to components and parts of newly deemed tobacco products that do not contain tobacco or nicotine. They stated that the Tobacco Control Act does not permit FDA to regulate such objects if they do not employ tobacco as a raw material.

(Response) FDA disagrees. To clarify, FDA is finalizing its proposal to deem all tobacco products, including all components and parts, but excluding accessories of newly deemed tobacco products, to be subject to chapter IX of the FD&C Act. However, the additional restrictions (*i.e.,* minimum age and identification, vending, and health warnings provisions) only apply to ''covered tobacco products.'' The health warning provisions apply to ''covered tobacco products,'' cigarette tobacco, and roll-your-own tobacco. The term ''covered tobacco products'' includes all newly deemed tobacco products except those components and parts that are not made or derived from tobacco.

FDA also disagrees that the FD&C Act does not authorize FDA to regulate products that do not employ tobacco as a raw material. Section 901 of the FD&C Act states that chapter IX of the FD&C Act 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 chapter IX. Section 201(rr) of the FD&C Act defines ''tobacco product,'' in relevant part, as 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). Therefore, the statute gives FDA authority to deem additional tobacco products, including all components, parts, and accessories, except for raw materials (other than tobacco) that go into manufacturing of components, parts, or accessories of a tobacco product. Examples of such raw materials would be unprocessed acacia gum (taken from a tree and not processed) and minted titanium dioxide (used for whitening cigarette and tipping paper). In this rule, FDA is not deeming accessories to be subject to chapter IX and, although it is deeming all components and parts to be subject to chapter IX, it is not applying the additional restrictions (*i.e.,* minimum age and identification, vending, and health warnings provisions) to components and parts that are not made or derived from tobacco. Nevertheless, if FDA were to consider extending its authority to accessories or to apply additional restrictions to components or parts, FDA would do so through the rulemaking process.

(Comment 69) A few comments expressed concern that the rule would create incentives for manufacturers to separate nicotine-containing components from nonnicotine-containing components to evade regulatory requirements. They stated that the rule would allow minors to purchase nicotine delivery systems, as long as they do not contain e-liquids, and obtain the e-liquids from other sources (*e.g.,* friends, parents, online).

(Response) FDA understands these concerns. However, this deeming rule covers tobacco product components and parts intended or reasonably expected to be used with or for the human consumption of a tobacco product. In addition, as stated in § 1140.16, retailers of newly deemed tobacco products may not sell covered tobacco products (through any medium, including the Internet) to individuals under 18 years of age. FDA will continue to actively enforce the minimum age restriction for

mail order and Internet sales, which will help to reduce youth access to the nicotine and tobacco containing components, without which they cannot use the other components of ENDS.

(Comment 70) Some comments stated that the objects used in or with an e-cigarette (including batteries, wire, screws, silica) should be beyond the scope of FDA's authority, because they do not become part of the tobacco product until they are constructed by the consumer. Others stated that FDA should regulate these objects given reports regarding the malfunctioning of certain e-cigarette components (*e.g.,* dangers of exploding batteries (Ref. 65)) and the fact that the e-liquid cannot be consumed without each component working in conjunction to deliver nicotine to the consumer. These comments asked FDA to clarify whether the Agency will regulate only the nicotine-containing cartridges in a line of products that includes varying degrees of nicotine including cartridges advertised as nicotine free if they are intended to be used with or for the human consumption of a tobacco product.

(Response) This final deeming rule deems all tobacco products as they are defined in section 201(rr) of the FD&C Act, except accessories of newly deemed products, but including components and parts as defined in this rule. The wires, screws, and silica meet the definition of component or part, as they are an assembly of materials intended or reasonably expected to be used with or for the human consumption of a tobacco product and are not accessories of a tobacco product. FDA also remains concerned about reports of exploding batteries. Batteries that are co-packaged with other components or parts of an ENDS (*e.g.,* cartridges and tanks) or otherwise intended or reasonably expected to be used with or for the consumption of ENDS are components or parts and subject to FDA's tobacco product authorities. However, as noted elsewhere in this document, for ENDS hardware or delivery system components or parts, such as batteries, FDA expects that it may be difficult for manufacturers to obtain premarket authorization for such products, given the great extent of possible variations in combinations of hardware components, if all considered and sold separately. Thus, with respect to such apparatus, FDA expects that manufacturers will be most successful where authorization is sought for entire delivery systems, rather than individual components. Elsewhere in this issue of the **Federal Register**, FDA also has made available draft guidance, which when final will represent some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products and will include FDA's current thinking regarding compliance with existing voluntary standards for ENDS batteries.

In addition, nicotine-containing cartridges that include varying degrees of nicotine are components or parts and subject to FDA's chapter IX authorities because they constitute an assembly of materials intended or reasonably expected to be used with or for the human consumption of a tobacco product and do not constitute a tobacco product accessory. Upon the effective date of this final rule, FDA intends to regulate the entire line of cartridges (including cartridges that include varying degrees of nicotine or those that do not contain nicotine, if they meet the definition of component or part).

(Comment 71) Several comments urged FDA to include all e-liquids in the minimum age and identification requirements and vending machine restrictions in the revised part 1140, including e-liquids that do not contain nicotine, because they are easily accessible to minors online and can be mixed with nicotine. In addition, they suggested that FDA require the proposed addiction warning on all components or parts sold in conjunction with e-liquid.

(Response) FDA disagrees. Under this deeming rule, e-cigarettes that contain nicotine cannot be sold to youth under the age of 18. In addition, an e-liquid with nicotine is a covered tobacco product and, therefore, will be required to have a health warning under part 1143. As previously discussed, an e-liquid without nicotine is a component (and subject to FDA's tobacco control authorities), if it is intended or reasonably expected to be used with or for the human consumption of a tobacco product (*e.g.,* with liquid nicotine) and does not constitute a tobacco product accessory, but an e-liquid that does not contain nicotine or tobacco is not required to carry a warning, nor is it subject to the minimum age and identification requirements and vending machine restrictions under parts 1140 and 1143 because it is not a covered tobacco product as defined by this rule. Because components without nicotine or tobacco are intended to be used with a covered tobacco product, which contains nicotine or tobacco, FDA believes that it is appropriate to require only the covered tobacco product to be subject to the minimum age and vending machine provisions and to carry the warning. Moreover, if a warning is overused, there is the danger that it will grow stale.

(Comment 72) One comment disagreed with what it characterized as FDA's assertions that tobacco product accessories do not pose a public health risk or environmental risk and stated that such objects are harmful to humans and the food chain.

(Response) FDA wishes to clarify language included in the NPRM regarding accessories (79 FR 23142 at 23153). FDA did not propose, nor is it stating in this final rule, that tobacco product accessories do not pose any public health risk. Instead, we indicated that tobacco product accessories as defined in the rule likely have less (rather than ''no'') risk to the overall public health, which we reiterate in this final rule. FDA is regulating components and parts (and not accessories) of the newly deemed products, so the Agency can better focus its resources on those objects with a greater likely impact on public health. Similarly, FDA did not state that this rule would not impact the environment. Rather, the environmental analysis included in the NPRM stated that the impacts of this rule will not have a significant impact on the human environment according to the standard imposed by the National Environmental Policy Act, as stated in the proposed environmental assessment (EA). The final EA and Finding of No Significant Impact (FONSI) are included in the docket.

(Comment 73) The comments suggested several different regulatory approaches for components, parts, and accessories. First, several comments stated that FDA should weigh the relative risks of these products and impose the least burdensome requirements necessary to effectively manage or mitigate those risks. They suggested that FDA treat these products the way the Agency does with its review of marketing applications. For example, they noted that FDA's draft and final guidance documents on PMTAs and SE reports explain that FDA does not intend to enforce the requirements of either section 910 or 905(j) of the FD&C Act for components of regulated tobacco products that are sold or distributed solely for further manufacturing into finished tobacco products because the Agency anticipates ''receiving relevant information regarding such new tobacco products in the PMTA submission for the finished regulated tobacco products'' (citing draft guidance, ''Applications for Premarket Review of New Tobacco Products''). Second, some comments believed that manufacturers of e-cigarette components and parts

should be required to submit marketing applications given the aerosols and ''vapors'' that consumers generate when using certain components or parts. Third, some comments stated that instead of requiring manufacturers of components and parts to comply with the automatic requirements for the newly deemed products, FDA should require them to ensure that all of their components and parts that contain tobacco or tobacco derivatives are shipped and packaged with labeling that indicates that they are intended for further manufacture.

(Response) At this time, FDA intends to limit enforcement of the premarket review requirements to finished tobacco products. For purposes of this compliance policy applicable to newly deemed products, a finished tobacco product refers to a tobacco product, including all components and parts, sealed in final packaging intended for consumer use (*e.g.,* filters or filter tubes sold separately to consumers or as part of kits). FDA does not at this time intend to enforce these requirements for components and parts of newly deemed products that are sold or distributed solely for further manufacturing into finished tobacco products. In addition, FDA does not believe that it is warranted at this time to require components and parts that contain tobacco or tobacco derivatives to include labeling that indicates they are intended for further manufacture.

(Comment 74) Some comments stated that FDA should regulate all components, parts, and accessories, as long as they have a foreseeable impact on the public health. They believed that omitting accessories from the scope of the deeming rule ignores the clear statutory language that explicitly defines ''tobacco product'' to include accessories.

(Response) FDA disagrees. Although Congress included ''accessories'' within the definition of ''tobacco product'' in section 201(rr) of the FD&C Act, it did not explicitly require that FDA include all components, parts, and accessories within the scope of its rule to deem additional tobacco products under section 901. Accessories, as defined in this rule, likely have less risk to the overall public health, and the benefits to overall public health for deeming accessories subject to FDA's tobacco product authorities are also likely less. Therefore, FDA is excluding them from the scope of this deeming rule.

(Comment 75) Some comments stated that items also used for purposes other than for tobacco use (*i.e.,* a lighter or matches that can be used to light candles) should be classified as accessories and, therefore, not subject to FDA's chapter IX authorities. For example, batteries used in advanced personal vaporizers can be found in laptop battery packs or cordless drill packs. These comments also stated that items such as lighters and batteries may (or may not) be used in consumption of a tobacco product or are regulated by the Consumer Product Safety Act (as are child-resistant lighters) and, therefore, should not be subject to FDA's tobacco product authorities.

(Response) FDA agrees that it is not necessary to regulate batteries that are not intended or reasonably expected to be used with a tobacco product under its tobacco product authorities. However, it is important that batteries that are co-packaged with other parts of an ENDS (*e.g.,* cartridges and tanks) or otherwise intended or reasonably expected to be used with ENDS are components subject to FDA's tobacco product authorities. FDA remains concerned about reports of exploding e-cigarette batteries and finds that regulating them can help address these problems. Toward that end, elsewhere in this issue of the **Federal Register**, FDA has made available draft guidance, which when final will describe FDA's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products, including compliance with existing voluntary standards for ENDS batteries.

(Comment 76) Some comments stated that walk-in humidors for cigars should not be subject to FDA regulation because they are important to retailers and allow consumers to browse a retailer's stock and make a selection.

(Response) As discussed previously, any item that is intended or reasonably expected to be used with or for the human consumption of a newly deemed tobacco product; does not contain tobacco or a tobacco derivative; and is intended or reasonably expected to affect or maintain the characteristics of the newly deemed tobacco product but solely controls moisture and/or temperature of a stored newly deemed tobacco product, is an accessory and excluded from this deeming rule. Therefore, unless the humidor is designed to affect the tobacco product in a manner other than controlling moisture or temperature, such walk-in cigar humidors are not subject to this rule.

(Comment 77) A few comments expressed concern that e-cigarette tanks and cartridges would not be included within the proposed vending machine restrictions because they do not contain nicotine at the time of sale. They said that such objects are not standardized and that their quality, composition, and safety are not regulated and, therefore, they should be subject to FDA's chapter IX authorities.

(Response) FDA does not believe it is necessary for tanks and cartridges that do not contain nicotine or tobacco to be subject to the vending machine restrictions because they can only be used to consume tobacco or nicotine derived from tobacco with other products that are subject to the additional restrictions. However, FDA is aware of the current lack of regulation or standardization of tanks and cartridges, which are components and parts that FDA is deeming to be subject to FDA's chapter IX authorities with this rule. After the effective date of this final rule, FDA will have authority to issue tobacco product manufacturing practice regulations under section 906(e) of the FD&C Act and product standards under section 907 of the FD&C Act to address the quality, composition, and safety of these components and parts. FDA also notes that these components and parts will usually be subject to premarket review, either by themselves, as components and parts intended for consumer use, or as components and parts of products that undergo further manufacturing for which the end product will be subject to premarket review.

(Comment 78) A few comments expressed concern with FDA's characterization of objects used during a waterpipe tobacco session (*i.e.,* the burners, holders, screens, and other objects used with waterpipe tobacco). They stated that all waterpipe burners and holders can affect waterpipe tobacco emissions, and noted that foil is heated to the same extent as charcoal during waterpipe use and, therefore, can present a burning danger (Ref. 66). In addition, the heating source, screen (or aluminum foil), and hose can have a significant impact on passive and active exposure and smoking/puffing behaviors and, therefore, should be components or parts subject to chapter IX of the FD&C Act.

(Response) FDA has included definitions of ''component,'' ''part,'' and ''accessory'' with this final rule to provide additional clarity regarding the characterization of products used during a waterpipe session. According to these definitions, the screen (or aluminum foil) and hoses that are co-packaged with other parts of a hookah or marketed, advertised, or otherwise intended for use with a hookah are parts or components and subject to FDA's tobacco product authorities. However, for example, an external burner or

heating source that is not incorporated into the hookah would be an accessory, provided that it does not contain tobacco or a tobacco derivative and solely provides an external heat source to initiate but not maintain combustion of a tobacco product. The holder also is an accessory and not subject to chapter IX of the FD&C Act.

(Comment 79) A few comments suggested that charcoal or wood cinder used with waterpipe tobacco should be considered a tobacco product and deemed under this regulation. They explained that combustion of these products produces toxicants and may emit carcinogens, carbon monoxide, polycyclic aromatic hydrocarbons, and other cancer causing agents.

(Response) FDA finds that such products are components or parts; therefore, they are subject to FDA's chapter IX authorities. They are an assembly of materials intended or reasonably expected to be used with or for the human consumption of a tobacco product and are not accessories. As we have noted throughout this document, an accessory does not contain tobacco and is not made or derived from tobacco, and it meets one of the following: (1) Is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product; or (2) is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a tobacco product but (i) solely controls moisture and/or temperature of a stored product; or (ii) solely provides an external heat source to initiate but not maintain combustion of a tobacco product. Therefore, the charcoal or wood cinder intended or reasonably expected to be used with or for the human consumption of waterpipe tobacco are components or parts. Further, charcoal and wood cinders are not considered accessories given that they: (1) Do not contain tobacco and are not made or derived from tobacco; and (2) are intended or reasonably expected to alter the characteristics of a tobacco product but do not solely control moisture and/or temperature of a stored product and do not solely provide an external heat source to initiate but not maintain combustion. Instead, both charcoal and wood cinder are used to maintain the combustion of waterpipe tobacco.

(Comment 80) Many comments asked for clarification as to whether certain items associated with cigar use should be termed ''accessories,'' including cigar tip cutters, permeable humidor buttons, removable tips, mouthpieces, removable filters, holders, lighters, ashtrays, and cases.

(Response) FDA generally expects cigar tip cutters, permeable humidor buttons, holders, ashtrays, and cases would be accessories that are not subject to FDA regulation. In addition, as stated in this section (discussing the definitions of component or part and accessory), for the purposes of this regulation, any item that does not contain tobacco or a tobacco derivative and is not integrated in a tobacco product, but rather solely provides an external heat source, to initiate but not maintain combustion of a tobacco product (such as a lighter) is not subject to this deeming rule. However, removable tips, mouthpieces, and filters are all intended to be used by adult consumers in the human consumption of a tobacco and do not meet the definition of accessory, therefore, are included within the scope of this final rule.

(Comment 81) A few comments expressed concern that vaporizers sold separately without nicotine can be modified or ''hacked,'' which researchers found could increase toxins and other dangerous components, including formaldehyde (Ref. 67). They stated that online videos show how to ''hack'' an e-cigarette, including how to change the apparatus to increase the temperature of the ''vapor.'' Because of these concerns, they argued that such items should be considered components and parts and under FDA's jurisdiction.

(Response) FDA agrees that vaporizers are components or parts of a tobacco product. These objects are an assembly of materials intended or reasonably expected to be used with or for the consumption of a tobacco product and do not constitute tobacco product accessories. Therefore, they are tobacco product components or parts and subject to FDA's chapter IX authorities. FDA considers components or parts sold directly to consumers to be finished tobacco products. A finished tobacco product refers to a tobacco product, including all components and parts, sealed in final packaging intended for consumer use (*e.g.,* filters or filter tubes sold separately to consumers or as part of kits). FDA remains concerned about adverse events associated with ENDS use and finds that regulating them can help address these problems. Toward that end, elsewhere in this issue of the **Federal Register**, FDA has made available draft guidance, which when final will describe FDA's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products.

(Comment 82) One comment requested that flavored rolling papers be included as a newly deemed tobacco product. Another comment claimed that flavored papers should not be subject to FDA's tobacco control authorities, because they do not pose a danger to public health.

(Response) Rolling papers intended for use with cigarette tobacco or roll-your-own tobacco are already subject to FDA's tobacco control authorities under section 901 of the FD&C Act because they are components of cigarettes and cigarette tobacco. Upon the effective date of this final rule, rolling papers (including flavored papers) intended for use with newly deemed tobacco products would be tobacco product components or parts and subject to FDA's chapter IX authorities.

B. Discussion of Requirements Associated With Components and Parts

FDA received many inquiries about how the automatic provisions associated with deeming tobacco products would apply to components and parts. Components and parts of newly deemed tobacco products are subject to all of the automatic provisions included in the FD&C Act, as further discussed as follows.

1. Ingredient Listing (Sections 904(a)(1) and 904(c)); Health Document Submission (Section 904(a)(4)); and Registration and Product Listing (Section 905)

At this time, FDA intends to limit enforcement to finished tobacco products. A finished tobacco product refers to a tobacco product, including all components and parts, sealed in final packaging intended for consumer use (*e.g.,* filters, filter tubes, e-cigarettes, or e-liquids sold separately to consumers or as part of kits). FDA does not at this time intend to enforce these requirements for components and parts of newly deemed products that are sold or distributed solely for further manufacturing into finished tobacco products.

2. SE Reports and PMTAs (Section 905(j) and 910)

At this time, FDA intends to limit enforcement to finished tobacco products. FDA does not at this time intend to enforce these requirements for components and parts of newly deemed products that are sold or distributed solely for further manufacturing into finished tobacco products.

3. Reporting of HPHCs (Section 915)

At this time, FDA intends to limit enforcement to finished tobacco

products. See section IX for further discussion of ENDS retail establishments and the responsibilities of upstream manufacturers for reporting of HPHCs. The Agency is working to determine an appropriate compliance policy to deal with HPHCs for newly deemed products (including e-liquids) and is intending to issue guidance with enough time for manufacturers to report given the 3-year compliance period.

VII. Regulation of Cigars and Selection of Option 1

As discussed in the preamble to the NPRM (79 FR 23142 at 23150 through 23152), it has been suggested that different kinds of cigars may have the potential for varying effects on public health. Accordingly, FDA proposed two options for the categories of cigars to be subject to this deeming rule. Option 1 proposed to 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. Option 2 proposed to deem all products meeting the statutory definition of ''tobacco product,'' except accessories of a proposed deemed tobacco product and a subset of cigars referred to as ''premium cigars'' to be subject to FDA's tobacco product authorities under chapter IX of the FD&C Act. FDA notes that individual hand rollers of cigars would be considered manufacturers under chapter IX of the FD&C Act, and subject to the same requirements as other tobacco product manufacturers.

(Comment 83) Some comments that supported Option 1 stated that FDA should regulate premium cigars, in part, because they meet the statutory definition of ''tobacco product.''

(Response) FDA agrees. All cigars, including those referred to as premium cigars, meet the definition of a ''tobacco product'' under section 201(rr) of the FD&C Act.

After thorough review of the comments and the scientific evidence, FDA has concluded that deeming all cigars, rather than a subset, more completely protects the public health and therefore has adopted Option 1 in the final rule. FDA has concluded that: (1) All cigars pose serious negative health risks, (2) the available evidence does not provide a basis for FDA to conclude that the patterns of premium cigar use sufficiently reduce the health risks to warrant exclusion, and (3) premium cigars are used by youth and young adults. The fact that some premium cigar smokers might smoke such products infrequently or report that they do not inhale does not negate the adverse health effects of tobacco smoke or demonstrate that cigars do not cause secondhand smoke-related disease in others. Therefore, we find there is no appropriate public health justification to exclude premium cigars from the scope of the final deeming rule and that it is appropriate to deem them.

A. Health Risks of Premium Cigars

Researchers estimate that regular cigar smoking was responsible for approximately 9,000 premature deaths or almost 140,000 years of potential life lost among adults 35 years or older in 2010 (Ref. 68). Cigar smoke contains many of the same harmful constituents as cigarette smoke and may have higher levels of several harmful compounds (Ref. 68, citing Ref. 69 at 55–104). All cigar smokers have an increased risk of oral, esophageal, laryngeal, and lung cancer compared to non-tobacco users (Refs. 35, 69). Among those who report inhaling cigar smoke, there are significantly elevated levels of many types of cancer and other adverse health effects, such as increased risk of heart and pulmonary disease (Refs. 69, 70). Cigar smokers also are at a marked increase in risk for chronic obstructive pulmonary disease (COPD) and experience higher mortality risk from COPD than nonsmokers (Refs. 70, 71). In addition, cigar smokers have a higher risk of fatal and nonfatal stroke than nonsmokers (Ref. 72). All cigars produce secondhand smoke, which causes negative health effects such as heart disease and lung cancer in bystanders (Refs. 35, 69).

Nevertheless, we do note that the 2014 Surgeon General's Report states that when compared with persons who smoke cigarettes, those who use cigars exclusively have a lower risk for many smoking-related diseases (Ref. 9 at 428 citing Ref. 69). Although smoke from cigars contains the same toxic substances as cigarette smoke, cigar smokers generally smoke at a lower frequency and tend not to inhale the smoke, thus reducing (but not eliminating) their exposure to its toxic substances (id.). Former cigarette smokers are more likely to inhale cigar smoke than are primary cigar smokers who have never smoked cigarettes (id.).

While most studies cited in this section do not explicitly pertain to premium cigars, the bulk of the established data on the health effects of cigar smoking is based on smokers of traditional, large cigars and, therefore, is applicable to the toxicity of premium cigars given that they share the same characteristics and are generally smoked in similar ways.

While exposure to higher levels of cigar smoke for a longer period of time increases the adverse health risks due to cigar smoking (just as it does for cigarettes), the Surgeon General has stated that no amount of smoking is safe (Ref. 2). Further, there are no data indicating that premium cigar users are not susceptible to health risks, as discussed in section VII.C. FDA's responses to comments on the health risks of premium cigars are included in the following paragraphs.

(Comment 84) Proponents of Option 1 stated there is no public health justification for exempting premium cigars and that deeming premium cigars will benefit the public health immediately through the automatic and additional provisions and the imposition of future product standards. They also stated that exempting premium cigars would have a negative impact on the public health.

(Response) FDA agrees. As stated in the NPRM, there will be many public health benefits associated with deeming tobacco products (including products referred to as premium cigars). For example, the adulteration and misbranding provisions in sections 902 and 903 of the FD&C Act, as applied to the newly deemed products, will protect consumers because FDA will be able to take enforcement action against any non-compliant tobacco product, such as a product with false or misleading labeling or advertising. In addition, ingredient listings and reports of HPHCs under sections 904 and 915 of the FD&C Act will assist FDA in better understanding the contents of regulated products. 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. With application of the section 905 registration and listing requirements, FDA will be able to conduct biennial inspections of tobacco product manufacturers. Further, implementation of the premarket review provisions of sections 905, 910, and 911 of the FD&C Act will allow FDA to monitor product development and changes and to prevent more harmful or addictive products from reaching the market. Moreover, there were no data provided to support the premise that there are different patterns of use of premium cigars and that these patterns result in lower health risks.

(Comment 85) Some comments argued that exempting premium cigars from deeming would set a dangerous precedent that it is appropriate for FDA not to regulate certain tobacco products by virtue of their potential for varying

effects on public health. An exemption could mislead consumers to believe that premium cigars are safe, which contradicts the available evidence that all cigars are harmful and potentially addictive. In addition, the current population of premium cigar users would be left unprotected, potentially decreasing the likelihood that they would quit, and leading more youth and young adults to initiate use of premium cigars or substitute products.

(Response) FDA agrees with these comments. Accordingly, FDA has selected Option 1 deeming all cigars, rather than a subset, for the scope of this final rule.

(Comment 86) Many comments that supported Option 2 argued that premium cigars do not present a public health threat significant enough to warrant regulation and that no evidence was presented that regulation of premium cigars would substantially improve the public health. These comments stated that premium cigars represent a small portion of the tobacco product and cigar markets (annual premium cigar estimate in the United States of 300 million units compared to nearly 14 billion total cigar units and nearly 300 billion cigarettes) (Ref. 73), and there is no evidence that premium cigars have the same health consequences or habitual use patterns as other tobacco products. They generally relied on two studies, Funck-Brentano et al. and Turner et al., to claim that premium cigars deliver little nicotine to users, by inhalation or oral absorption (Refs. 74, 75). They also claimed that cigars do not significantly elevate the risk of addiction or death (Refs. 76, 77) and stated that, in some studies, there were a very small number of cancer cases or deaths among cigar smokers (Refs. 78, 79). They also noted the nonsignificant odds ratios for those consuming 1 to 2 cigars per day (Refs. 69, 79) and for the risk of lung cancer and ''tobacco-related cancers'' among exclusive cigar smokers (Ref. 80).

(Response) FDA disagrees with these claims and finds that the cited studies or critiques are not persuasive. Regarding the claim that premium cigars deliver little nicotine to users, the Turner study (Ref. 75) was a study of only 10 male hospital workers conducted more than 30 years ago. The findings of the Turner study, based on carboxyhemoglobin and plasma nicotine levels, suggested that former cigarette smokers who occasionally smoked cigars or regularly smoked pipes had greater cigar smoke inhalation and absorption than primary cigar and pipe smokers (*i.e.,* those who never smoked cigarettes). This study also reported that average plasma nicotine concentrations among primary cigar and pipe smokers were somewhat elevated 60 minutes into a cigar smoking session compared with levels measured after smoking abstinence (Ref. 75). Notwithstanding the small sample size, the study results still demonstrate that cigars deliver nicotine to users.

Similarly, the Funck-Brentano et al. study (Ref. 74) assessed biomarkers of tobacco exposure and toxicity in a small sample of cigar (corona-sized or larger cigar) or pipe smokers (n = 30), cigarette smokers (n = 28), and nontobacco users (n = 30), making this small biomarker study less persuasive. In fact, the study authors state: ''These results should not be seen as a justification for the smoking of pipes and cigars, which are clearly associated with clinically significant health hazards. We emphasize that we cannot determine whether our results are explained by the type of tobacco smoked or by the different inhalation pattern in pipe/cigar smokers and cigarette smokers.''

A recent analysis of biomarkers of tobacco exposure among cigar smokers used data from the 1999–2012 National Health and Nutrition Examination Survey, a nationally representative survey (Ref. 81). The sample included more than 220 primary cigar (*i.e.,* current cigar/never cigarette) smokers and more than 180 secondary cigar (*i.e.,* current cigar/former cigarette) smokers (id.). The researchers found that serum cotinine concentrations among primary (and secondary) cigar smokers were substantially higher than in nontobacco users in crude and adjusted analyses (id.). In addition, adjusted analyses showed that concentrations of NNAL (4-(methylnitrosamino)-1-(3-pyridyl)-1-butanol), blood cadmium, and lead were also higher among primary (and secondary) cigar smokers compared with nontobacco users (id.). Therefore, not only were the cited studies unpersuasive, but this robust and recent analysis contradicts those studies.

In addition, FDA did not find persuasive studies cited in comments for the proposition that cigars do not significantly elevate the risk of addiction or death. To support this proposition, comments relied in part on a study (Ref. 76) in which a panel scored the worldwide harmfulness of 12 nicotine products using a multicriteria decision analysis approach. Although cigarettes ranked higher than either little cigars and other cigars on an aggregate harm score, the study found cigar smoking does result in morbidity, mortality, and dependence.

The other study used to support the proposition that cigars are not a significant public health threat (Ref. 77) found a significant association between primary cigar or pipe smokers and lung cancer mortality risk, which refutes the claim that cigar use does not significantly elevate the risk of death. In addition, this study found an association between COPD mortality risk and secondary cigar or pipe smoking (but not for primary cigar and pipe smoking). Also, contrary to the assertions of commenters, a recent systematic review of cigar smoking and mortality summarized the results of 22 published studies from 16 different prospective cohorts and found that primary cigar smoking was associated with increased risk of mortality from all causes, several types of cancers, coronary heart disease, and aortic aneurysm (Ref. 82). Mortality risks were greater with increasing number of cigars smoked per day and self-reported level of inhalation, however, primary cigar smokers reporting no inhalation still had highly elevated mortality risks for oral, esophageal, and laryngeal cancers (id.). In addition, a recent study estimated that in 2010 more than 9,000 premature deaths annually were attributable to regular cigar smoking (*i.e.,* those who reported smoking cigars on at least 15 of the past 30 days) (Ref. 68).

Moreover, FDA reviewed a study by Boffetta et al. (Ref. 78), which commenters relied upon to claim that a very small number of cancer cases existed among cigar smokers and, therefore, premium cigars should not be regulated. The Boffetta et al. study (id.) used a case-control design to assess the association between lung cancer risk and cigar smoking. The authors determined that the overall association between primary cigar or cigarillo smokers and lung cancer was significant and found significant associations in all but one area (id.). For all other estimates, the results were statistically significant. We also note that, despite the relatively small number of cancer cases in this study, it is only one part of a larger body of evidence that demonstrates the increased risk of serious adverse health effects associated with cigar smoking (Refs. 35, 69, 70, 71, 72, 77, 79, 83).

(Comment 87) Some comments stated cigar smokers are not at risk of becoming addicted to tobacco products based on their use of cigars. Other comments stated that certain attributes of premium cigars increase the likelihood for nicotine dependence, including their size, the amount of tobacco (and, therefore, nicotine) in the cigar, and the longer amount of time that it takes to smoke the cigar.

Additionally, these comments suggested that because cigar tobacco is more alkaline than cigarette tobacco, nicotine may be absorbed into the blood stream more rapidly, even without inhaling (Refs. 84, 85).

(Response) FDA agrees that all cigars are potentially addictive. As discussed in the preamble to the NPRM, a cigar can contain as much tobacco as a whole pack of cigarettes, and nicotine yields from smoking a cigar can be up to eight times higher than yields from smoking a cigarette (79 FR 23142 at 23154). Although the amount of nicotine taken in by a cigar user depends on various factors like how long the person smokes the cigar, the number of puffs taken, and the degree of inhalation, a leading review of the science of cigar smoking concluded that ''[c]igars are capable of providing high levels of nicotine at a sufficiently rapid rate to produce clear physiological and psychological effects that lead to dependence, even if the smoke is not inhaled'' (Ref. 35). In addition, regardless of whether premium cigar smokers inhale, buccal absorption of nicotine does occur, and cigar smokers may also absorb nicotine through the lips due to the alkalinity of cigar tobacco (Refs. 86, 87). This increased nicotine yield and absorption increases the risk of nicotine addiction from cigar smoking. Researchers analyzing data from the NYTS found that although the percentage of youth reporting various measures of dependence was lower for cigars than for cigarettes or smokeless tobacco, some youth did report some measures of cigar addiction (Ref. 88). This study found that 6.7 percent of middle and high school students who only smoked cigars also reported strong cravings for a tobacco product during the past 30 days, and 7.8 percent reported sometimes/often/always feeling irritable or restless when not using tobacco—which are measures of dependence (id.) We note that the Surgeon General has found that all forms of nicotine delivery do not pose an equal risk in establishing or maintaining nicotine addiction (Ref. 9).

(Comment 88) Many comments remarked that premium cigars do not pose the same adverse health effects as cigarettes and other types of cigars because most studies of cigar health effects do not differentiate between types of cigars. They claimed this lack of evidence precludes conclusions about the health effects of premium cigars specifically.

(Response) The science is clear that cigar use of all types can lead to negative health effects, as discussed throughout this section of the document. Thus, the contention that studies are inconclusive about the health effects of premium cigars because they do not differentiate between types of cigars is not persuasive.

All cigar use is harmful and potentially addictive. Cigar smokers have an increased risk of oral, esophageal, laryngeal, and lung cancer compared to nonsmokers (Refs. 35, 69). Among those who report inhaling cigar smoke, there are significantly elevated levels of many types of cancer and other health effects, such as increased risk of heart and pulmonary disease (Refs. 69, 70). Cigar smokers also have a marked increase in risk for COPD and experience higher mortality risk from COPD than nonsmokers (Refs. 70, 71). In addition, cigar smokers have a higher risk of fatal and nonfatal stroke than nonsmokers (Ref. 72). All cigars produce secondhand smoke, which causes negative health effects such as heart disease and lung cancer in bystanders (Refs. 35, 69).

We note that the Surgeon General reported in 2014 that, ''[c]ompared with persons who smoke cigarettes, smokers who smoke pipes or cigars exclusively have a lower risk for many smoking-related diseases (internal citation omitted). Smoke from pipes and cigars contains the same toxic substances as cigarette smoke, but those who use a pipe or cigar usually smoke at a lower frequency; observation indicates that they tend not to inhale the smoke, thus reducing their exposure to its toxic substances (internal citations omitted). Evidence indicates that former cigarette smokers are more likely to inhale pipe or cigar smoke than are primary pipe and cigar smokers who have never smoked cigarettes (internal citations omitted)'' (Ref. 9 at 428–429). However, research indicates that most cigar smokers do inhale some amount of smoke, even when they do not intend to inhale, and are not aware of doing so (Refs. 32, 33).

Finally, FDA specifically sought comment on how the potential different patterns of use for premium cigars might result in different or decreased health impacts, but no such evidence was submitted (see discussion in section VII.C of document).

(Comment 89) Some comments indicated that many cigar users, including those who smoke premium cigar brands, are also current or former cigarette users, increasing their exposure to toxic constituents and the health risks of using combusted tobacco products (Refs. 89, 90). Additionally, they stated that these users are more likely to inhale when they use cigars and may smoke more cigars per day, significantly increasing their health risks (Refs. 33, 91, 92, 93, 94).

(Response) FDA agrees. Given the adverse health effects of all cigars, FDA has selected Option 1 deeming all cigars, rather than a subset, for the scope of this final deeming rule.

(Comment 90) Some comments raised concerns about dual and polyuse of cigars and other tobacco products, which is common among both adults and youth (Refs. 90, 95). For example, in one study, 35.1 percent of adult premium cigar users, 58.3 percent of cigarillo and other mass market cigar users (*i.e.,* those reporting their usual cigar did not have a filter and the usual brand was not premium), and 75.2 percent of little filtered cigar users also smoked cigarettes (Ref. 90). Some comments noted that multiple product use is concerning because polytobacco users are more likely to report symptoms of nicotine dependence (Ref. 88).

(Response) As FDA stated in the NPRM, we are concerned about the use of multiple products, especially combusted tobacco products.

B. Youth and Young Adults Use Premium Cigars

Proponents of Option 2 have stated that an exemption for premium cigars is warranted because youth prefer machine-made cigars (as opposed to hand-rolled) given their low price, flavoring, and easier availability. However, although youth and young adults have a higher use of cigarillos and other mass market cigars, studies indicate that they are also using premium cigars.

(Comment 91) Many comments cited data showing that among those age 12 and older, past month cigar use decreased slightly from 5.4 percent in 2002 to 5.2 percent in 2012 after peaking at 5.7 percent in 2004 (Ref. 89 at Figure 4.1). Among youth only (ages 12 to 17), cigar smoking prevalence declined between 2004 (4.8 percent) and 2012 (2.6 percent) (Ref. 89 at Figure 4.1). Trend data from the National Youth Risk Behavior Survey also indicate that cigar use among male high school students, female students, and white, black, and Hispanic students either declined or remained stable from 1997 to 2011 (Ref. 9). Additionally, from 1997 to 2013, ''a significant linear decrease occurred overall in the prevalence of current [youth] cigar use (22.0 percent–12.6 percent)'' (Ref. 96), which was observed from data collected by the CDC 1997–2013 YRBS (Ref. 29). Accordingly, they questioned whether FDA should be regulating cigars.

Other comments included data indicating that youth cigar use has not declined when compared to use of other tobacco products. They noted that many youth surveys show youth cigar smoking to be higher than, or about the same as, cigarette smoking. For example, in 2013, among U.S. high school males, the prevalence of current (past 30 day) cigar smoking (16.5 percent) was comparable to current (past 30 day) cigarette smoking (16.4 percent) (Ref. 96). Additionally, in 21 U.S. cities that conducted the 2013 YRBS, the prevalence of current cigar smoking (8.6 percent) was comparable to current cigarette smoking (7.7 percent) among high school students (id.). In 2014, NYTS reported that among high school Non-Hispanic black students, 8.8 percent reported smoking cigars in the past 30 days, whereas 4.5 percent reported smoking cigarettes in the past 30 days (Ref. 22). In addition, among high school males overall, the prevalence of past 30 day cigar smoking (10.8 percent) was comparable to past 30 day cigarette smoking (10.6 percent) (id.). Measures of youth use of cigars may underestimate prevalence due to incorrect self-identification as a non-cigar smoker and confusion between the various cigar products (Refs. 97, 98, 99). Accordingly, the comments supported FDA's regulation of all cigars.

(Response) FDA remains concerned about the use of all tobacco products, particularly combusted tobacco products like cigars and cigarettes, and remains most concerned about use by youth and young adults given their *unique* susceptibility to the addictiveness of nicotine. Although supporters of Option 2 relied upon NSDUH data showing a decline in cigar smoking prevalence among individuals aged 12 to 17 from 2004 to 2012, the NSDUH's questions about ever and past 30-day use of cigars did not include examples of specific brands. We note that the Surgeon General's 2014 report states that ''data from the 1997–2011 obtained from the National YRBS indicate that current cigar use among male high school students declined from 1997–2005 and then remained stable from 2005–2011. Among female students, current cigar use declined from 1997–2011.'' (Ref. 9 at 736, internal references omitted). The 2013 YRBS, a nationally representative survey of 13,000 youths, indicated that cigar use prevalence trends have *decreased* from 1997–2013 for youth in grades 9 through 12 (22 percent in 1997 to 12.6 percent in 2013) (Ref. 29).

Evidence suggests that some youth may recognize the brand of cigar they smoke, but not that it is a ''cigar'' in general terms and, therefore, may not report their cigar use (Refs. 98, 100). When examples of brand names were added to the 2012 NYTS, there was a pronounced increase from 2011 in reported cigar smoking among non-Hispanic black females (Ref. 100). Among NYTS high school students overall from 2000 to 2011, there was no change in prevalence of cigar smoking (Ref. 101). This lack of decline in cigar smoking is a concern considering cigarette smoking among high school students did significantly decline over these periods (id.). Among NYTS high school students overall from 2011 to 2014, there was a decrease in prevalence of current use of cigars from 11.6 percent to 8.2 percent (Ref. 22).

(Comment 92) The comments were divided as to whether youth use premium cigars. Some comments provided data demonstrating youth use of premium cigars. Others submitted mainly informal industry surveys and anecdotal evidence illustrating that the majority of premium cigar users are older adult males who smoke infrequently and often in a celebratory nature. A few other comments stated that patterns of use studies are inconclusive, because many studies do not differentiate between premium cigars and mass-market cigars.

(Response) Although youth and young adults tend to smoke mass market cigar brands, they are also using premium cigars. In one study, researchers used data from the 2010–2011 NSDUH and Nielsen market scanner data to define a study sample consisting of 6,678 past 30-day cigar smokers who reported smoking a usual brand of cigars (Ref. 59). While many youth identified a mass market cigar as the brand they used most often, this analysis reveals that 3.8 percent of youth aged 12 to 17 and 12.1 percent of young adults aged 18 to 25 also identified certain premium cigars to be the brand they smoked most often (id.). Individuals in both cohorts reported at least eight different premium cigar brands among the brands they used most often, providing evidence that youth and young adults are smoking premium cigars (id.).

One study analyzing data from the 2012–2013 National Adult Tobacco Survey (NATS), with 60,192 participants 18 years and older found that of those smokers whose type of cigar could be identified based on the attributes of their usual product (*e.g.,* premium cigar smoker, little cigar smoker, cigarillo smoker), 19.9 percent were premium cigar smokers (Ref. 90). More specifically, 15.1 percent of cigar smokers aged 18 to 29 years old, who identified themselves as smoking every day, some days, or rarely, indicated the cigar they usually smoked on those occasions was a premium cigar (id.), which clearly illustrates that young adults are using premium cigars. Although some comments questioned the applicability of the NATS data on premium cigar use by youth and young adults (in part, because the study did not use the proposed definition of ''premium cigar'' in the NPRM), FDA is not persuaded. FDA does not believe it is necessary for the definition of premium cigars in this study to match exactly the definition in the NPRM in order to draw inferences about the use of different types of cigar products. These data, along with the NSDUH and Nielsen market scanner data discussed previously, clearly indicate that youth and young adults are using premium cigars.

Some comments stated the previously mentioned studies show only minimal premium cigar use by minors. By contrast, they relied on Soldz et al. (Ref. 102), which examined preferred cigar brands based on a survey of Massachusetts middle and high school students. Although the study did not include any particular premium cigars among the brands reported, 16.4 percent of youth cigars users were categorized as preferring a ''non-listed'' brand which the authors suggested ''may largely consist of premium cigars.'' The authors based this determination given the participants' positive association between the ''non-listed'' brands and parental cigar use and the negative association between the listed cigar brands and parental cigar use. Consequently, FDA does not believe this study demonstrates that youth do not use premium cigars. These comments also did not provide persuasive peer-reviewed evidence indicating that youth and young adults do not use these products. In addition, comments stating that youth and adult cigar use studies are not conclusive with regard to premium cigars because they do not differentiate between cigar types are not persuasive. Such studies show that youth and young adults smoke cigars, and other studies that do differentiate between product types, such as those previously discussed, indicate that youth and young adults do, in fact, use premium cigars.

In light of the health risks associated with the use of all types of cigars, FDA has selected Option 1 and is deeming all cigars, including premium cigars, in this rule.

(Comment 93) A few comments disagreed with FDA's characterization of one study cited in the NPRM (Ref. 103) for the proposition that young

adults often mistakenly view non-cigarette tobacco products, such as cigars, as safe alternatives to cigarettes. They noted that most young adult participants in the study rated shisha, herbal cigarettes, and herbal smokeless as ''safer than cigarettes,'' but rated cigars and kreteks as more harmful.

(Response) Many consumers believe that noncigarette tobacco products, including cigars, are less harmful than cigarettes. Although the overall study population did rate cigars as more harmful, there were subgroups (such as African Americans and non-Hispanic whites) that rated cigars from ''a little safer'' to ''much safer.'' Deeming all tobacco products, including premium cigars, to be subject to chapter IX of the FD&C Act will help to alleviate mistaken beliefs that certain tobacco products are safe alternatives to cigarettes by virtue of the fact that they are not subject to FDA regulation.

(Comment 94) A few comments also stated that premium cigar use among young adults is irrelevant because Congress did not task FDA with protecting young adults who are lawfully permitted to purchase tobacco products.

(Response) FDA is concerned with tobacco use by all age groups, including young adults and adults who may lawfully purchase these products. The Tobacco Control Act charges FDA with protecting the public health generally, not only the health of minors (section 3 of the Tobacco Control Act). Nevertheless, FDA is particularly concerned with tobacco use by youth and young adults, as they are uniquely more susceptible to becoming addicted to nicotine than adults or older smokers. As discussed in the NPRM, most tobacco users begin using prior to the age of 18 and believing they will be able to quit. However, most youth are unable to stop tobacco use once they become addicted. Accordingly, FDA is taking steps to reduce the potential harm to youth and young adults from tobacco products.

(Comment 95) Many comments expressed concerns regarding flavored cigars, including flavored premium cigars, and their effect on youth initiation. Some comments concluded there is no evidence that minors consume flavored premium cigars, relying on one study in which the flavored premium cigar brands of youth use accounted for only a fraction (0.1 percent) of the less than 4 percent reported use of premium cigar brands (Ref. 59).

(Response) FDA is announcing that it intends in the future to issue a proposed product standard that, if finalized, would eliminate characterizing flavors in all cigars including cigarillos and little cigars.

(Comment 96) Some comments argued that premium cigars do not pose youth access issues because manufacturers and retailers do not market them to youth (*i.e.,* they are not cheap, candy- and fruit-flavored, or easy to access) and age verification is already required at the point of sale limiting access to adults only. They relied, in part, on FDA's statements in the 1996 tobacco youth access rule in which FDA stated there was insufficient evidence of youth cigar use to warrant cigar regulation (61 FR 44396). The comments stated there is no evidence that the situation has changed since then and that exempting premium cigars from tobacco product regulation is also warranted because youth do not use premium cigars to any significant degree.

(Response) FDA disagrees. The Agency's statement regarding the availability of evidence to support cigar regulation was made 18 years ago and based on the evidence available at that time. In fact, FDA explicitly stated that there was insufficient evidence to regulate cigars ''at this time'' (*i.e.,* 1996) (61 FR 44396 at 44422). Moreover, the 1996 rule was issued under the authority of the FD&C Act prior to the passage of the Tobacco Control Act. Consequently, one of the reasons FDA did not assert jurisdiction over cigars in the 1996 rule was because it did not have sufficient evidence ''that these products satisfy the definitions of drug and device in the act'' (61 FR 44396 at 44423). Cigars, including premium cigars, clearly do satisfy the definition of a ''tobacco product'' and evidence has become available since 1996 indicating that youth and young adults use cigars, including premium cigars (Refs. 59, 68, 90).

C. Patterns of Use Do Not Preclude Users From Experiencing Negative Health Effects

Proponents of Option 2 claimed that patterns of use preclude premium cigar smokers from experiencing the negative health effects of tobacco smoke because they smoke infrequently and do not inhale. However, despite our explicit requests in the NPRM, the comments did not include data indicating that premium cigar smokers are not subject to disease risk and addiction. FDA's responses to comments regarding these issues are included as follows.

(Comment 97) Many comments stated that a majority of cigar users are occasional smokers (two to six cigars per week) and do not inhale (citing Refs. 69, 75). They also indicated that premium cigar use does not lead to addiction. Finally, some comments noted that occasional cigar users have not been studied in epidemiological research, and data for the lowest level of cigar users (one to two cigars per day) do not reveal mortality rates that are significantly different from nonsmokers (Refs. 69, 79). However, other comments included evidence suggesting increased disease risk and nicotine dependence among infrequent cigar users and those reporting they do not inhale.

(Response) FDA disagrees that patterns of use preclude premium cigar users from experiencing the negative health effects of these products. All cigars produce toxic cigar smoke (Refs. 35, 69). In addition, studies have shown that cigar smoking can cause several different types of cancer even without inhalation (Refs. 69, 104). For example, one study found an increased risk in head and neck cancers in people who were not cigarette smokers but had previously smoked only cigars (Ref. 104).

While inhaling cigar smoke poses much higher morbidity and mortality rates than not inhaling, significant risk still exists for those who do not inhale. Researchers found that the risk of stomach cancer mortality was significantly higher among cigar users who reported they did not inhale when compared to those who did not use tobacco products (Ref. 105). Additionally, among primary cigar smokers reporting that they do not inhale, relative mortality risk was still highly elevated for oral, esophageal, and laryngeal cancers (Ref. 83). A recent systematic review of cigar smoking and mortality summarized the results of 22 published studies from 16 different prospective cohorts and found that primary cigar smoking was associated with increased risk of mortality from all causes, several types of cancers, coronary heart disease, and aortic aneurysm compared to nonsmokers (Ref. 82). Mortality risks were greater with increasing number of cigars smoked per day and self-reported level of inhalation; however, primary cigar smokers reporting no inhalation still had highly elevated mortality risks for oral, esophageal, and laryngeal cancers compared to nonsmokers (id.). In addition, even if they do not intend to inhale and are not aware that they are doing so, most cigar smokers do inhale some amount of smoke (Refs. 32, 34).

Although studies indicate that some cigar smokers may absorb less tobacco smoke, they also show that all cigar smoking is harmful. Regardless of whether cigar smokers inhale, they are

still subject to the addictive and other adverse health effects of the product through absorption of nicotine and harmful constituents (Refs. 32, 81).

(Comment 98) Supporters of Option 2 claimed that premium cigar smokers use cigars less frequently than cigarette and smokeless tobacco users and, therefore, premium cigars should either not be regulated or should be subject to less regulation. They relied upon a study showing that the adult prevalence of everyday or occasional use of cigarettes was 18 percent and 2.6 percent for smokeless tobacco products, compared to 2 percent for cigars, cigarillos, and little filtered cigars (Ref. 106).

(Response) Although the prevalence of cigar smoking in the U.S. population is lower than cigarette smoking, use of cigars still presents health risks. Researchers estimate that regular cigar smoking was responsible for approximately 9,000 premature deaths or almost 140,000 years of potential life lost among adults 35 years or older in 2010 (Ref. 68). As stated in the previous response, all cigars produce toxic cigar smoke (Refs. 35, 69). Any cigar use exposes the mouth and throat to tobacco smoke and studies have shown that cigar smoking can cause several different types of cancer even without inhalation (Refs. 69, 104). Health risks still exists for those who do not inhale. For example, researchers found that the risk of stomach cancer mortality was significantly higher among cigar users who reported they did not inhale when compared to those who did not use tobacco products (Ref. 107). Additionally, among primary cigar smokers reporting that they do not inhale, relative mortality risk was still highly elevated for oral, esophageal, and laryngeal cancers (Ref. 83). Therefore, all cigars expose users to toxic and cancer-causing substances and increase the risk of harm. Basing an exemption for premium cigars on current use patterns would be inappropriate given that patterns may change over time and in response to regulation. Consequently, FDA has concluded that deeming all cigars, including premium cigars, is appropriate for the protection of the public health.

D. Responses to Other Cigar Comments

(Comment 99) Some comments expressed concern that if FDA did not deem all tobacco products subject to regulation, the tobacco industry would adjust its products to fit the exemption for premium cigars in Option 2 and preferential economic treatment of certain manufacturers would result. These comments argued that just as manufacturers of roll-your-own tobacco changed their roll-your-own product to classify it as pipe tobacco to take advantage of positive tax treatment, manufacturers would seek similar ways to circumvent regulations and continue marketing products that are detrimental to public health.

(Response) Because FDA has selected Option 1 deeming all cigars, rather than a subset, for this final rule, these comments are moot.

(Comment 100) Many comments stated that it is important for FDA to regulate all tobacco products, including cigars, pipe tobacco, and e-cigarettes in the same way, and that the Agency should ensure that a consistent set of regulatory criteria is applied to all tobacco products and nicotine delivery systems. According to the comments, failure to regulate all tobacco products would provide incentives for manufacturers to market new tobacco-based or tobacco-derived products that are unregulated and may induce people to switch to the unregulated products.

(Response) FDA agrees that it is appropriate for the protection of the public health to regulate all tobacco-derived products meeting the definition of ''tobacco product.'' There is inherent risk in all tobacco-derived products. Further, the Agency agrees that use patterns may change (and have changed) over time and in response to regulation.

(Comment 101) At least one comment expressed concern that FDA relied upon an abstract presented at the Conference for the Society for Research on Nicotine and Tobacco (SRNT) as a basis for proposing Option 1. The comment stated that because the abstract was not a full peer-reviewed research article, stakeholders were unable to adequately respond to the claims made.

(Response) FDA disagrees. Additional analysis of the data that was the subject of this SRNT abstract was conducted and a paper was published and submitted to the docket, allowing for stakeholders to comment on it (Ref. 90). The abstract presented at SRNT also was not the sole basis for proposing Option 1. FDA appropriately characterized this as preliminary data and included additional data and information to support this proposed option. In addition, FDA has supplemented the information and data supporting Option 1, as discussed in section VII, to provide additional evidence of premium cigar use by youth and young adults and to illustrate that the patterns of use for premium cigars do not preclude users from negative health effects.

(Comment 102) Comments urged FDA to adopt a category-specific approach to regulation of cigars in order to more effectively address the variations in use patterns, manufacturing, and ingredients across the product category. Other comments, however, urged FDA to broadly regulate all cigars in the same way to reduce initiation and current use among youth. More specifically, comments advocated prohibiting flavors, including menthol, in all cigars, prohibiting self-service displays, and establishing minimum pack size requirements for all cigars.

(Response) Although the statute does not require FDA to make any public health finding in order to deem tobacco products, the Agency has determined that cigar use presents health risks and that all cigars should be brought under its regulatory authority. However, FDA is providing a compliance policy that will provide additional time for manufacturers of newly deemed products to comply with certain requirements, and which will reduce the burdens on manufacturers as they become regulated by FDA for the first time. As explained elsewhere in this document, FDA is announcing that it intends in the future to issue a proposed product standard that would eliminate characterizing flavors in all cigars including cigarillos and little cigars.

(Comment 103) Some comments supporting Option 2 argued that FDA is not obligated to deem all tobacco products that meet the statutory definition of ''tobacco product.'' They also stated that the intent of the Tobacco Control Act was to target tobacco products marketed to children and products that cause addiction, which is why ''cigarette'' and ''little cigar'' were specifically defined in the Tobacco Control Act and large and premium cigars were not similarly defined. Thus, they claim exempting premium cigars is consistent with Congress' intent that premium cigars not be regulated, which they state is further evidenced by introduction of such legislation in Congress.

(Response) FDA agrees that the Agency is not obligated to deem all tobacco products but disagrees with comments purporting to explain Congress' intent to only regulate products marketed to children. The purpose of the Tobacco Control Act was to provide authority to FDA to regulate tobacco products and protect not only the health of minors, but also the health of the public overall (section 3 of the Tobacco Control Act). While use of tobacco products by youth was and continues to be a significant focus of the law, it is clear that Congress did not intend that the Tobacco Control Act reach only products marketed to children, as they included many

provisions applicable to tobacco products marketed to adults.

(Comment 104) Many comments expressed concern that premium cigar regulation would impose considerable costs and place excessive burdens on small businesses without quantifiable benefits. In particular, many comments stated that premarket review would be cost-prohibitive for premium cigar manufacturers, effectively eliminating their ability to release special editions and seasonal blends. They also claimed that HPHC testing and reporting and other regulatory requirements like the prohibition on free samples would be equivalent to a de facto ban on premium cigars. They also expressed concern about the political and economic impact of premium cigar regulation on two foreign nations given the potential impact on production and exports of their premium cigars to the United States.

Some comments also argued that an exemption for premium cigars is appropriate, because premium cigars are unique in the way that they are made, marketed, sold, purchased, and used. They stated that regulation would stifle innovation in the premium cigar market, devastate a long-time social and cultural phenomenon, and limit the freedoms of businesses and consenting adults to sell and purchase a legal product.

(Response) FDA understands these concerns. The Agency has determined that cigar use presents health risks and that all cigars should be brought under its regulatory authority.

To assist newly regulated firms, FDA is announcing in this final rule a compliance policy to address some of the possible burdens suggested by comments (section IV.D). For example, FDA does not intend to enforce the premarket review requirements against cigar manufacturers that make tobacco blending changes to address the natural variation of tobacco (*e.g.,* tobacco blending changes due to variation in growing conditions) in order to maintain a consistent product. However, FDA intends to enforce the premarket requirements for products that have tobacco blending changes (including those involved in seasonal and boutique blends) that are intended to alter chemical or perception properties of the new tobacco product (*e.g.,* nicotine level, pH, smoothness, harshness). FDA also is working to determine an appropriate compliance policy to deal with HPHCs for newly deemed products and is intending to issue guidance regarding HPHC reporting, and later a testing and reporting regulation as required by section 915, with enough time for manufacturers to report given the 3-year HPHC reporting compliance period. As noted elsewhere in this document, FDA does not intend to enforce the reporting requirements for newly deemed products before the close of the 3-year compliance period, even if the guidance is issued well in advance of that time. In addition, as discussed in section IV.D, FDA is announcing a compliance policy for small-scale tobacco product manufacturers (which likely would include premium cigar manufacturers), which states that FDA generally intends to grant small-scale tobacco manufacturers additional time to respond to SE deficiency letters and to not bring enforcement action against those small-scale tobacco product manufacturers who submit ingredient lists within 12 months of the effective date of the rule, and is granting these manufacturers an additional six-month compliance period for the requirements to submit tobacco health documents. FDA believes that this compliance policy will help to assist these manufacturers with regulatory compliance.

FDA also understands concerns from cigar retailers about the effect that a ban on free samples could have on their ability to promote new products. FDA wishes to clarify that allowing prospective adult buyers to smell or handle a cigar is not considered the distribution of a ''free sample'' for the purpose of 21 CFR 1140.16 as long as the product is not actually consumed in the retail facility and the prospective buyer does not leave the facility with a free tobacco product (whole or part). Affording adult consumers the opportunity to handle the product will give them the ability to feel the resistance of the cigar's structure, and allow them to clearly see the color of the product, which is an indication of the fermentation period for the tobacco. It also will allow users to capture the aroma of the cigar and the box (if the cigar is sold in a package). Therefore, it would not be considered a free sample if a prospective buyer smells the cigar while handling it. We believe that in most circumstances, other retail facilities, including ENDS retail establishments, can similarly allow customers to touch, hold, and smell their products without violating the free sample ban. However, if the prospective buyer lights and draws or puffs on the cigar to keep the cigar lit, or otherwise uses the free cigar or leaves the retail establishment with a free cigar, this would constitute a ''free sample'' in violation of § 1140.16.

(Comment 105) Many comments requested that the exemption for premium cigars be extended to hand-operated, vintage machine-made cigars. Comments stated such cigars are indistinguishable from handmade premium cigars, are sold on the same shelves as premium cigars, and do not resemble mass-market cigars. The comments further argued that consumers perceive them to be just like value-priced handmade cigars and treating them differently would create significant enforcement issues for FDA. They stated that, without an exemption, manufacturers of these products would be forced to close and eliminate jobs, negatively impacting the regional economy where such cigars are produced.

(Response) As already stated, FDA has selected Option 1 deeming all cigars, rather than a subset, for this final deeming rule. Therefore, all cigars, including hand-operated, vintage machine-made cigars, are deemed and subject to the requirements of chapter IX of the FD&C Act and implementing regulations. Concerns noted by some comments about the burdens of regulation are addressed in sections IV.C and IV.D.

(Comment 106) At least one comment expressed concern that retailers may not be able to determine whether a cigar meets all of the elements of the final definition of a ''covered cigar.'' Therefore, the comment stated that retailers should not be liable for a manufacturer's improperly labeled premium cigars (similar to the retailer ''safe harbor'' for required warning labels and advertising in the proposed cigarette graphic warning rule (75 FR 69524 at 69535, November 12, 2010)).

(Response) FDA has selected Option 1, which requires all cigars (rather than a subset) to include the textual health warnings. FDA also notes, however, that § 1143.5(a)(4) does provide a retailer ''safe harbor'' for required warning labels for packaging that contains a health warning; 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 is not altered by the retailer in a way that is material to the requirements of § 1143.5. Retailers must have the required warnings on advertisements as stated in § 1143.5(b)(1).

(Comment 107) Some comments stated that FDA has the authority to assert jurisdiction over all cigars and differentially apply regulations to certain cigars if shown to be appropriate based on scientific evidence. Thus, according to the comments, if it were established that premium cigar risk is of a different nature and degree than the

risks of other types of cigars based on who uses them and how they are used, the Agency could apply its authority in a way that fits the risks posed by the product. These comments concluded that because of this, it is unnecessary and would be inappropriate to completely exempt premium cigars.

Similarly, some comments applied the notion of a ''continuum of risk'' to cigars. They stated that premium cigars are at the lower end of the spectrum (Ref. 76) due to the common usage patterns (*i.e.,* described as most frequently used by adults, on special occasions, and users do not inhale). Therefore, they urged that FDA regulate premium cigars in line with the notion of a continuum of risk.

(Response) FDA agrees that a continuum of nicotine-delivering products does exist as demonstrated by the lower levels of toxicants in ENDS in comparison to cigarettes, and may warrant different requirements for products at different ends of this continuum. However, commenters have not substantiated their claims that the patterns of use for premium cigars preclude users from negative health effects. Instead, as discussed throughout this section, cigar use poses a greater risk than not smoking, and lack of inhalation do not prevent the onset of cigar-related morbidity and mortality. Therefore, FDA has concluded that it is appropriate for all cigars to be brought under its regulatory authority.

(Comment 108) Several comments stated that it would be inappropriate and inaccurate for FDA to treat ''cigars'' as a single homogenous category or to simply overlay the existing regulatory framework for cigarettes onto the diverse suite of deemed products. They further stated that because of the significant differences among cigar products, it is critical that FDA distinguish between the specific cigar subtypes in determining whether any, some, or all cigars should be subject to regulation. If FDA were to do otherwise, they believe the Agency would risk establishing an arbitrary and capricious, overly broad regulatory scheme that fails to meet its burden to protect the public health without imposing undue burden on the industry.

(Response) FDA disagrees. Upon review of comments and scientific evidence, FDA has determined that all cigars present a risk to public health and, consequently, should be deemed.

(Comment 109) A few comments discussed different regulatory approaches for make-your-own cigar products (*e.g.,* cigar wrappers and cigar tobacco). At least one comment suggested treating these products as cigars while others urged regulation of them in a manner similar to cigarette papers and roll-your-own tobacco.

(Response) With this final rule, make-your-own cigar products, including cigar wrappers and cigar tobacco, are tobacco products and subject to FDA's tobacco control authorities under chapter IX of the FD&C Act. Cigar wrappers containing tobacco or tobacco-derived nicotine and cigar tobacco packaged and sold individually are also subject to the warning requirement for ''covered tobacco products'' found in § 1143.3.

(Comment 110) At least one comment stated that FDA should not permit manufacturers to self-classify their products as cigarettes or cigars, and if premium cigars are exempted, should not permit self-classification of cigars as premium or nonpremium.

(Response) Regardless of how they may be classified by their manufacturers, cigars and cigarettes will be classified based on the definitions included in this final rule.

(Comment 111) A few comments argued that bias existed for any study or analysis cited in the NPRM that was written or contributed to by FDA employees. These comments were concerned that FDA employees generating and analyzing data did so to support the proposed regulation of cigars.

(Response) FDA disagrees. FDA notes that most of the studies cited in the NPRM that were authored by FDA employees have been published in peer-reviewed journals. Where the NPRM discussed research results presented at a professional conference, SRNT, but not yet included in a peer-reviewed journal, FDA clearly stated so and specifically requested comment (79 FR at 23151). That research has since been published (Ref. 90).

(Comment 112) Some comments criticized the methodologies used by researchers in studies FDA cited in the NPRM (*e.g.,* Ref. 59). For example, they claimed that the Delnevo, et al. study regarding youth use of flavored cigars (id.) was flawed, because the study cites any use of the brand by youth as use of the flavored variety of that cigar brand (even though the respondent might use an unflavored variety of that cigar). The comments had additional concerns regarding the study, such as missing data on cigar brand from 13 percent of cigar smokers, as well as concerns about whether study participants provided accurate information regarding cigar brand used, and whether the study population was representative of the U.S. population. Other comments stated that studies in peer-review journals are politically biased and that studies that oppose tobacco product regulation are often prohibited from publication.

(Response) The Delnevo, et al. publication found that youth and young adults are significantly more likely than older adults to prefer cigar brands that are more likely to be flavored (Ref. 59). Because no national data directly compared youth and adult flavored cigar use within the same study, Delnevo and colleagues conducted an ecological analysis combining data from the 2010–2011 NSDUH on cigar brand smoked most often, with Nielsen data indicating the percent of the cigar brands' market share that are labeled as flavored cigar products. These results, coupled with information on the prevalence of flavored cigar use from studies restricted to youth or to young adults, provide additional indirect evidence of the popularity of flavored cigars among younger cigar smokers as compared to older adult cigar smokers. Especially when coupled with research results on the prevalence of flavored cigar use in studies restricted to youth or young adults, this study provides additional supporting evidence of the widespread appeal of flavored varieties of these products among young Americans. The comments noted that, in the 2010–11 NSDUH, 13 percent of cigar smokers did not report a usual cigar brand and expressed concern about the ability of those who reported their usual cigar brands to do so accurately. Some cigar smokers may in fact not actually have a cigar brand they smoke most often and consequently did not provide a brand response, while other respondents may have chosen not to provide their usual brand information. Among the latter group, missing data is always a concern, although there is no evidence from the study to suggest that those who provided brand information were systematically different than those who did not. Additionally, the comments did not provide evidence to substantiate the concern that respondents were not reporting the brand names they actually used. Lastly, FDA does not agree with concerns about representativeness of the survey. The NSDUH is designed to be representative of the U.S. civilian, non-institutionalized population, ages 12 and older (*http://www.samhsa.gov/data/population-data-nsduh*). FDA does not rely on any single study to support decisions included in this final rule. FDA cited many peer reviewed studies in the NPRM and relies upon many peer-reviewed studies to support the decisions included in this final rule, including the Delnevo publication.

VIII. Regulation of Electronic Nicotine Delivery Systems (Including E-Cigarettes) and the Continuum of Nicotine-Delivering Products

In the preamble to the NPRM, FDA noted that there are distinctions in the health risks presented by various nicotine-delivering products. FDA requested comment as to how e-cigarettes should be regulated based on this continuum of risk. We explained that some studies have revealed the existence of toxicants in both the e-cigarette liquid and the exhaled aerosol of some e-cigarettes but that we do not have sufficient data to determine what effects e-cigarettes have on public health at the population level. We also noted that some individuals report using e-cigarettes to successfully quit smoking, but we expressed concerns about dual use of e-cigarettes and combusted tobacco products and the possibility that flavored e-liquids are leading children to initiate tobacco use with e-cigarettes.

In this final rule, FDA clarifies that although there are many types of ENDS (including e-cigarettes, e-cigars, e-hookah, vape pens, personal vaporizers, and electronic pipes), all are subject to FDA's chapter IX authorities with this final deeming rule. Comments regarding e-cigarettes, including comments on how the products should be regulated in light of this continuum, and FDA's responses are discussed in the following sections.

A. Terminology

(Comment 113) Some comments expressed confusion as to what is encompassed by the term ''e-cigarette.'' Other comments stated that the ''electronic smoking devices'' covered under this deeming rule should include e-cigarettes, e-cigars, e-hookah, and vape pens.

(Response) FDA agrees that electronic nicotine delivery systems or ENDS are sold under several different names including e-cigarettes, e-cigars, e-hookah, vape pens, personal vaporizers, and electronic pipes. These products all meet the definition of ''tobacco product'' and, therefore, under this rule, all are subject to FDA's tobacco control authorities, regardless of a novel name or heating source. In addition, the definition of tobacco product includes components and parts (the objects intended or reasonably expected to be used with or for the human consumption of a tobacco product that are not accessories) (*e.g.,* e-liquids, tanks, cartridges, pods, wicks, atomizers), which, under this rule, have also been deemed to be subject to FDA's authority under chapter IX of the FD&C Act.

B. Prevalence

In the NPRM, FDA expressed concern about the increase in prevalence of the newly deemed products, particularly the alarming rise in e-cigarette use by middle school and high school students. The comments included peer-review studies, focus group results, and data regarding the prevalence of ENDS use.

(Comment 114) Some comments noted that it was difficult to fully ascertain prevalence of use of these products because they are sold under many different names. However, they generally agreed that the prevalence of e-cigarette use has increased in recent years, citing peer-reviewed studies and data from state or regional surveys (*e.g.,* Ref. 108). For example, comments cited the 2013 North Carolina Youth Tobacco Survey (NCYTS) and expressed concern that, while the current cigarette smoking rates among North Carolina high school students decreased in recent years, the overall current use of tobacco products increased from 22.5 percent in 2011 to 24.5 percent in 2013. In particular, the rate of e-cigarette use increased from 1.7 percent in 2011 to 7.7 percent in 2013, and 2.7 percent of high school students who had never tried a cigarette indicated that they were considering using e-cigarettes in the next year.

However, some of these comments believed that the data showing an increase in e-cigarette use among youth and young adults only reflects their experimentation (and not long-term use) and that there are no data showing that this experimentation leads to long-term use or dual use with combusted tobacco products. Others stated that although e-cigarette use may be increasing among youth and young adults, this increase is due to the fact that young adult smokers are switching to e-cigarettes, as are adult smokers.

(Response) FDA agrees with comments stating that the prevalence of use of the newly deemed tobacco products has been increasing, which further substantiates the need for this final rule. FDA remains concerned about the rise in use of newly deemed products by youth and young adults, particularly the increase in use of ENDS. As we stated in the NPRM and throughout this document, long-term studies are not yet available to determine whether these youth and young adults are only experimenting with tobacco use, becoming established ENDS users or dual users, or transitioning to combusted products. In addition, there is not sufficient evidence to conclude that youth and young adults are using ENDS as a means to quit smoking.

(Comment 115) Many comments contended that the great majority of e-cigarette users consist of former smokers and those trying to quit smoking, rather than those who are initiating tobacco use with e-cigarettes (*e.g.,* Ref. 109). The comments included data from regional surveys indicating that even where there has been a significant increase in youth and young adult e-cigarette use, the increase is seen in experimenters and not daily users. For example, a few comments referred to a report commissioned by Public Health England which referred to a study that found that only 1 percent of 16 to 18-year-old never smokers have experimented with e-cigarettes and few, if any, progress to sustained use (Ref. 110).

(Response) Data reported by the CDC's National Center for Health Statistics (NCHS), which provides the first estimates of e-cigarette use among U.S. adults from a nationally representative household interview study, indicate that current cigarette smokers and recent former smokers (*i.e.,* those individuals who quit smoking within the past year) were more likely to use e-cigarettes than long-term former smokers (*i.e.,* those individuals who quit smoking more than one year ago) and adults who had never smoked (Ref. 24). In addition, the CDC states that current cigarette smokers who had tried to quit smoking in the past year were more likely to use e-cigarettes than those who had not tried to quit (id.). It is noted that it cannot be determined by the research findings: (1) Whether former cigarette smokers who now exclusively use e-cigarettes would have ceased smoking cigarettes regardless of e-cigarette use; and (2) whether the e-cigarette use preceded or followed smoking cessation. Similar patterns have been observed in Europe, where researchers found that ''e-cigarette use was more likely among smokers who had made a past year quit attempt'' when compared to smokers who had not (Ref. 111). As discussed in further detail in response to Comment 144, a meta-analysis of 15 cohort studies, 3 cross-sectional studies, and two clinical trials (one RCT, one non-RCT) found that cigarette smokers who also used e-cigarettes had statistically significantly worse quit rates than those cigarette smokers who did not use e-cigarettes (Ref. 112).

However, FDA also remains concerned about the dramatic rise in ENDS use among youth; between 2011 and 2014, past 30 day e-cigarette use among high school students increased nearly 800 percent from 1.5 percent in 2011 to 13.4 percent in 2014 (Ref. 22),

and between 2011 and 2013, the number of never-smoking youth who had reported ever using an e-cigarette increased 3-fold, from 79,000 to more than 263,000 youth (Ref. 113). The Surgeon General has stated that adolescents appear to be particularly vulnerable to the adverse effects of nicotine on the central nervous system (Ref. 9), and ENDS may deliver as much nicotine as other tobacco products (Ref. 114).

FDA is investing in long-term, population-level research, such as the PATH Study, to help assess the likelihood that previous nonusers of tobacco who experiment with ENDS will initiate regular tobacco use over time. Such longitudinal studies can further assess the factors associated with potential smoking cessation among e-cigarette users.

(Comment 116) The comments generally agreed that youth are increasingly using e-cigarettes, but disagreed as to the product's impact on nicotine addiction. As FDA noted in the proposal and as discussed by many comments, the CDC found that ever use of e-cigarettes by middle and high school students in the United States increased from 3.3 percent in 2011 to 6.8 percent in 2012 (Ref. 108). While the majority of comments recognized an increase in dual use, some suggested that this was not an issue because youth are using e-cigarettes to quit smoking, resulting in some dual use until they can completely abstain from conventional cigarettes (Ref. 115).

(Response) FDA remains concerned about the rise in ENDS use among youth and young adults as well as the trends in dual use of ENDS and combusted products in both youth and adults (Ref. 116). In addition, as stated in the NPRM and throughout this final rule, all tobacco products are potentially addictive and some ENDS may deliver as much nicotine as other tobacco products (Ref. 20). The Surgeon General has stated that adolescents appear to be particularly vulnerable to the adverse effects of nicotine on the central nervous system (Ref. 9). FDA believes that this final deeming rule, along with the minimum age restrictions and health warning requirements, is an important step toward combatting this rise in tobacco product use among youth and young adults.

A recently published paper by Friedman (Ref. 42) looked at youth smoking rates in states that enacted early bans on sales of e-cigarettes to minors and concluded, based on state-level data available through 2013, that the decline in adolescent smoking rates slowed in states that enacted restrictions on access to ENDS by minors before January 2013, relative to states that did not. Given the various issues with this study (see previous discussion regarding this publication in response to comment 33), FDA acknowledges this paper as a first attempt to study potential impacts of youth ENDS access restrictions, but emphasizes that further research will be needed to explore the effects of this rule on product switching and dual usage.

C. Toxicity and Nicotine in E-Liquid and Aerosol

Although FDA noted in the NPRM that we do not currently have sufficient data about e-cigarettes and similar products to fully determine what effects they have on the public health, we identified concerns regarding the toxicants in e-liquid and the exhaled aerosol and the nicotine delivery from e-cigarettes. Comments were divided on the safety and toxicity of e-liquids, e-cigarettes, and the exhaled aerosol.

(Comment 117) The comments expressed concerns that e-cigarette users subject themselves to dangerous constituents, including formaldehyde and other toxicants. One comment stated that the release of formaldehyde occurs only when the voltage on e-cigarettes is set to 4.8 volts or higher (Ref. 67). Some comments also submitted studies showing the existence of other e-liquid constituents, including prescription weight loss and erectile dysfunction drugs (Ref. 117).

(Response) Studies show that e-liquid tobacco products contain nicotine, propylene glycol, glycerin, tobacco specific nitrosamines, tobacco alkaloids, carbonyls, ethylene glycol, diacetyl, and acetyl propionyl (Refs. 19, 118, 119). Chemicals such as nicotine, carbonyls, tobacco specific nitrosamines, heavy metals, and volatile organic compounds have been identified in e-cigarette aerosols (Refs. 19, 118, 119, 120, 121, 122).

In addition, several studies substantiated the data included with comments, finding that flavored e-liquids contain chemicals that could be dangerous to consumers when inhaled. For example, researchers in one study tested 159 e-liquids with sweet flavors, such as toffee, chocolate, and caramel, and found that almost three quarters of the samples (74 percent) contained diacetyl or acetyl propionyl (Ref. 123), both of which pose known inhalation risks (*e.g.*, Ref. 124). Among those that tested positive, nearly half of the e-liquids in the study could expose users to levels that exceed recommended workplace limits for breathing these chemicals (Ref. 123). An additional recent study analyzed 51 types of flavored e-cigarettes for total mass of diacetyl, 2,3-pentanedione, and acetoin (Ref. 125). Researchers detected diacetyl above the laboratory limit of detection 39 of the 51 flavors tested, ranging from limit of qualification (LOQ) to 239 µg/e-cigarette. 2,3-pentanedione and acetoin were also detected in 23 and 46 of the 51 flavors tested at concentrations up to 64 and 529 µg/e-cigarette (id.). It is noted that the study involved a convenience sample of 51 types of flavored e-cigarettes and may not be representative of the types of e-liquids currently available to users. Absent a regulatory standard, FDA acknowledges that it may not be possible to account for the wide variability of concentrations of constituents in the flavors of current ENDS products. Another study analyzed 30 e-cigarette liquids and found that many flavors, including cotton candy and bubble gum, contained aldehydes, a class of chemicals that can cause respiratory irritation, airway constriction, and other effects (Ref. 126). Specifically, researchers noted that two flavors, a dark chocolate and a wild cherry, would expose e-cigarette users to more than twice the recommended workplace safety limit for the aldehydes vanillin and benzaldehyde (id.). Similarly, researchers found that several cinnamon-flavored e-liquids contained a chemical, cinnamaldehyde, which researchers stated was highly toxic to human cells in laboratory tests (Ref. 127).

Some studies have found that lower levels of toxicants are observed in e-cigarette aerosols than in combusted tobacco smoke (Ref. 122). FDA recognizes that specific product design parameters, such as voltage, can affect toxicant deliveries (Ref. 67). For example, some ENDS devices and some power levels of operating ENDS devices have been reported to deliver more formaldehyde than other ENDS products and conventional cigarettes (Refs. 67, 128, 129) and can affect the public health. In addition, a 2010 study conducted by the Virginia Commonwealth University determined that in a controlled evaluation of smokers naïve to the use of e-cigarettes and using a particular model of e-cigarette, acute effects of using the product did not result in measurable levels of nicotine or carbon monoxide, although e-cigarettes did suppress nicotine/tobacco abstinence symptom ratings (Ref. 130). Moreover, a recent evaluation of the relative health risks of ENDS products conducted by Public Health England has drawn attention to scientific reviews concluding that ENDS

are ''likely to be much less, if at all, harmful to users or bystanders'' and a prior paper that reported the findings from an international expert panel of academics. Employing an analysis model that quantifies the relative health harms of 12 tobacco products using a series of 14 harm criteria, the expert panel determined that while cigarettes scored 100 percent in their assessment of maximum relative harm, ENDS products were rated to have only 4 percent maximum relative harm, which contributed to Public Health England's assessment that ENDS are around 95 percent safer than smoking combusted cigarettes (Ref. 131; see Refs. 76, 132).

The recent evaluation's use of the prior paper has several limitations, and the prior paper itself observed that it was reporting outcomes based on the decision-conferencing process from a group of experts who were selected without any ''formal criterion,'' though ''care was taken to have raters from many different disciplines'' and primarily based on geographic location ''to ensure a diversity of expertise and perspective'' (Ref. 76). In addition, the authors acknowledge that there is a ''lack of hard evidence for the harms of most products on most of the criteria'' (Refs. 76, 133, 134). The authors did not explain what scientific information was available to the experts upon which they should base their ratings. The authors did not explain the derivation of the quantitative assessment of each harm criterion. It is unclear if the authors carried out or referenced a quantitative risk analysis, a standard practice when assessing relative risk, nor did the authors indicate that they used mean levels of exposure to HPHCs in users or other quantitative evidence as an approximation of risk. In addition, population effects appear to be largely outside the scope of this analysis since the manuscript did not address the likelihood that the characteristics of the products would make them more or less likely to appeal to new users, be used in conjunction with other tobacco products or discourage quitting. They did not describe an assessment of population effects such as a quantitative assessment of youth use prevalence. FDA does not find the beliefs reported in the prior paper (Ref. 76) to be sufficiently conclusive on the relative risks of using different tobacco products.[14] However, previous studies detected the presence of aldehydes, especially formaldehyde, in the vapor from some ENDS to exist at levels much lower than in cigarette smoke (Ref. 132). Moreover, across several Japanese brands evaluated by another researcher in a self-published Web site, under some use conditions, ENDS released 1/50th of the level of formaldehyde released by cigarettes (Ref. 135). The highest level detected was six times lower than the level in cigarette smoke (id.). A clinical investigation comparing the levels of toxicants and carcinogen metabolites in the urine of e-cigarette users and combusted cigarette users found that e-cigarette users had significantly lower levels of all evaluated toxicants, which included acrolein and crotonaldehyde (Ref. 136). But other research, published as a letter to the editor of the *New England Journal of Medicine,* reported that ENDS devices operated at 5 volts delivered a mean of 390+/−90 μg per 10 puff sample which is greater than 150 μg, the estimated average delivery of formaldehyde than conventional cigarettes. No formaldehyde-releasing agents were detected when ENDS were operated at 3.3 volts (Ref. 128). A subsequent peer-reviewed article on 5 variable-power ENDS devices found large variations in formaldehyde delivery across devices (Ref. 129). The first device yielded more formaldehyde than combustible cigarettes at every power level tested, and the second device delivered more formaldehyde at the highest power level tested; the remaining three devices delivered less formaldehyde than combustible cigarettes at all power levels tested (*id.*) The same research found that aldehyde delivery varied by 750-fold from one ENDS device to another (*id.*). The article referenced in one comment (Ref. 67) reported that increasing the voltage from 3.2 to 4.8 volts increased formaldehyde, acetaldehyde, and acetone levels from 4-fold to over 200-fold.

(Comment 118) The comments in support of limited or no regulation for e-cigarettes cited studies showing that e-cigarette use resulted in improvements in many health indicators of former cigarette smokers. Most of these comments relied upon published literature concluding that, despite the lack of long-term health data, e-cigarettes are ''likely to be much less, if at all, harmful to users and bystanders'' (Ref. 132). They also noted that clinical studies to date indicate that e-cigarettes generally are well-tolerated and do not produce serious adverse events following use for up to 24 months (Refs. 107, 137). Many relied upon an analysis of the 47 e-cigarette adverse event reports FDA received from 2007 to 2012, which found that only 8 of them were considered serious (*e.g.,* pneumonia, congestive heart failure, disorientation, seizure, hypotension, facial burns, chest pain and rapid heartbeat, infant choking on an e-cigarette cartridge, loss of vision) (Ref. 138).

Some comments also stated that e-cigarettes provide subjective health benefits to current smokers. For example, in one Internet survey of 1,347 current e-cigarette users, among those who were former smokers, 75 percent reported improved breathing, less coughing, and feeling healthier overall after switching to e-cigarettes (Ref. 139). They also claimed that e-cigarette use leads to improved sense of smell and taste and general physical status (Ref. 109). In addition, they stated that some of the harms caused by smoking can be reversed by switching to e-cigarettes (Ref. 140).

(Response) FDA agrees that the majority of reported adverse events appear to have been not serious. The FDA adverse event reporting system has inherent limitations as a measure of the impact of e-cigarettes since ENDS are a newly deemed product and reporting adverse events associated with tobacco products (including e-cigarettes and other ENDS) is voluntary; therefore, the reports received may have underrepresented the true number and types of adverse events associated with ENDS. The data cannot be used to calculate incidence (occurrence) rates or to estimate risk. Moreover, FDA has concerns with relying upon the types of short-term studies provided in the comments. Short-term studies fail to analyze the exposure risk of tobacco use and inhalation that damage health over a lifetime of repeated, extended exposure. Given the relatively new entrance of ENDS on the market, consumers have not had the duration of use for researchers to fully assess the morbidity and mortality effects for ENDS on either the individual or the population.

FDA recognizes that completely switching from combusted cigarettes to ENDS may reduce the risk of tobacco-related disease for individuals currently using combusted tobacco products, given the products' comparative placements on the continuum of nicotine-delivering products. A recent review from Public Health England (discussed in greater detail in response to Comment 117) suggests substantial reductions in the exposure to harmful constituents typically associated with smoking in ENDS products compared to cigarettes, and that most of the chemicals causing smoking-related

[14] In addition, at least one source has identified other flaws with the expert panel employed in the Nutt et al. report, including potential conflicts of interest and no prespecified expertise on tobacco control among the panel members (Ref. 133).

disease from combusted tobacco use are absent and the chemicals that are present pose limited danger (Ref. 131). A scientific review of published studies of the toxicity of certain e-liquids found that ''[e-cigarette] aerosol can contain some of the toxicants present in tobacco smoke, but at levels which are much lower. Long-term health effects of [e-cigarette] use are unknown but compared with cigarettes, [e-cigarettes] are likely to be much less, if at all, harmful to users or bystanders'' (Ref. 132). ENDS products have been found in some studies to release aldehydes at much lower levels than that in cigarette smoke, with one Web site posting stating that, across several Japanese brands, under some use conditions, that ENDS products release 1/50th the level of formaldehyde released in cigarettes (Ref. 133).

However, study results have been inconsistent about the effects of these products. Some short-term studies suggest that ENDs may not affect heart rate, cardiac function, lung function, or complete blood count indices to the extent of conventional cigarettes (Refs. 130, 141, 142). A literature search, however, concluded that the current scientific evidence on short-term effects are limited and there are no adequate data on long-term health effects (Ref. 143). Other studies have demonstrated increase in mean heart rate and inflammatory measures (such as white blood cells) and changes in lung function after use (Refs. 141, 142, 144, 145). Some research has found that there are some ENDS devices and some power levels of operating ENDS devices that deliver more formaldehyde than other ENDS products and conventional cigarettes (Refs. 67, 128, 129). Further, the review by Hajek et al. (Ref. 132) referred to in this comment as showing health benefits and finding a lack of negative health effects of e-cigarettes, may have limited generalizability due to the variability of e-cigarette products. The authors expressly recognized that there are many deficiencies in the available data.

(Comment 119) Some comments believed that FDA should not be concerned about e-liquids because they are restricted to the same nicotine levels as other products (*e.g.,* cigarettes, hookah, smokeless tobacco, NRTs).

(Response) FDA disagrees with comments stating that the Agency should not be concerned with ENDS use. First, a direct comparison of the nicotine level in cigarettes (and other currently regulated tobacco products) with the nicotine level in e-liquids is not a particularly helpful or relevant comparison. More helpful and clinically meaningful is the comparison between the amount of nicotine delivered to the user after using a cigarette (or other conventional tobacco product) versus the amount of nicotine delivered after using an ENDS (Ref. 146). Therefore, even if an e-liquid has the same nicotine level, it may deliver a different level of nicotine than the comparator product. It is also possible that comparable nicotine delivery consistently produced by ENDS that meet the requirements of the Tobacco Control Act may increase the facilitation of product switching from cigarettes to ENDS—which could (with appropriate regulatory oversight) potentially reduce the overall health harm caused by combusted tobacco. Further research is necessary to determine the causal factors that influence product switching from cigarettes to ENDS (or vice versa) and the subsequent health impacts.

Second, FDA disagrees with the notion that e-liquids are restricted to the same level of nicotine as other tobacco products. E-liquids are available in a wide range of nicotine concentrations, but delivery to the user is based on multiple factors, including the humectant in the e-liquid, the temperature to which the e-liquid is heated, the user experience, device designs, and design modifications (Ref. 147). Data suggest that experienced ENDS users are able to achieve clinically significant nicotine levels and levels similar to those generated by traditional cigarettes (Refs. 114, 148, 149, 150). Moreover, heating the e-liquids to higher temperatures and using the ENDS in ways other than intended (*e.g.,* dripping the e-liquid directly onto the atomizer) may result in nicotine delivery that is actually higher than that of a conventional cigarette (Ref. 16).

Third, FDA disagrees with the premise that the Agency should not be concerned with tobacco products that may have lower nicotine levels than cigarettes or other tobacco products, as may be the case with some ENDS. Even if ENDS products have lower levels of nicotine, they still have the potential to addict users, particularly youth and young adults, as discussed in section VIII.C. As the Surgeon General has stated, nicotine is the primary addictive substance in tobacco products (Ref. 9). Regardless of the nicotine content of the tobacco products, FDA believes that deeming tobacco products will result in significant public health benefits and that the additional restrictions imposed by this rule are appropriate for the protection of the public health.

(Comment 120) One comment expressed concern about the lack of research regarding the environmental impacts of e-cigarette use and storage.

(Response) FDA is funding studies regarding environmental impacts due to ENDS manufacturing, use, and disposal following use. In addition, FDA has been conducting a series of public workshops to obtain information on e-cigarettes and their impact on public health. Potential environmental impacts were discussed during the first workshop (79 FR 55815, September 17, 2014).

(Comment 121) Some comments expressed concern about the health effects of propylene glycol exposure from e-cigarette use. They also stated that the use of glycerol and propylene glycol, both of which are humectants, may cause uninformed users to become inadvertently dehydrated.

(Response) FDA recognizes that information about the health effects of the constituents in e-liquids and ENDS aerosols in both users and nonusers is limited and that this issue should be explored to better understand the impacts of these products on the population health.

(Comment 122) As FDA noted in the NPRM, one study detected diethylene glycol in one e-cigarette cartridge (79 FR 23142 at 23157). A few comments took issue with FDA's reliance on the study, because the amount of diethylene glycol reported was so low that it was unlikely to cause harm to consumers and had not been replicated in other scientific studies to date.

(Response) FDA appropriately characterized this study in the NPRM, stating that diethylene glycol ''was found in only 1 of 18 cartridges studied and it was not found at all in another 16 studies'' (79 FR 23142 at 23157). FDA agrees that the amount found was low, but reiterates that diethylene glycol is a toxicant and, therefore, is a cause for concern.

(Comment 123) We received many comments regarding the safety of the aerosol that is emitted from e-cigarettes. These comments expressed concern that individuals incorrectly believe that the aerosol emitted from e-cigarettes is harmless and stated that e-cigarette aerosol is not simply water ''vapor,'' as is sometimes advertised (Ref. 151). They provided studies indicating that the primary or mainstream and exhaled or secondhand e-cigarette aerosols have been found to contain at least 10 chemicals known to cause cancer, birth defects, or other reproductive harm (Ref. 65). They also noted that potentially harmful constituents have been identified in some e-liquids and their aerosol, including tobacco-specific nitrosamines, heavy metals, and

carbonyls, albeit at significantly lower levels than in cigarette smoke (Refs. 65, 118, 152, 153, 154, 155, 156). Studies have shown that the primary aerosol contains measurable amounts of nicotine, which can have an impact on both users and nonusers (Ref. 144, 147).

We also received comments stating that the aerosol is completely harmless or significantly less harmful than tobacco smoke from combusted tobacco products; the comments included data from peer-reviewed publications (Refs. 144, 156, 157, 158), a presentation at a professional conference (Ref. 159), and individual company testing. These comments also submitted research that was not peer-reviewed, which stated that there were no key tobacco smoke toxicants in e-cigarettes (Ref. 160).

(Response) FDA recognizes that the aerosol that is exhaled by users of some e-cigarettes and similar electronic apparatus may not pose as much harm as smoke emitted from combusted tobacco products. However, given that studies do indicate that both nicotine and other toxicants are found in the exhaled aerosol, limiting exposures must be considered. (See section XII regarding the potential for product standards and tobacco product manufacturing practices on manufacturers of newly deemed products.) In the absence of short- and long-term studies on the potential impact of secondary exposure to aerosol, FDA cannot conclude that the aerosol is harmless. Moreover, as stated throughout this document, the Tobacco Control Act does not require that FDA make a finding that a product is harmful in order to deem it to be subject to chapter IX of the FD&C Act; FDA is authorized to deem any product that meets the definition of a ''tobacco product'' pursuant to section 901 of the FD&C Act.

(Comment 124) A few comments stated that the aerosol must be safe because the primary constituents of the liquid that generate the e-cigarette aerosol are propylene glycol and glycerin. They stated that inhalation of such constituents is harmless because they are designated as ''generally recognized as safe'' (GRAS) by FDA. They cited animal inhalation studies showing limited toxicological effects from either propylene glycol or glycerin (*e.g.,* Ref. 161).

(Response) FDA disagrees with comments claiming that the aerosol is safe due to certain components being recognized as GRAS. It is important to note that the definition of food additive in section 201(s), and its exclusion of GRAS substances, relates to intended uses that may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (section 201(s) of the FD&C Act). E-liquid is not food or intended for ingestion; therefore, the fact that propylene glycol and glycerin have been designated GRAS for food does not necessarily mean that these components are safe for inhalation. (See additional responses in this section of the document regarding FDA's concerns with ENDS aerosol.)

(Comment 125) Several comments that stated that e-cigarettes are harmless cited one study in which the author concluded that there ''is no serious concern about the contaminants such as volatile organic compounds'' in the e-cigarette ''vapor'' and that tobacco-specific nitrosamine (TSNA) levels in the ''vapor'' are just as hazardous as those TSNAs in NRT products (Ref. 162). Some of these comments specifically asked why FDA did not include this study in the proposed deeming rule.

(Response) FDA has considered these findings and agrees that the exhaled aerosol from ENDS users is potentially less hazardous than secondhand smoke from combusted cigarettes. However, FDA disagrees with the author's conclusion that exposure to aerosol (''vapor'') ''pose[s] no apparent concern'' (Ref. 162). FDA recognizes that the aerosol that is exhaled by users of some e-cigarettes and similar electronic apparatus may not pose as much harm as smoke emitted from combusted tobacco products. However, given that studies do indicate that both nicotine and other toxicants are found in the exhaled aerosol, limiting exposures must be considered. FDA has repeatedly noted the potential benefits and need for additional information regarding ENDS and, therefore, the research included in the NPRM accurately summarized the state of the research on e-cigarettes (and the other newly deemed products) at the time it was drafted.

(Comment 126) A few comments claimed that there are many e-liquids on the market that do not contain nicotine and, therefore, e-liquids should not be regulated. Other comments provided studies that showed that e-cigarettes deliver nicotine but noted that delivery is dependent on the e-cigarette apparatus and liquid type, the rate at which the nicotine is delivered, and the user's experience with e-cigarette use (Ref. 130).

(Response) FDA is aware that, although some ENDS and e-liquids are *marketed* as nicotine free, as stated in section VIII.D, studies have found that certain types of ENDS do not have consistent quality and the labels may not accurately reflect the amount of nicotine in the e-liquid. The World Health Organization (WHO) also has noted that the level of nicotine delivered in currently marketed ENDS varies widely depending on product characteristics, user puffing behavior and nicotine solution concentration, leaving smokers unaware of the nicotine levels they are receiving (Ref. 163). In addition, FDA agrees that many factors influence the delivery of nicotine. For example, an experienced ENDS user may be exposed to amounts of nicotine similar to those delivered by cigarette smoking (Ref. 114). Also, as stated earlier, nicotine-free e-liquid that is intended or reasonably expected to be used with or for the human consumption of tobacco products in most cases would be a component or part of a tobacco product and, therefore, within the scope of this rule. These products will be evaluated on a case-by-case basis.

(Comment 127) Many comments discussed the possibility of nicotine poisoning due to improper access to, or use of, e-liquids. Most of these comments expressed concerns about the growing number of calls to poison control centers due to accidental nicotine poisoning. Others believed this concern was overstated and noted that many drugs can cause poisoning if stored improperly. They stated that the addition of child-resistant containers would alleviate this concern. Some also noted that e-cigarette users self-titrate the nicotine dosage, so concerns about overdosing should be minimal (Ref. 84).

(Response) FDA is concerned about the risk of nicotine poisoning in both users and nonusers. The CDC has reported more than 2,400 calls to U.S. poison control centers for e-liquid exposure between September 2010 and February 2014 (Ref. 164). In another study of 1,700 e-liquid exposures reported to U.S. poison control centers from June 2010 through September 2013, children 5 years of age or younger represented the largest proportion of e-liquid exposures and the group with the greatest increase in exposures per month in the first three quarters of 2013 (Ref. 165). Studies show that nicotine in sufficient concentrations, either when ingested or in contact with the skin, can result in serious or fatal poisoning and is concerning (Refs. 166, 167). Symptoms of toxicity include nausea, vomiting, seizures, coma, cardiovascular instability, respiratory arrest, and sometimes death. Although there was disagreement among the comments as to the level of nicotine that causes

poisoning, the nicotine content of many refillable vials could be toxic to adults and children regardless of the measurement used. Accordingly, elsewhere in this issue of the **Federal Register**, FDA has made available draft guidance, which when final will describe FDA's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products, including recommendations for exposure warnings and child-resistant packaging that would help support a showing that the marketing of a product is appropriate for the protection of the public health. In addition, FDA issued an ANPRM prior to this deeming rule, seeking comments, data, research, or other information that may inform regulatory actions FDA might take with respect to nicotine exposure warnings and child-resistant packaging.

(Comment 128) Some comments compared the poison risks of nicotine against other household products, noting that the incidence of nicotine poisoning is significantly lower than for other household products (Ref. 168).

(Response) Regardless of the incidence of nicotine poisoning in comparison to poisonings attributed to other household products, the dramatic rise in nicotine poisoning from e-liquid exposures is very concerning. FDA is taking under advisement the submitted data regarding nicotine poisoning and suggestions for measures that FDA can take in a separate rulemaking to address the issue, including establishment of tobacco product manufacturing practice regulations under section 906(e) and tobacco product standards under section 907 of the FD&C Act. In addition, as stated previously, FDA issued an ANPRM prior to this deeming rule seeking comments, data, research, or other information that may inform regulatory actions FDA might take with respect to nicotine exposure warnings and child-resistant packaging. Moreover, elsewhere in this issue of the **Federal Register**, FDA has made available draft guidance, which when final will describe FDA's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products, including recommendations for exposure warnings and child-resistant packaging that would help support a showing that the marketing of a product is appropriate for the protection of public health.

(Comment 129) Comments were divided as to whether nicotine is dangerous to humans. Some comments stated that liquid nicotine is completely benign (and that FDA should not regulate e-cigarettes given the lack of harms). They claimed that FDA's findings regarding NRTs illustrate that nicotine is not carcinogenic to humans. (See ''Modifications To Labeling of Nicotine Replacement Therapy Products for Over-the-Counter Human Use,'' 78 FR 19718, April 2, 2013.) Other comments stated that although nicotine has some side effects, it is significantly less hazardous than the toxicants ingested with combusted products. Still others claimed that nicotine is very dangerous.

Comments that claimed that nicotine is dangerous cited studies showing that although nicotine may not be a primary carcinogen, it likely promotes cancers established through angiogenic (promoting of blood vessels in tumors) effects (*e.g.,* Ref. 169). The comments also noted that the 2014 Surgeon General's Report stated that the health risks of nicotine are more serious than previously thought and that FDA should consider this when evaluating the impacts of the newly deemed products on vulnerable populations. Others believed that nicotine is so dangerous that individuals should be required to obtain a certification before being permitted to acquire and handle it.

(Response) In the proposed deeming rule, FDA recognized the impact of nicotine on a youth's brain (see 79 FR 23142 at 23153 and 23154) and also noted poisoning concerns. The inhalation of nicotine (*i.e.,* nicotine without the production of combustion) is of less risk to a user than the inhalation of nicotine delivered by smoke from combusted tobacco products. However, limited data suggests that the pharmacokinetic properties of inhaled nicotine can be similar to nicotine delivered by combusted tobacco products. Thus, inhaled nicotine from a non-combustible product may be as addictive as inhaled nicotine delivered by combusted tobacco products. Researchers recognize that the effects from nicotine exposure by inhalation are likely not responsible for the high prevalence of tobacco-related death and disease in this country (Refs. 10, 11). Although nicotine has not been shown to cause the chronic disease associated with tobacco use, the 2014 Surgeon General's Report noted that there are risks associated with nicotine (Ref. 9 at 111). For example, nicotine at high enough doses has acute toxicity (id.). Nicotine exposure during fetal development has lasting adverse consequences for brain development (id.). Nicotine also adversely affects maternal and fetal health during pregnancy, contributing to multiple adverse outcomes such as preterm delivery and stillbirth (id.). Further, data suggest that nicotine exposure during adolescence may have lasting adverse consequences for brain development (id.). Some studies also have found that nicotine can have detrimental effects on the cardiovascular system and potentially disrupt the central nervous system (Refs. 14, 15). See also section VIII.C discussing the increase in poisoning due to accidental nicotine ingestion.

FDA is not stating that nicotine is harmless. Unlike ENDS, which have not been reviewed by FDA, the NRT products mentioned in the comments are regulated and have undergone premarket review by FDA's Center for Drug Evaluation and Research (CDER) and been found to be safe and effective before obtaining authorization to enter the market (sections 505 and 506 of the FD&C Act). The Agency does not have sufficient data to be able to conclude that consumers are inhaling only nicotine, and no other chemicals or toxicants, when using ENDS. Although ENDS likely do not deliver the same level of toxicants as cigarettes, studies show that there are dangers associated with ENDS use and that exhaled aerosol is not simply ''water vapor,'' as some believe. (See section VIII.C for additional discussion about the toxicants in ENDS vapor.)

(Comment 130) At least one comment suggested that to help address the dangers of nicotine and its use in future tobacco products, manufacturers registering future products with FDA should provide documents demonstrating the accuracy of stated nicotine levels and that the products are diacetyl and acetyl propionyl free.

(Response) FDA agrees with the need to carefully monitor future tobacco products and to evaluate the toxicological concern of chemical ingredients, such as diacetyl and acetyl propionyl, in e-liquids and that statements about the nicotine concentration in the e-liquid as well as the amount of nicotine that will be delivered to the user are accurate. FDA's review of SE reports and PMTAs under sections 905 and 910 of the FD&C Act will often include analysis of the chemicals included in the products. In addition, the requirements to submit ingredient listings under section 904 and HPHC testing data under sections 904 and 915 are expected to alert FDA to the existence of these HPHCs in e-liquids.

(Comment 131) Many comments expressed concerns regarding the high

cost associated with testing for HPHCs in each individual e-liquid and e-cigarette product. They suggested that FDA use enforcement discretion, as the Agency has done previously, to reduce the regulatory burden for e-cigarette manufacturers. For example, they noted that FDA has compliance policies for the submission of SE reports for certain product modifications and HPHC reporting. To reduce the regulatory burden, they suggested that FDA not require ingredient disclosure of all unique e-liquid products under section 904(a)(1) of the FD&C Act because such a requirement is unreasonable given the many different e-liquid formulations in these retail establishments. They stated that in lieu of ingredient listings, FDA should accept a table of all ingredients used in e-liquids along with use-level (concentration) ranges (*i.e.,* minimum and maximum percentages) of those ingredients in their products. These comments further suggested that FDA allow companies to simply amend their ingredients lists when altering products rather than requiring them to submit PMTAs.

(Response) Once this rule becomes effective, newly deemed products automatically become subject to chapter IX and all of its provisions applicable to tobacco products, without exception. Therefore, all manufacturers and importers of the newly deemed products will be subject to the requirements under sections 910, 905, and 904 of the FD&C Act upon the effective date of this final rule.

However, FDA has established a compliance policy for certain circumstances. See section IV.D describing the compliance policy regarding certain provisions and small-scale tobacco product manufacturers.

D. Quality Control

In the NPRM, FDA recognized previous instances of lack of quality control for certain e-cigarette products (79 FR 23142 at 23149). FDA indicated that the premarket review requirements that will automatically apply to the newly deemed products can help to address quality control concerns.

(Comment 132) Many comments expressed concern regarding the lack of controls in place for the mixing of e-liquids. They stated that these liquids are often mixed by individual consumers or employees of e-cigarette retail establishments who may lack training or knowledge of guidelines for handling such products. Several retailers of e-liquids submitted comments stating that they have controls in place to ensure the safety of their e-liquids.

(Response) FDA understands the comments' concerns about the safety of e-liquids. As stated previously, FDA issued an ANPRM prior to this deeming rule seeking comments, data, research, or other information that may inform regulatory actions FDA might take with respect to nicotine exposure warnings and child-resistant packaging. Also, elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a draft guidance, which when finalized will provide FDA's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products, including recommendations for exposure warnings and child-resistant packaging that would help support a showing that the marketing of a product is appropriate for the protection of public health. FDA also intends to consider these and other issues during its premarket review of these products. Further, after the effective date of this rule, FDA can exercise its authorities under the Tobacco Control Act to take additional steps to address the safety of e-liquids.

(Comment 133) Some comments included data regarding the variations among the nicotine levels in e-liquids, including data showing that the nicotine levels of the products are not accurately reflected in the nicotine concentration stated on the labels. For example, one study found nicotine content labels to be highly inaccurate and determined that products claiming to be nicotine-free actually contained high levels of nicotine (Ref. 170). Other comments stated that the variations are no longer as significant among the newer e-cigarette products, and that newer studies reported more consistent nicotine levels (Ref. 171).

Many comments cited several studies of newer e-cigarettes which continued to find wide variability in e-cigarette engineering, including nicotine concentrations in e-liquid, that were inconsistent with the information contained on the product label (Ref. 16). For example, one 2014 study of e-liquid refills found that the actual nicotine level of 65 percent of the e-liquids deviated by more than 10 percent from the nicotine concentrations printed on the labels (Ref. 17). Other studies found variability among nicotine concentrations, but the nicotine levels were equivalent to or lower than advertised (Refs. 18, 19). In one study, researchers stated that the total amount of nicotine in the e-liquid studied was potentially lethal if an individual were to drink it or absorb it through the skin (Ref. 18). They based this finding on the lethal level of nicotine being in the 10 to 60 milligram (mg) range; however, other comments claimed the lethal dose of nicotine is actually much greater (Ref. 172).

Some comments expressed concern that this rule does not address the possibility of a dangerous contamination of a batch of e-liquid because it does not include quality control measures or product standards that could prevent such contamination. They believed that FDA's authority to establish tobacco product manufacturing requirements or product standards in the future was insufficient to address this concern.

(Response) FDA is aware of the variability of nicotine among certain ENDS and that the labeling may not accurately reflect the nicotine levels. After this rule becomes effective, FDA has the authority to issue tobacco product manufacturing practice regulations under section 906(e) of the FD&C Act to address this issue. The PMTA process (particularly, the requirement to submit information on manufacturing methods) also provides a mechanism through which products that are more harmful or addictive than products on the market at the time of submission would be denied entrance to the market. Moreover, immediately upon the effective date of this rule, if FDA determines that an e-liquid has been contaminated and is therefore adulterated under section 902 or that it is misbranded under section 903 of the FD&C Act because its labeling is false or misleading, it can initiate enforcement action such as a seizure, injunction, or criminal prosecution.

(Comment 134) A few comments expressed concern that FDA may limit the availability of e-liquids to established manufacturers only and prohibit individuals from mixing their own e-liquids. These comments stated that they need access to products of reasonable potency, high purity, and high quality.

(Response) This final deeming rule places some restrictions on the sale and distribution of tobacco products, such as minimum age restrictions, but it does not bar sales to individuals generally.

(Comment 135) At least one comment noted that, although there have been fires due to mishandling of e-cigarette batteries, cases of accidental poisoning, and concerns about functionality, the ''de facto regulations'' that are in place, ''namely brand equity, potential civil liability, and word-of-mouth'' have been effective in helping the market evolve and controlling behavior.

(Response) FDA disagrees. FDA's adverse event reporting system has

inherent limitations as a measure of the impact of e-cigarettes since ENDS are a newly deemed product and reporting adverse events associated with tobacco products (including e-cigarettes and other ENDS) is voluntary. FDA remains concerned about adverse events associated with ENDS use, including overheating and exploding batteries as reported in the news, and the vast evidence that accidental nicotine poisoning is increasing in the wake of growing e-cigarette use. Toward that end, elsewhere in this issue of the **Federal Register**, FDA has made available draft guidance, which when final will describe FDA's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products, including compliance with existing voluntary standards for ENDS batteries. In addition, concerns remain regarding quality control, which could impact the functionality of these products. FDA believes that the automatic statutory provisions that will apply to these products as a result of this deeming rule, in conjunction with additional authorities under the law that FDA can exercise after the effective date, will help address these concerns.

(Comment 136) At least one comment sought clarification as to why FDA expressed concern about quality control issues for e-cigarette products but not for combusted products that contain thousands of toxic constituents.

(Response) FDA is concerned about quality control for all tobacco products and will continue to monitor these products to determine if there are quality control issues. FDA's premarket review of the newly deemed products will increase product consistency. For example, FDA's oversight of the constituents of e-cigarette cartridges would help to ensure quality control related to the chemicals and their quantities being aerosolized and inhaled. Quality control issues will also be addressed in a tobacco product manufacturing practices regulation that FDA intends to issue at a later date. Also, FDA may take enforcement action if an ENDS or any other tobacco product is adulterated or misbranded within the meaning of the FD&C Act.

(Comment 137) A few comments expressed concerns regarding the quality of e-cigarettes manufactured overseas. They stressed the importance of issuing regulations to require the registration of foreign establishments so that FDA knows the identity of foreign manufacturers and the products they import into the United States.

(Response) FDA agrees with comments' concerns regarding quality control and the safety of ENDS manufactured both domestically and in other countries. One of the immediate benefits of deeming ENDS is that all newly deemed products, including ENDS, that meet the definition of ''new tobacco product'' will be subject to the premarket authorization requirements in sections 905 and 910 of the FD&C Act. In addition, FDA has announced its intention in the Unified Agenda to issue a NPRM that would apply the registration and listing requirements of section 905 to foreign establishments.

(Comment 138) Some comments suggested that to properly regulate e-cigarettes, given their position on the continuum of nicotine-delivering products, FDA should regulate these products based on the size of the manufacturer—which is generally smaller than the size of companies that manufacture cigarettes and smokeless tobacco products. They also suggested that FDA stagger the compliance periods for submission of PMTAs so that smaller companies have additional time to prepare their submissions.

(Response) Section IV.D has additional information about compliance periods for small-scale tobacco product manufacturers. FDA's compliance policy for the submission of SE reports, SE exemption requests, and PMTAs for all manufacturers of deemed products is included in section IV.C.

(Comment 139) One comment recommended that FDA collaborate with other Federal Agencies, including the National Institutes of Health (NIH), CDC, and the Substance Abuse and Mental Health Services Administration (SAMHSA), as well as international agencies including the EU, to continue research on tobacco products and increase surveillance and other enforcement of quality control and other issues.

(Response) FDA agrees. FDA intends to continue to review available studies and fund studies on tobacco products, including studies on ENDS initiation, use (including transitions to other tobacco products and multiple use), perceptions, dependence, and toxicity (Ref. 173). FDA also has been conducting a series of public workshops to obtain additional information on e-cigarettes and their impact on public health (79 FR 55815). These workshops will help to inform FDA's development of future rules and policies that have an impact on ENDS. Additional regulations regarding ENDS will be subject to the requirements of the APA.

(Comment 140) Some comments stated that FDA should regulate materials used in the manufacture of e-cigarette components and packaging that come into direct contact with e-liquids. They noted that improper e-cigarette construction and e-liquid packaging materials could also result in hazardous leachates or degradation of products in the e-liquid that may become aerosolized and inhaled upon use.

(Response) With this final rule, FDA is deeming all products, except for accessories of newly deemed products, that meet the definition of ''tobacco products'' under section 201(rr) of the FD&C Act, which includes the components and parts (including packaging of such products). FDA will consider the issues raised by the comments when it develops a NPRM on tobacco product manufacturing practices.

E. Misperceptions

In the NPRM, FDA noted its concerns regarding consumer misperceptions of currently unregulated products, particularly e-cigarettes. Many comments provided data to substantiate those concerns and others provided data and personal stories regarding the potential benefits of e-cigarettes. Other comments indicated that, based on these potential benefits, they believed e-cigarettes to be safe tobacco products.

(Comment 141) Many comments stated, but did not provide supporting data, that e-cigarettes: (1) Are approximately 99 percent less hazardous than cigarettes; (2) are only consumed by smokers and former smokers who quit by switching to e-cigarettes; and (3) have not been found to create nicotine dependence in any nonsmoker. They also stated that there is no evidence that ingesting e-liquid leads to fatalities.

(Response) As discussed throughout this document, FDA agrees that use of ENDS is likely less hazardous for an individual user than continued smoking of traditional cigarettes. One self-selected comparison reported that across several Japanese brands, under some use conditions, ENDS released 1/50th of the level of formaldehyde released by cigarettes (Ref. 135). The highest level detected was six times lower than the level in cigarette smoke (id.). But other research, published as a letter to the editor of the *New England Journal of Medicine,* reported that ENDS operated at 5 volts delivered a mean of 390+/−90 µg per 10 puff sample which is greater than 150 µg, the estimated average delivery of formaldehyde than conventional cigarettes (Ref. 128). No formaldehyde-releasing agents were detected when ENDS were operated at

3.3 volts (Ref. 128). A subsequent peer-reviewed article on 5 variable-power ENDS devices found large variations in formaldehyde delivery across devices (Ref. 129). The first device yielded more formaldehyde than combustible cigarettes at every power level tested, and the second device delivered more formaldehyde at the highest power level tested; the remaining three devices delivered less formaldehyde than combustible cigarettes at all power levels tested (*id.*) The same research found that aldehyde delivery varied by 750-fold from one ENDS device to another (*id.*). The article referenced in one comment (Ref. 67) reported that increasing the voltage from 3.2 to 4.8 volts increased formaldehyde, acetaldehyde, and acetone levels from 4 to over 200-fold.

Nevertheless, as discussed in section VIII.F, evidence shows that while most ENDS are consumed by smokers and former smokers (*e.g.,* Refs. 109, 110), some consumers (including youth and young adults) are initiating tobacco use with ENDS. Several studies have found that ENDS users, particularly experienced ENDS users, are able to achieve nicotine exposures similar to cigarette smokers (Refs. 114, 148, 149, 150). Although no studies have been done to-date assessing the development of dependence among non-smokers, several studies have found that ENDS users, particularly experienced ENDS users, are able to achieve nicotine exposures similar to cigarette smokers and that nicotine is a known addictive substance. Fourth, as discussed in section VIII.D, the incidence of nicotine poisoning has been on the rise and has resulted in severe poisonings and hospitalization (Ref. 174). In December 2014, after the close of the comment period for the NPRM, media reported the first death of a toddler from accidental poisoning from e-liquid (Ref. 175). Regulation of ENDS will help to alleviate consumer misperceptions such as those expressed in the comments.

(Comment 142) Many comments stated that e-cigarettes should be regulated given their appeal to youth and young adults and the belief that e-cigarettes are less harmful than conventional cigarettes. They agreed with FDA's concern that a failure to regulate the newly deemed products could reinforce consumers' existing confusion and misinformation about these products. However, other comments stated that FDA's concerns about youth's misperception of the safety of e-cigarettes should not be a factor in FDA's decision to regulate them. They stated that regulation cannot remedy the fact that many youth affirmatively disregard available safety information.

(Response) As FDA stated in its proposal, many people may believe that certain tobacco products covered by this rule present fewer health risks when compared to that of cigarettes (79 FR 23142 at 23158 and 23159), which is supported by some of the emerging scientific literature demonstrating that some ENDS products, operated at some power levels, may have lower delivery of harmful constituents and toxicants than that of combusted cigarettes (see discussion on the health harms of ENDS in response to Comment 117). In fact, a recent telephone survey of 1,014 adults indicates that a majority of American adults surveyed (nearly two-thirds, 65 percent) believe e-cigarettes are harmful to the health of the people who use them and 23 percent believe that they are not harmful (Ref. 176). In addition, 44 percent believe that electronic cigarettes are less harmful than combusted cigarettes while 32 percent thought they were equally harmful (id.). Of particular note, the survey found that ''[t]hose who have ever used e-cigarettes are significantly less likely than never-users to believe that e-cigarettes and marijuana are harmful to the health of people who use them, and more likely to believe in the benefits of e-cigarettes when it comes to smoking cessation'' (id.).

Although FDA expects that youth understanding and appreciation of the health effects and risks of certain newly deemed tobacco products will be improved if they are also FDA-regulated, that is only one of the many public health benefits that will accrue from deeming them subject to the FD&C Act, as discussed in the NPRM (79 FR 23142 at 23148 and 23149).

(Comment 143) Some comments expressed concern that the increase in e-cigarette use in places where cigarette smoking is not currently allowed creates confusion, particularly among children, who often cannot tell the difference between smoking and e-cigarette use. They referred to unpublished research and anecdotal evidence indicating that when children see pictures of people using e-cigarettes they report that someone is smoking.

Other comments disagreed, stating that e-cigarette use will more likely lead to normalization of e-cigarettes rather than cigarettes (Ref. 110). They stated that one study found that daily smokers (aged 18 to 35 years) who observed individuals using e-cigarettes only increased the smoker's desire for an e-cigarette, and not for a conventional cigarette (Ref. 177).

(Response) FDA is concerned that the growth in ENDS use, particularly among youth and young adults, could lead to the re-normalization of cigarette smoking. The Surgeon General recognized that adolescents are particularly vulnerable to visual cues to smoke and to social norms, making this an even greater concern (Ref. 49). FDA believes that subjecting ENDS to its tobacco control authorities, and requiring compliance with the various statutory and regulatory requirements (*e.g.,* ingredient listing and others), will help to address the common misunderstanding that these products are safe to use.

F. Use as a Cessation Product

In the preamble to the NPRM, FDA recognized that some consumers may use ENDS in tobacco cessation attempts. We note that if an ENDS product seeks to be marketed as a cessation product, the manufacturer must file an application with FDA's Center for Drug Evaluation and Research (CDER) and no ENDS have been approved by FDA as effective cessation aids.

Recently published population-wide data from the CDC's NCHS, which provides the first estimates of e-cigarette use among U.S. adults from a nationally representative household interview study, indicates that current cigarette smokers and recent former smokers (*i.e.,* those individuals who quit smoking within the past year) were more likely to use e-cigarettes than long-term former smokers (*i.e.,* those individuals who quit smoking more than one year ago) and adults who had never smoked (Ref. 24). Among current cigarette smokers who had tried to quit smoking in the past year, more than one-half had ever tried an e-cigarette and 20.3 percent were current e-cigarette users (id.).

(Comment 144) Comments were divided regarding the viability of e-cigarettes as a smoking cessation product. Some comments contended that the actual patterns of e-cigarette use, citing a meta-analysis showing the rapid penetration of the youth market and high levels of dual use among both adults and adolescents, will lead to a lower probability that smokers using e-cigarettes will quit smoking cigarettes (Ref. 16). They also cited another study in which, although 85 percent of e-cigarette users reported that they were using e-cigarettes to quit smoking, they were no more likely to have quit smoking than nonusers of e-cigarette (Ref. 178).

However, consumers and manufacturers of e-cigarettes provided information showing positive impacts of e-cigarettes on cessation, including

personal anecdotes from former smokers (Ref. 132). For example, they cited a 1-year multinational study where researchers found that among smokers who were using e-cigarettes at the baseline, 22 percent had quit smoking after 1 month and 46 percent had quit smoking after 1 year (Ref. 179). In a survey of adults in the United Kingdom who tried to quit smoking at least once in the past year, respondents who used e-cigarettes had a higher quit rate (20 percent) than those who used NRTs like patches or gum (10 percent) or those that did not use a cessation aid (15 percent) (Ref. 180). These comments also asserted evidence that e-cigarette use, at a minimum, leads to decreased cigarette use (*e.g.,* Refs. 107, 181). One comment also noted that tribes use e-cigarettes as an alternative to smoking and to promote cessation.

(Response) As we have stated throughout this document, we recognize that there is emerging data that some individual smokers may potentially use ENDS to transition away from combustible tobacco products. For instance, prospective studies of varying duration examining the efficacy of e-cigarettes as cessation devices suggest their potential to decrease combustible cigarette use as well as promote abstinence from combustible cigarettes (Refs. 107, 149, 182, 183, 184). Three randomized controlled clinical trials (Ref. 107, 149, 184) report that e-cigarettes may help some smokers to stop smoking. The trial that compared e-cigarettes to nicotine replacement therapy found verified abstinence in all experimental groups, but no significant difference among e-cigarettes, placebo e-cigarettes (*i.e.,* e-cigarettes with no nicotine), and nicotine patches in six-month abstinence rates (Ref. 184). Achievement of abstinence was substantially lower than the optimistic estimates on which the power calculation and study sample size were based, and thus, the researchers could conclude no more than that ''among smokers wanting to quit, nicotine e-cigarettes might be as effective as patches for achieving cessation at 6 months'' (id.). It is possible that longer term prospective studies may—or may not—demonstrate statistically significant cessation outcomes for e-cigarettes in relation to conventional nicotine replacement therapies (id). It is noteworthy that a third of the participants allocated to the e-cigarettes groups in this study reported continued product use at 6 months, suggesting that they might have become long-term e-cigarette users (id.). However, some systematic reviews of available evidence indicate that there is currently insufficient data to draw a conclusion about the efficacy of e-cigarettes as a cessation device (Refs. 185, 186). The Cochrane Collaboration's systematic review and meta-analysis assessed approximately 600 scientific records to include two randomized controlled trials and 11 cohort studies on e-cigarettes and smoking cessation in their review (Ref. 186). As the Cochrane review judged RCTs to be at low risk of bias, the investigators combined results from two randomized controlled trials, totaling over 600 people, and conducted a quantitative meta-analysis. Results indicated that using e-cigarettes with nicotine was associated with increased smoking cessation as compared with e-cigarettes without nicotine. Investigators also found evidence that using e-cigarettes with nicotine also helped more smokers reduce the amount they smoked by at least half compared to e-cigarettes without nicotine. However, the authors cautioned that ''the small number of trials, low event rates and wide confidence intervals around the estimates mean that our confidence in the result is rated 'low'.'' (Ref. 186) In addition, the authors observed that ''the overall quality of the evidence for our outcomes was rated 'low' or 'very low' because of imprecision due to the small number of trials'' (id.). Another meta-analysis of the same two trials of e-cigarettes with and without nicotine found comparable results (Ref. 187). The authors also reported a pooled estimate of cessation among nicotine e-cigarette users, but the lack of non-e-cigarette control groups in the studies prevented them from comparing the efficacy of e-cigarettes against no e-cigarette use and against standard interventions for cessation, such as nicotine patches (id.).

An alternate systematic review and meta-analysis of approximately 600 scientific records to include 15 cohort studies, 3 cross-sectional studies, and two clinical trials (one RCT, one non-RCT) examined the association between e-cigarette use and cessation in observational epidemiological studies and clinical trials; all 20 studies compared smoking cessation rates for e-cigarette users against control groups of smokers who did not use e-cigarettes (Ref. 112). This meta-analysis found overall that odds of quitting cigarettes were on average 28 percent lower for smokers who used e-cigarettes than those who did not (odds ratio = 0.72, with 95 percent confidence interval 0.57 to 0.91) (Ref. 112). Of note, this meta-analysis included chiefly observational studies whose control groups were not randomized, and included a wide range of designs as well as variable exposures and outcome definitions (id.). While some potential confounders were controlled for in most of the studies, the investigators acknowledged that there may be other unidentified confounders that could be a source of bias. This potential bias as well as other limitations described may impact interpretability of the overall findings (id.).

We also note that ENDS have not been approved as effective cessation aids. FDA remains committed to supporting long-term population-level research that will help fill in current data gaps.

(Comment 145) At least one comment suggested that FDA provide physicians with guidelines about e-cigarette use, including its health impact and efficacy as a cessation tool.

(Response) To the extent the comment is about ENDS products that are drugs because they are marketed for cessation, an ENDS product marketed for therapeutic purposes is a drug or device subject to FDA's regulations and laws for those products.

(Comment 146) A few comments expressed concern that FDA misrepresented certain studies in the NPRM and would not consider research released since the issuance of the NPRM, particularly regarding the effectiveness of e-cigarettes as a cessation tool.

(Response) FDA has considered the preliminary evidence regarding the effectiveness of ENDS to help smokers quit or to reduce their consumption of combusted tobacco products. There is some indication that such products may have the potential to help some individual users to quit using combusted tobacco products or to reduce their use of such products, as reported by scientific literature describing a small number of randomized controlled trials evaluating the impact of ENDS use on smoking outcomes (Refs. 137, 148, 184) and pilot studies evaluating ENDS use on smoking reduction and cessation (Refs. 182, 183). But other evidence is to the contrary. Beyond the meta-analysis discussed in section V(B)(3), a year-long study of over 5,000 20-year-old Swiss men found that, even after adjusting for nicotine dependence, individuals who were smokers at the start of the study and who reported e-cigarette use at the end of the study were more likely to still be smoking and more likely to have made one or more unsuccessful quit attempts at the end of the year than individuals who were smokers at the start and who reported no e-cigarette use (Ref. 188). The most important consideration is that ENDS are not an

FDA-approved cessation product. If an ENDS manufacturer wishes to make a cessation claim or otherwise market its product for therapeutic purposes, the company must submit an application for their ENDS to be marketed as a medical product.

(Comment 147) Some comments expressed concern that e-cigarette users are developing an addiction to nicotine while seeking to overcome their smoking addiction and that the lack of regulation makes it difficult for users to know the nicotine level that they need in their e-cigarettes to overcome their addiction. They stated that for cigarette smokers who are trying to replace their cigarette-derived nicotine with e-cigarettes, ingredient listing and other requirements are vital to ensure that users know how much nicotine they are ingesting.

(Response) By deeming ENDS, FDA has ensured that these products are now subject to requirements related to ingredient and HPHC reporting, among other requirements. In addition, the registration and listing requirements and premarket applications will provide FDA with vital information as to the extent of ENDS use and how many ENDS products consumers are using on a daily basis.

(Comment 148) Some comments perceived the newer generation of e-cigarettes to be less addictive than combusted cigarettes and closer in profile (including risk profile) to NRTs (Ref. 76). They noted the limited number of significant adverse events resulting from e-cigarette use and claimed that such adverse events are not distinguishable from NRTs (Ref. 184). Some comments also believed that FDA should consider the advantages that e-cigarettes have (as compared to NRTs) when establishing the regulatory approach for these products, including the fact that they offer appealing visual, tactile, and gestural similarities to cigarettes, and that e-cigarettes provide quicker nicotine delivery than NRTs (Ref. 189).

(Response) As we have stated throughout this document, we recognize that individual smokers may report cessation benefits from ENDS and that preliminary research outcomes from randomized controlled trials indicate that ENDS may decrease some individuals' cigarette consumption and promote cessation. However, the risk profile is likely to be different as compared to NRTs, and the long-term risks associated with chronic use of ENDS are unknown. Finally, contrary to ENDS, the nicotine patch and other NRTs were found to be safe and effective by FDA's CDER after reviewing premarket applications containing data and information establishing safety and effectiveness. No ENDS has yet been approved by CDER.

(Comment 149) Comments in support of limited or no regulation of e-cigarettes stated that these products have a positive impact on the public health at the population level. They cited online surveys and convenience store data showing that most e-cigarette users do not use additional tobacco products (see section VIII.H) and claimed that FDA cherry-picked the evidence regarding dual use in the NPRM. They also claimed FDA did not adequately assess the reduction in smoking that would result from increased e-cigarette use and, as a result, the Agency underestimated the potential positive impacts of e-cigarettes on the public health at the population level.

(Response) Many provisions of the FD&C Act call for a population-level public health analysis that takes into account the population as a whole, including users and nonusers of tobacco products (*e.g.,* section 906(d) of the FD&C Act). Even products that are less toxic than combusted tobacco products on an individual user basis may increase public health harms if, for example, they encourage nonusers to start using tobacco products that can lead to lifelong nicotine addiction.

As we have stated throughout the document, FDA has examined data regarding health harms generally associated with all of the categories of tobacco products regulated under this rule (including ENDS, which FDA recognizes may potentially provide cessation benefits to some individual smokers). FDA is regulating these products in accordance with this knowledge and will continue to regulate as we learn more about the potential for product-specific health harms. FDA recognizes that some ENDS users report that the products have the potential to help individual users to quit smoking. However, FDA's responsibility is to assess the population health impact of ENDS, including increasing youth use, as well as the frequency of dual use of ENDS and combusted tobacco products. FDA believes that data from long-term population level studies, such as the PATH Study, will help to provide information about the overall population health impacts of ENDS.

(Comment 150) Many comments provided personal stories and peer-reviewed studies to illustrate the benefits of e-cigarettes as a cessation product and to request that FDA treat this product category differently based on where the product falls within the continuum of nicotine delivering products. For example, they suggested that FDA differentiate between substances that contain tobacco and those that are derived from tobacco and provide a separate regulatory approach for each product category.

Some comments also suggested that FDA tailor its regulatory approach based on the type of electronic apparatus—*e.g.,* advanced refillable personal vaporizers (ARPVs) or open-system vapor products versus ''cigalike'' products (ready for use products that look like cigarettes and are sold in convenience stores). These comments believed FDA should only deem ''cigalike'' products that are ready for consumption, because they are easily accessible to youth and have been associated with quality control issues (see section VIII.D). They noted that ARPVs and other open systems are significantly more expensive than ''cigalike'' products and are only offered in vape or specialty shops. They compared this to Option 1 (to deem all cigars) and Option 2 (to deem all cigars except premium cigars) and suggested that FDA should have provided similar options for regulating different e-cigarettes. They also expressed the need for a different regulatory approach for ARPVs because they provide users with the best opportunity to cease using combusted tobacco products (Ref. 190). However, other comments provided focus group research in which smokers rated cigalikes to be significantly more satisfying than ARPVs and asked for a minimal regulatory approach for cigalikes.

Further, some comments stated that it was not feasible to regulate ARPVs. They stated that the wide varieties of e-liquids available at e-cigarette retail establishments and the ability of users to customize their experience, including by altering the product's voltage/wattage, puff duration, coil resistance, cartridge/battery duration, and design aesthetics, make oversight, application review, and other regulation untenable.

Other comments stated that, instead of establishing a different regulatory approach, FDA should ban ARPVs because there is greater risk associated with their use and children may tamper with them. They suggested that if FDA does not ban these products, FDA should require the disclosure of all ingredients in e-liquids and other vaporized nicotine products in both their pre-use and vapor states.

(Response) To the extent that comments are asserting that FDA should not regulate ENDS or subject them to certain provisions, FDA disagrees with these comments, especially given that

ENDS use among youth and young adults is increasing. Although recent data on young adults and adults indicate that ENDS users are more likely to be former cigarette smokers and current cigarette smokers who have tried to quit (*e.g.,* Ref. 24), there is still some use among adult non-tobacco users, particularly among young adults. In addition, the rapid increase in use among adolescents is concerning. FDA also remains concerned that ARPVs present the risk of accidental nicotine poisoning. In addition, researchers recently reported that the new generation of high voltage ENDS may put users at increased risk of negative health effects (Ref. 67) and that ARPVs have the potential for increased abuse liability (*e.g.,* Refs. 109, 132, 171). FDA will continue to monitor research regarding the health effects of different types of ENDS and may tailor the regulatory requirements accordingly.

(Comment 151) Some comments requested that FDA either exempt e-cigarette products from the deeming regulation or strike the entire proposal for e-cigarettes and replace it with what they considered a more science-based approach or with rules that address good manufacturing practices and consumer safety, given their potential for use as cessation products.

(Response) FDA disagrees. This final deeming rule is a foundational rule that will provide many public health benefits, as described in the NPRM (79 FR 23142 at 23148 and 23149), and will provide FDA with critical information about the health risks of ENDS and other newly deemed products, including data from ingredient listing submissions and reporting of HPHCs required under the FD&C Act. Also, once this rule becomes effective, newly deemed products may be subject to additional regulations. For example, FDA has the authority under section 906(e) of the FD&C Act to issue a rule establishing tobacco product manufacturing practices, and this authority applies to deemed products. FDA also has the authority under section 907 of the FD&C Act to establish product standards for deemed products, including requirements with respect to packaging. The Agency issued an ANPRM prior to this deeming rule, seeking comments, data, research, or other information that may inform regulatory actions FDA might take with respect to nicotine exposure warnings and the use of child-resistant packaging. In addition, elsewhere in this issue of the **Federal Register,** FDA has made available a draft guidance for public comment, which when final will describe FDA's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products, including recommendations for nicotine exposure warnings and child-resistant packaging that would help to support a showing that the marketing of a product is appropriate for the protection of the public health.

(Comment 152) Some comments stated that e-cigarettes should be subject to little or no FDA regulation, because e-cigarettes inhibit withdrawal symptoms in users with a history of relapse (Ref. 191) and lead to reduction and cessation in asthmatic smokers (Ref. 107).

(Response) FDA disagrees. Although ENDS may potentially provide cessation benefits to individual smokers, no ENDS have been approved as effective cessation aids. If an ENDS manufacturer wishes to make a cessation claim, the company must submit an application for their ENDS to be marketed as a medical product.

G. Modified Risk Claims

In the NPRM, FDA noted that it expects public health benefits through the application of section 911 of the FD&C Act to the newly deemed tobacco products. Historically, certain users have initiated and continued using certain tobacco products based on unauthorized modified risk claims and consumers' unsubstantiated beliefs. Application of section 911 will prohibit the introduction into interstate commerce of MRTPs unless FDA issues an order permitting their marketing.

(Comment 153) A few comments expressed concern that imposition of section 911 of the FD&C Act will force e-cigarette manufacturers to implicitly lie by not permitting them to tell consumers that their products are safer alternatives to conventional cigarettes, to advertise that they do not contain tobacco, and to state that they are ''smoke free.'' They added that the public already overwhelmingly believes that e-cigarettes are reduced risk products and, therefore, the section 911 requirements are irrelevant (Refs. 178, 192). However, other comments stated that manufacturers should be prohibited from making cessation claims without providing scientific evidence to support their efficacy as a cessation mechanism.

(Response) FDA disagrees with concerns that ENDS manufacturers will not be able to make claims that properly represent their products. Section 911 is one of the provisions of the statute that applies automatically to deemed products. It was included in the FD&C Act to protect consumers from manufacturers making invalid or unsubstantiated claims, as many had done with respect to their designation of cigarettes as ''light,'' ''low,'' or ''mild.'' The mistaken belief that ''light'' and ''low-tar'' cigarettes were safer than other cigarettes prompted many smokers to switch to such products instead of quitting altogether. Section 911 will prevent consumers from being similarly misled by ensuring a manufacturer may not make unsubstantiated claims. Manufacturers that have data to substantiate modified risk claims for a particular product can submit an MRTP application so that FDA can determine that the product meets the statutory standard and can issue an order authorizing it to be marketed as an MRTP.

As Congress recognized,

> [u]nless tobacco products that purport to reduce the risks to the public of tobacco use actually reduce such risks, those products can cause substantial harm to the public health to the extent that the individuals, who would otherwise not consume tobacco products or would consume such products less, use tobacco products purporting to reduce risk. Those who use products sold or distributed as modified risk products that do not in fact reduce risk, rather than quitting or reducing their use of tobacco products, have a substantially increased likelihood of suffering disability and premature death. The costs to society of the widespread use of products sold or distributed as modified risk products that do not in fact reduce risk or that increase risk include thousands of unnecessary deaths and injuries and huge costs to our health care system.

(section 2(37) of the Tobacco Control Act).

(Comment 154) Some comments believed that e-cigarettes should only be authorized as MRTPs, rather than new tobacco products via the PMTA or SE pathways, because that would allow them to meet the predominant expectations of consumers.

(Response) FDA disagrees. The Tobacco Control Act requires all new tobacco products, including MRTPs, to go through premarket review and obtain a marketing authorization order via the PMTA, SE., or SE exemption pathways. A manufacturer who wants to sell a product for use to reduce harm or risk of tobacco-related disease can also obtain authorization to market an MRTP if the manufacturer submits an application under section 911 of the FD&C Act and FDA issues such an order.

(Comment 155) A comment suggested that to address unauthorized modified risk claims, we add the following language to the final rule: No vapor product or alternative nicotine product shall be considered to be ''sold or

distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products'' solely because its label, labeling, or advertising uses the following phrases to describe such product and its use: ''not consumed by smoking,'' ''does not produce smoke,'' ''smokefree,'' ''without smoke,'' ''no smoke,'' or ''not smoke.''

(Response) Section 911 of the FD&C Act requires FDA to assess MRTP claims for specific products. Therefore, FDA will evaluate products on a case-by-case basis to determine whether they are ''sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco product'' as stated in section 911. However, we note that e-cigarettes and similar ENDS products are not ''smokeless'' products, as the user is inhaling constituents (which are different from a smokeless tobacco product, as defined in the Tobacco Control Act). In addition, FDA is aware that some ENDS might heat their product to a level high enough to cause combustion.

(Comment 156) Many comments stated that the NPRM may promote conventional tobacco use because e-cigarette manufacturers will be unable to inform smokers that their products are safer alternatives or that they do not contain tobacco. They believed the NPRM weakens the impact that the e-cigarette industry might otherwise exert on the tobacco industry.

(Response) FDA disagrees. First, this final rule does not prohibit ENDS manufacturers from making claims that they are safer than conventional tobacco products if they can provide evidence to satisfy the requirements and obtain marketing authorization from FDA under section 911 of the FD&C Act. Second, FDA believes that ENDS could serve as alternatives to combusted tobacco products.

H. Dual and Polytobacco Use

In the NPRM, FDA noted its concerns that adult consumers may use one or more of the proposed deemed products in conjunction with cigarettes or other tobacco products. FDA also noted that studies suggest that some noncigarette tobacco users may go on to become addicted cigarette smokers (79 FR 23142 at 23159).

It is also recognized that some dual users of ENDS and cigarettes may be transitioning away from combustible tobacco use and that such transient periods of dual use may not present greater health risks than that observed during sole use of combustible tobacco. In a peer-reviewed study published recently in *Cancer Prevention Research,* investigators evaluated users of a single brand of ''cig-a-like'' ENDS and found that both cigarette smokers who switched to using the evaluated ENDS products and those who switched to dual use of the evaluated ENDS and cigarettes all demonstrated significant reductions in exposure to carbon monoxide and the toxicant acrolein (Ref. 194).

(Comment 157) Many comments expressed concern that the rate of dual use of e-cigarettes and combusted tobacco products is high, particularly among middle and high school students (Ref. 16). They stated that adolescents do not use e-cigarettes as cessation aids but rather use them in conjunction with conventional cigarettes (Ref. 193; see Ref. 194). They also indicated that this dual use and the fact that youth who experiment with e-cigarettes are 7.7 times more likely to become established smokers than those who do not experiment (Ref. 116) suggest that e-cigarette use leads to increased use of combusted tobacco products. However, they noted that we need long-term studies like FDA's PATH Study to confirm that assertion. Some comments also stated that cigarette smokers who use a second tobacco product even occasionally are at higher risk for continued tobacco use (Ref. 195).

Other comments believed that dual use should not be a concern, generally relying upon an Internet study of more than 19,000 e-cigarette users in which dual users had decreased from 20 to 4 cigarettes per day by the end of the study (Ref. 109). Some comments also expressed the belief that, because clinical studies show that e-cigarettes deliver only modest concentrations of nicotine to novice e-cigarettes users (Ref. 196), this would also be the case for nonsmoking youth and young adults and, therefore, would make the possibility of addiction less likely. Others argued that advanced e-cigarette products deliver nicotine more effectively, making adult consumers less likely to dual use or revert back to smoking. In addition, they claimed that if e-cigarettes were acting as a gateway to cigarette use, the current increase in e-cigarette use would lead to a corresponding increase in youth cigarette use (which has not occurred). In fact, they said an overlap of combusted tobacco and e-cigarette use is necessary if a tobacco user begins e-cigarette use to transition away from combusted tobacco consumption.

(Response) FDA is aware of dual use of ENDS and combusted tobacco products and is concerned about the potential impact of this practice on nicotine addiction and cessation. FDA also is concerned because this dual and polytobacco use pattern appears to be common among adolescents and young adults (Ref. 197). However, recent CDC NCHS data on young adult and adult use patterns of e-cigarettes indicate that former smokers and current smokers trying to quit are more likely to use e-cigarettes than former smokers who quit smoking more than 1 year ago and those who had never smoked (Ref. 24). These results indicate that dual use of tobacco may also be present during the transitional phase when smokers of combusted tobacco products are attempting to quit, which is also supported by personal stories included in the comments. In addition, the largest study to date in the EU found that e-cigarette use was more likely among smokers who had made a quit attempt during the past year as compared to those who never smoked (Ref. 109).

Other studies illustrate that current or former smokers have tried e-cigarettes not intending to quit tobacco use, but instead, because they are ''Easy to use when I can't smoke'' (Ref. 198) or can be used in places where conventional tobacco use is not allowed (Ref. 199). FDA remains committed to supporting long-term population-level research, such as the PATH Study, that will help elucidate reasons for and patterns in tobacco initiation, product switching, and dual use across the spectrum of tobacco products on the U.S. market, including ENDS and conventional cigarettes.

(Comment 158) Many comments noted that almost all e-cigarettes contain nicotine (Ref. 192). This nicotine delivery varies within and across brands (Refs. 200, 201) and by the user's level of experience with these products (*e.g.,* Ref. 202). While many comments expressed minimal concerns about abuse liability of e-cigarettes, believing that users will eventually switch entirely to e-cigarettes, others expressed the belief that long-term use of e-cigarettes may lead to addiction in youth and young adults.

(Response) FDA shares similar concerns that youth may initiate tobacco use with ENDS, become addicted, and then dual use or move on to traditional tobacco products. FDA discussed available data regarding dual and polytobacco use in the NPRM and is unaware of long-term studies finding that dual or polytobacco users eventually switch to using just one tobacco product (79 FR 23142 at 23159 and 23160). However, findings from a recent study of 694 participants aged 16 to 26 years old suggest that youth e-cigarette users might transition to

smoking traditional cigarettes (Ref. 203). Therefore, FDA remains concerned that youth may use one of the newly deemed products, whether it be an ENDS or any other tobacco product, and dual use with other tobacco products in the future.

(Comment 159) Some comments urged FDA to evaluate e-cigarettes based on their scientific merit and contribution to public health. At least one comment felt that certain researchers in the tobacco field were biased based on their connections to public health advocates or what the comment refers to as ''big tobacco companies.'' Some comments stated that FDA only considered journal articles when it should have considered other available information.

(Response) FDA uses the best evidence available from peer reviewed journals and other reputable sources to support this rule and fulfill our public health mandate. In the context of rulemaking, FDA follows the requirements of Executive Orders 12866 and 13563 by basing its decisions ''on the best reasonably obtainable scientific, technical, economic and other information.'' As stated in the NPRM, we will continue to fund research to help us determine the public health impacts of ENDS. Long-term studies are not available to conclude that ENDS are a proven cessation product or to establish what effect e-cigarettes have on users who might otherwise quit but instead engage in dual use of ENDS and other tobacco products (79 FR 23142 at 23152).

I. Applicability of Section 901

In the preamble to the NPRM, FDA stated that the rule applies to all products that meet the definition of ''tobacco product'' under section 201(rr) of the FD&C Act and any future products that meet the definition. FDA stated that e-cigarettes meet the definition of ''tobacco product.''

(Comment 160) Many comments seeking to exclude e-cigarette products from the scope of the deeming rule stated that Congress only meant for FDA to regulate products with the greatest threat (*i.e.,* cigarettes and smokeless tobacco products). They stated that regulating all tobacco products as strictly as cigarettes are regulated is not warranted and that the rigid application of the Tobacco Control Act is not consistent with public health objectives.

(Response) FDA disagrees. Congress gave FDA immediate authority over certain tobacco products (*i.e.,* cigarettes, smokeless tobacco, cigarette tobacco, and roll-your-own tobacco) and the authority to deem other products (including ENDS and other products that meet the statutory definition of ''tobacco product''). All tobacco products, regardless of the category of products, pose a health risk. Further, at this time, only some of the restrictions in part 1140 (which, prior to the rule, applied only to cigarettes and smokeless tobacco) will apply to the newly deemed products. Specifically, while the minimum age and identification, vending machine, and free sample provisions will apply to the newly deemed products, additional provisions in part 1140 (including minimum pack size and restrictions on self-service displays, sale and distribution of nontobacco items, and sponsorship of events) will not apply to the newly deemed products at this time.

(Comment 161) Many comments expressed concern that Congress did not wish to effectively ban e-cigarettes (as they claimed would occur as a result of deeming these products), because such a ban violates section 907(d)(3) of the FD&C Act. They stated that if Congress wanted to ban them, they would have done so under their drug authority.

(Response) FDA is not banning any category of tobacco product by issuing this final deeming rule.

(Comment 162) Many comments claimed that Congress did not intend for FDA to strictly apply the Tobacco Control Act requirements to all newly deemed products, especially those that do not contain tobacco leaf. They believed because e-liquids do not contain tobacco leaf, such products should be regulated differently than cigarettes and traditional smokeless tobacco products.

(Response) With this rule, FDA is deeming all products that meet the definition of ''tobacco product,'' including e-liquids, to be subject to the tobacco product authorities in chapter IX of the FD&C Act, to address the public health concerns associated with them. The FD&C Act does not include any requirement that a product contain ''tobacco leaf'' to meet the definition of ''tobacco product'' and be deemed under this final rule. As stated previously, FDA is not requiring that ENDS and the other newly deemed products comply with all of the requirements of part 1140 at this time.

(Comment 163) Some comments suggested that we need more toxicological, epidemiological, and behavioral studies before deeming e-cigarettes under section 901. Other comments stated that FDA must regulate e-cigarettes despite not having the level of scientific evidence that is available for most conventional tobacco products.

(Response) FDA continues to research and fund studies regarding ENDS initiation, use (including transitions to other tobacco products and multiple use), perceptions, dependence, and toxicity (Ref. 195). FDA also has been conducting a series of public workshops to obtain additional information on e-cigarettes and their impact on public health (79 FR 55815). These workshops are not necessary to inform this deeming rule; however, they may inform FDA's development of future rules impacting ENDS. Any additional regulations regarding ENDS will be subject to the requirements of the APA.

(Comment 164) Some comments sought clarification as to FDA's authority over e-liquids that do not contain nicotine or other chemicals derived from tobacco plants and those e-liquids that contain nicotine derived from a nontobacco source (*e.g.,* eggplants or tomatoes). Others claimed that FDA does not have regulatory authority over e-cigarettes that are refillable and do not contain nicotine, but does have authority over e-liquids if the liquid contains nicotine. Yet, some said that e-liquids used in e-cigarettes should have an entirely new classification, because use of the words ''tobacco product'' in marketing materials would cause undue confusion for consumers.

(Response) As stated in section 201(rr) of the FD&C Act, the definition of ''tobacco product'' includes any product made or derived from tobacco, including any component, part, or accessory of a tobacco product. An e-liquid made or derived from tobacco meets this definition and, therefore, is subject to FDA's chapter IX authorities. E-liquids that do not contain nicotine or other substances derived from tobacco may still be components or parts and, therefore, subject to FDA's tobacco control authorities, if they are an assembly of materials intended or reasonably expected to be used with or for the human consumption of a tobacco product and do not meet the definition of accessory.

(Comment 165) Some comments tried to compare pipes and rolling papers (which are required to smoke tobacco) with e-cigarettes (which are required to ''vape'' e-liquids), stating that e-cigarettes should not be regulated. They indicated that, unlike rolling paper which is ''intended for human consumption'' and therefore a tobacco product component, a pipe is ''non-consumable'' and should not be considered a tobacco product component. They said that, like pipes, e-cigarettes are ''non-consumable products'' and, therefore, are not

components or parts of tobacco products and not subject to regulation. They also stated that only the e-liquid is the consumable product and should be the only part of the e-cigarette subject to regulation.

(Response) The definition of ''tobacco product'' as set forth in section 201(rr) of the FD&C Act includes all components, parts, and accessories of tobacco products (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). FDA interprets components and parts of a tobacco product to include any assembly of materials intended or reasonably expected: (1) To alter or affect the tobacco product's performance, composition, constituents or characteristics; or (2) to be used with or for the human consumption of a tobacco product. Both e-cigarettes and pipes meet this definition. Thus, such products are subject to FDA's chapter IX authorities as a result of this rule.

(Comment 166) Many comments stated that FDA lacks any type of meaningful justification for deeming e-cigarettes because e-cigarettes do not represent the same level of public health threat as cigarettes. They claimed that FDA has the burden of showing a rational basis for regulation and that the lack of data showing that these products do not cause harm cannot serve as a basis for regulating them. In addition, some comments stated that FDA has no justification for regulating products simply because they may deliver nicotine. They likened such authority to imposing onerous regulations on caffeine, another plant-derived chemical.

(Response) FDA disagrees. FDA is deeming these products to address public health concerns (79 FR 23142 at 23148 and 23149). ENDS are tobacco products. As stated throughout this document, FDA has determined that deeming all products meeting the statutory definition of ''tobacco product'' will significantly benefit public health. We also note that by merely deeming ENDS to be tobacco products, FDA is not imposing the same level of regulation as is currently imposed on cigarettes. For example, restrictions on self-service displays, sale and distribution of nontobacco items, and sponsorship of events will not apply to ENDS at this time. FDA will consider the health effects of all products before determining whether to issue additional regulations.

(Comment 167) Many comments stated that the NPRM would ban virtually all of the e-liquid products and premium vaporizers (including mods, tanks, and open systems) and other components or parts because manufacturers of such products would not have adequate resources to comply with the requirements of the law.

(Response) FDA disagrees. FDA is not banning *any* tobacco product under this final rule. Rather, FDA is extending its authority to regulate such products under section 901 of the FD&C Act. Manufacturers of ENDS products were on notice that they could be considered FDA-regulated tobacco products since the enactment of the Tobacco Control Act and the issuance of the *Sottera* decision shortly thereafter. See section VIII.K for additional discussion regarding the *Sottera* case. Therefore, FDA disagrees with any comments referring to this rule as banning any categories of tobacco products.

(Comment 168) Some comments stated that FDA does not have the authority to regulate the ingredients that can be used in e-liquids.

(Response) FDA clarifies that, although it will not be directly regulating the individual ingredients in e-liquids at this time, sections 905 and 910 of the FD&C Act give FDA authority to review and consider ingredients in making determinations on SE reports and PMTAs (*i.e.,* the Agency will look at ingredients within a specific e-liquid and determine whether the overall tobacco product meets the statutory standard for marketing authorization). In addition, section 904 requires manufacturers to submit a listing of all ingredients 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, and section 915 of the FD&C Act authorizes FDA to issue a regulation to require that ''tobacco product manufacturers, packagers, or importers make disclosures relating to the results of the testing of tar and nicotine through labels or advertising or other appropriate means, and make disclosures regarding the results of the testing of other constituents, including smoke constituents, *ingredients,* or additives, that the Secretary determines should be disclosed to the public to protect the public health and will not mislead consumers about the risk of tobacco-related disease'' (emphasis added).

(Comment 169) A few comments noted the differences among products in the ENDS category in contrast to the relatively uniform category of combusted tobacco products. Given these differences and the rapid cycle of innovation and product development for ENDS products, they stated that FDA cannot use the Tobacco Control Act framework to regulate them.

(Response) FDA agrees that there are many differences among the products in the ENDS category. However, there are many differences among combusted tobacco products as well. For example, many cigars are wrapped in whole tobacco leaf, whereas cigarettes are not. Waterpipe tobacco is consumed in a manner very different from the consumption of cigarettes and cigars. The differences among these products do not affect the Agency's ability to regulate them in accordance with the requirements of the Tobacco Control Act.

J. Definitions

Several comments suggested that we add definitions specific to e-cigarettes and their components and parts. Comments stressed the importance of defining terms broadly enough to ensure all manufacturers of the finished products or components and parts of the finished products are covered by the definitions.

(Comment 170) Some comments suggested that FDA clearly identify nomenclature and constituents of ENDS products because ENDS is a much broader category than e-cigarettes. Similarly, some comments stated that not defining these products would fail to address the exploding market of e-cigarettes and their e-cigarette components and parts. They also stated that an ENDS definition is necessary so State and local governments can use consistent definitions.

(Response) FDA agrees that there is an expanding market of tobacco products that meet the FD&C Act definition of ''tobacco products.'' However, FDA does not believe it is necessary to define individual categories of tobacco products for purposes of this rule. In fact, by deeming ''tobacco products'' generally, it will help ensure that novel and future tobacco products are introduced into the market in an appropriate and efficient manner. FDA may issue specific definitions at a later time if it determines that doing so is appropriate.

(Comment 171) At least one comment recommended that we establish a definition of ''vapor product'' and define it as ''any noncombustible tobacco-derived product containing nicotine that employs a heating element, power source, electronic circuit, or other electronic, chemical or mechanical means, regardless of shape or size, including any component thereof, that can be used to produce vapor from nicotine in a solution or other form.'' The comment stated that

several States have adopted variations of this definition and that it would provide necessary clarity.

Likewise, at least one comment suggested that we establish a definition of ''alternative nicotine product,'' which would be defined as ''any noncombustible tobacco-derived product containing nicotine that is intended for human consumption, whether chewed, absorbed, dissolved or ingested by any other means.'' The comment stated that several States have adopted variations of this definition and that it would provide necessary clarity.

(Response) For the reasons explained previously, FDA finds that it is not necessary to add these definitions to the codified for this final rule.

(Comment 172) A few comments suggested that FDA clarify the differences between ''liquid nicotine'' and ''e-cigarette liquid (or e-liquid).'' They noted that, throughout the NPRM, FDA referred to the liquid component of e-cigarettes as ''e-cigarette liquid,'' which contains nicotine, flavorings, and other ingredients. However, in a few instances, FDA referred to ''nicotine solutions'' or ''nicotine liquids.'' They asked that we clarify the difference to avoid confusion and unintended coverage under chapter IX of the FD&C Act.

(Response) FDA agrees that clarification is necessary. Liquid nicotine does not have flavorings or other ingredients added to it. E-cigarette liquid (or ''e-liquid'') is a liquid containing nicotine, flavorings, and/or other ingredients. This final rule regulates e-liquid and liquid nicotine that is made or derived from tobacco.

(Comment 173) Some comments requested that FDA refer to ENDS products as vapor products and use definitions that differentiate between the products that use combustion and those that use vaporization. They stated that this distinction is necessary because the potential harms posed by these products are different and consumers may believe that vapor products are as dangerous as combusted smoking products. One comment provided an example as to how to recategorize tobacco products based on their delivery method and combustion. Another comment requested that FDA add ''combustion'' to the current definition of cigarette to differentiate between combusted and vaporized products.

(Response) For purposes of this deeming regulation, FDA does not believe it is necessary to distinguish between vapor products and combusted products. The statutory definition of ''cigarette'' was established by Congress and describes conventional cigarettes (section 900(3) of the FD&C Act). If FDA finds reason to differentiate between the combusted and vaporized products for the purpose of future regulations, FDA will issue a new NPRM to propose such definitions. In addition, FDA is aware that some e-cigarettes are heated to a high enough level to cause combustion of the e-liquid.

(Comment 174) At least one comment suggested that FDA alleviate any potential confusion between conventional cigarettes and e-cigarettes by adding a third subsection to the proposed definition of ''cigarette'' to read as follows: '' '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; (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; and (3) does not include a product such as nicotine [or products containing nicotine] that is derived from tobacco but does not contain tobacco.''

(Response) FDA finds that this addition to the cigarette definition is unnecessary to prevent confusion between the two product categories. The definition of ''cigarette'' in § 1140.3 of this final rule conforms to the definition in section 900(3) of the FD&C Act.

(Comment 175) One comment requested that FDA establish one common name for all vapor products, so the manufacturers, distributers, importers, and retailers of these products can comply with section 903(a)(4) of the FD&C Act, which requires that the manufacturer include an established name on the product labeling.

(Response) At this time, FDA has not established a common nomenclature for this group of products. FDA will consider these comments in determining whether future regulatory action is appropriate.

K. Sottera Decision

In the NPRM, FDA explained that, as set forth in the *Sottera* decision, e-cigarettes that are ''customarily marketed'' are tobacco products over which the Agency cannot exercise its tobacco product authority until it finalizes a regulation that deems them to be subject to chapter IX of the FD&C Act.

(Comment 176) Some comments provided analysis of the D.C. Circuit's decision in *Sottera, Inc.* v. *Food and Drug Administration,* 627 F.3d 891 (D.C. Cir. 2010), which formed part of the basis for FDA's decision to deem ''tobacco products'' subject to FDA's tobacco product authorities. They took issue with FDA's description of the key points of the case, stating that FDA is misreading the holding of *Sottera* to conclude that the court there held that FDA has jurisdiction over e-cigarettes as tobacco products because that question was not presented in the case.

(Response) FDA's analysis of the *Sottera* decision in the proposed deeming rule (79 FR 23142 at 23149 and 23150) was correct. On December 7, 2010, the D.C. Circuit held that FDA has the authority to regulate customarily marketed tobacco products under the Tobacco Control Act and products made or derived from tobacco that are marketed for a therapeutic purpose under the medical product provisions of the FD&C 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*).) On April 25, 2011, FDA issued a letter to stakeholders indicating its intent to deem additional tobacco products, including e-cigarettes, to be subject to FDA's authorities in chapter IX of the FD&C Act.

(Comment 177) A few comments claimed that FDA had attempted to ban e-cigarettes, the *Sottera* decision established the legality of e-cigarettes, and FDA's purported ban was unlawful.

(Response) FDA disagrees. Prior to the *Sottera* case, FDA did not seek to ban e-cigarettes. Instead, FDA had detained several shipments of e-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. FDA did not attempt to categorically ban e-cigarettes for sale in the United States but, instead, sought to regulate them under its drug/device authorities.

(Comment 178) A few comments stated that manufacturers are marketing e-cigarettes as cessation products and, therefore, they should be regulated as cessation products.

(Response) As stated in the D.C. Circuit's decision in *Sottera,* e-cigarettes that are customarily marketed tobacco products are subject to FDA's tobacco product authorities. If an e-cigarette

manufacturer wishes to market its product for a therapeutic purpose, the company would be subject to FDA's drug/device authorities and must submit an application to be marketed as a medical product.

IX. Effect of Deeming Rule on Vape Shop Manufacturers

Some comments requested clarification regarding the regulatory status of an ENDS retail establishment that sells e-liquids (sometimes known as a vape shop). Such establishments sell a variety of products including ENDS, replacement pieces, hardware, custom mixed e-liquids, and other related accessories.

If an establishment mixes or prepares e-liquids or creates or modifies aerosolizing apparatus for direct sale to consumers for use in ENDS, the establishment fits within the definition of ''tobacco product manufacturer'' in section 900(20) of the FD&C Act and the combinations it mixes and/or prepares are new tobacco products within the meaning of section 910(a)(1). For requirements not covered by the compliance policy set forth in this section, ENDS retail establishments that meet the definition of a manufacturer should refer to the compliance periods in tables 2 and 3. As discussed in the Analysis of Impacts (Ref. 204), FDA expects that most vape shops will stop mixing e-liquids (and preparing other new tobacco products) to avoid being ''manufacturers'' under the Tobacco Control Act.

The definition of ''tobacco product manufacturer'' in section 900(20) includes ''any person, including any repacker or relabeler, who manufactures, fabricates, assembles, processes, or labels a tobacco product.'' Additionally, for purposes of section 905, the FD&C Act defines ''manufacturing, preparation, compounding, or processing'' to include ''repackaging, or otherwise changing the container, wrapper or labeling of any tobacco product package from the original place of manufacture to the person who makes the final delivery or sale to the ultimate consumer or user.'' Section 910(a)(1) defines a ''new tobacco product'' as ''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.'' Therefore, establishments engaged in mixing or preparing e-liquids or creating or modifying aerosolizing apparatus for direct sale to consumers for use in ENDS are tobacco product manufacturers and, consequently, are subject to all of the statutory and regulatory requirements applicable to manufacturers.

The statute authorizes FDA to regulate the manufacture of all new products, including those manufactured at the retail level. This is important to FDA's ability to protect the public health since products manufactured at the retail level pose many of the same public health risks as those manufactured upstream and possibly additional risks related to the lack of standard manufacturing practices and controls. The introduction of statutory controls and oversight into a historically unregulated market inevitably will lead to some market change and consolidation. FDA recognizes that, with the implementation of this final rule, vape shops that meet the definition of tobacco product manufacturer may cease engaging in manufacturing activities rather than comply with requirements for manufacturers under this final rule. However, FDA notes that such entities will have the option to continue operating solely as retailers, as some vape shops currently do. In addition, as noted earlier, FDA believes that this policy (and the deeming rule as a whole) will not stifle innovation but could, instead, encourage it. Over time, FDA expects that its premarket review authorities will spur creative evolution and help to create a market where available products present a lower risk of user and population harm, provide a more consistent delivery under varying conditions of use, are less likely to lead to initiation of tobacco use, and/or are easier to quit. In recent years, ENDS products have proliferated in the absence of regulation, in some cases resulting in a lack of quality control and consistency, consumer confusion and even availability of acutely toxic products. In this context, we expect that changes in the market in response to regulation will have significant benefits for public health and will be a net benefit overall.

As the ENDS market continues to evolve, it is important that FDA exercise its authority to oversee all establishments engaged in manufacturing activities and their products, in order to protect consumers and to carry out the public health objectives of the Tobacco Control Act.

A. Premarket Requirements (Sections 905 and 910)

As stated throughout the document, manufacturers of newly deemed products that are not grandfathered will be required to obtain premarket authorization of their products through one of three pathways—PMTA, SE or SE exemption (sections 905 and 910 of the FD&C Act). Therefore, ENDS retailers engaged in mixing or preparing e-liquids or creating or modifying aerosolizing apparatus will be required to obtain premarket authorization for each non-grandfathered product that they prepare for sale or distribution to consumers. However, under the compliance policy laid out in section V.A, FDA does not intend to enforce, during specified compliance periods, the premarket review requirements including for ENDS retailers that mix or prepare the same e-liquids they have been preparing and offering for sale as of the effective daterule, or that create or modify aerosolizing apparatus resulting in the same products they have been creating as of the effective date. An initial compliance period, the length of which is dependent on the type of application to be submitted, is intended to provide additional time to prepare and submit premarket applications. In addition, for the 12 months following this initial compliance period, FDA intends to continue the compliance policy and does not intend to enforce the premarket review requirements if the firm has a pending submission. This means that, during this 12-month continued compliance period of FDA review, FDA expects that ENDS retailers of any kind will sell only those products that are (1) grandfathered; (2) authorized by FDA; or (3) tobacco products for which the ENDS retailer or another (upstream) manufacturer has submitted a marketing application/submission to FDA during the initial compliance period. (For PMTAs, the initial compliance period to submit is 24 months after the final rule effective date.)

FDA expects that this 12-month continued compliance period of FDA review will benefit manufacturers and retailers of newly deemed products, including ENDS retailers, since upstream manufacturers that submit applications will have a significant incentive to make retailers aware of their pending applications/submissions. Specifically, we expect that upstream manufacturer suppliers will inform ENDS retailers selling their products whether the upstream manufacturer has submitted a premarket application for such e-liquids and other ENDS products

within the initial compliance period such that the retailers can benefit from the continued compliance period while FDA reviews such applications. FDA expects that manufacturers will have an incentive to make retailers aware of which products are the subject of applications, which will enable retailers to know whether a marketing application has been submitted and whether FDA has acted on an application. In addition, retailers may contact suppliers for relevant product information. Therefore, after 36 months from the effective date (*i.e.,* at the end of the initial compliance period plus 12-month continued compliance period), FDA expects that all ENDS retailers will sell only those products that are either grandfathered or for which they have, or an upstream supplier has, received premarket authorization.

TABLE 4—COMPLIANCE POLICY FOR PREMARKET REQUIREMENTS—ENDS RETAIL ESTABLISHMENTS

0–24 months after the rule goes into effect	24–36 months after the rule goes into effect	Beyond 36 months after the rule goes into effect
FDA does not intend to enforce premarket authorization requirements for e-liquid products that retailers mix and sell without marketing authorization, provided that final mixture is the same as a product the retailer was selling or offered for sale as of the effective date.	FDA does not intend to initiate enforcement action for e-liquid products that retailers mix and sell where a marketing application has been submitted and is still pending for the final mixture.	The compliance period no longer applies, even if the final mixture has a pending marketing submission/application. All products for which a marketing submission/application is pending are subject to enforcement action.

As stated previously, because products manufactured at the retail level pose many of the same public health risks as those manufactured upstream, and possibly additional risks, it is important to enforce the statutory requirements for all new products, even those currently manufactured by ENDS retailers.

In general, the FD&C Act provides three pathways that manufacturers may use to seek market authorization for a new product: The premarket tobacco product application pathway, the SE pathway, and the exemption from SE pathway. FDA anticipates that most manufacturers of e-liquids and apparatus components/complete delivery systems will seek authorization through the PMTA pathway. To obtain marketing authorization under the PMTA pathway, manufacturers are required to establish, among other things, that permitting their product to be marketed would be appropriate for the protection of the public health. In establishing this, manufacturers should take into account, and FDA will consider, the ways in which the new product is likely to be used. For example, PMTAs for these products should contain information on whether the product is likely to be used alone or together with other legally marketed tobacco products (such as available delivery systems), as well as the type and range of the other products with which it is likely to be used.

While the statutory standard will apply to all products for which a PMTA is filed, FDA expects that different classes of products may have differing likelihoods of success in meeting the standard, by virtue of their expected use. As stated previously, to meet the statutory standard, PMTAs should contain information on whether a product is likely to be used alone or together with other legally marketed products and the public health implications of those likely uses. FDA has issued a draft guidance on PMTAs for ENDS, published concurrently with this final rule, which, when finalized, will explain FDA's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed e-liquids and hardware/apparatus components. FDA intends to act as expeditiously as possible with respect to all new applications, while ensuring that statutory standards are met.

To reduce research burdens and increase efficiency for ENDS retail establishments that file applications, FDA suggests that ENDS retail establishments use master files whenever possible. By obtaining permission from a master file holder, manufacturers could reference extensive ingredients lists and constituent testing that they otherwise would be required to perform themselves for marketing authorization. To facilitate this process, elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a final guidance to provide information on how to establish and reference a TPMF. This information will help applicants of newly deemed products prepare premarket and other regulatory submissions because they can reference information in TPMFs rather than develop the information on their own.

Given the anticipated availability and use of master files (as discussed in a separate, final guidance published concurrent with Deeming), which allows manufacturers to rely on the data and analysis submitted to FDA by separate entities, FDA anticipates that manufacturers will, over time, benefit from significantly increased efficiencies and reduced costs for complying with the statute. Such a system prevents and reduces duplication and allows for manufacturer reliance on confidential or sensitive non-public information while maintaining its confidentiality, thus saving time and reducing burdens for multiple manufacturers. Because of the nature of upstream supply of many components for ENDS products, especially e-liquids, FDA anticipates that commercial incentives will be sufficient to drive manufacturer reliance on the system of master files. We also note that at present, FDA understands that, based on the Agency's review of publically available information as discussed in section III.C of the Analysis of Impacts (Ref. 204), the number of entities engaged in upstream production of liquid nicotine and flavors specifically developed for use with e-liquids is small, in the range of seven to thirteen entities (see earlier discussion in response to comment 34). Given the current marketplace, the master file system is likely to prove widely appealing and widely utilized by the ENDS industry, reducing burden significantly.

In addition, FDA intends to open public dockets for uniquely identified compounds likely to be used in an e-liquid product, such as propylene glycol, glycerin, nicotine, colorants, and flavoring agents. FDA intends to invite stakeholders to submit to the docket information regarding specific compounds, including data, studies, or other files, such as data on individual health effects of inhalation exposure, animal study data examining exposure to varying levels of compounds within e-liquids, or testing the impact of temperature on changes to the aerosol constituents. This information could

then be used to help support applications for premarket review, for example, generating information on HPHCs in ENDS products that is then submitted as part of a PMTA.

B. Ingredient Listing and HPHC Requirements (Section 904 and 915)

As of the effective date of this rule, the ingredient listing requirements of section 904 of the FD&C Act will apply to manufacturers of the newly deemed products, including ENDS retail establishments that mix or prepare e-liquids or create or modify aerosolizing apparatus for sale or distribution. At this time, FDA intends to limit enforcement to finished tobacco products. FDA does not at this time intend to enforce these requirements for manufacturers of components and parts of newly deemed products that are sold or distributed solely for further manufacturing into finished tobacco products. This means that FDA generally intends to enforce these requirements with respect to ENDS retail establishments that mix or prepare e-liquids or create or modify aerosolizing apparatus for sale or distribution directly to consumers but not to distributors who sell components for further manufacturing. However, if the upstream distributor submits an ingredient list for a particular product, FDA does not intend to enforce the ingredient listing requirement against an ENDS retailer with respect to that particular product. We note that FDA also intends to issue a guidance regarding HPHC reporting under section 904(a)(3), and later a testing regulation as required by section 915, with enough time for manufacturers to report given the 3-year compliance period for HPHC reporting. Section 904 (a)(3) requires the submission of a report listing all constituents, including smoke constituents, identified as harmful or potentially harmful (HPHC) by the Secretary. Section 915 requires the testing and reporting of the constituents, ingredients, and additives the Secretary determines should be tested to protect the public health. The section 915 testing and reporting requirements apply only after FDA issues a regulation implementing that section, which it has not yet done. Until these testing and reporting requirements have been established, newly deemed tobacco products (and currently regulated tobacco products) are not subject to the testing and reporting provisions found under section 915. As noted elsewhere in this document, FDA does not intend to enforce the reporting requirements under section 904(a)(3) for newly deemed products before the close of the 3-year compliance period, even if the HPHC guidance and the section 915 regulation are issued well in advance of that time.

C. Registration and Product Listing (Section 905)

Section 905 of the FD&C Act requires every person who owns or operates an establishment engaged in the ''manufacture, preparation, compounding, or processing of a tobacco product'' to register its establishment with FDA and submit a listing of its tobacco products to the Agency. If an ENDS retail establishment engages in these activities, section 905 requires the establishment to register and list its products with FDA in accordance with this section. These requirements apply under the statute for all distinct products manufactured, and they enable FDA to assess the landscape of products manufactured by these entities. If ENDS retail establishments are mixing or preparing e-liquids or creating or modifying aerosolizing apparatus for direct sale to consumers, then they will have to list each e-liquid combination that they sell. It will be the responsibility of the ENDS retail establishment, as a manufacturer, to determine how many and which products they plan to manufacture. For shops that prepare an expansive array of custom mixes, with many gradations of flavor, nicotine strength or other characteristic, this would mean identifying, listing, and reporting ingredients for a large number of distinct products. In reality, however, we expect that such entities will elect to narrow the list of combinations they sell (with more limited distinctions in strength and flavor, etc.), since such a narrowing will allow them to continue providing custom products and a variety of options while simplifying their reporting. However, since the time and cost of listing each additional mixture is expected to be very low, the reduction will not necessarily be significant. In addition, any narrowing may reflect a reduction in products that are listed but are not actually sold.

D. Tobacco Health Document Submissions (Section 904)

Section 904(a)(4) of the FD&C Act requires each tobacco product manufacturer or importer, or agent thereof, to submit all documents that relate to health, toxicological, behavioral, or physiologic effects of current or future products, their constituents (including smoke constituents), ingredients, components, and additives. As discussed in section IV.D (discussing the compliance policy for small-scale tobacco product manufacturers), FDA, for an additional 6 months following the end of the generally applicable compliance period, does not intend to enforce against those small-scale tobacco product manufacturers (including ENDS retail establishments) who submit the required information.

E. Office of Small Business Assistance

Under section 901(f) of the FD&C Act, one of FDA's initial activities upon passage of the Tobacco Control Act was to establish the OSBA within CTP to assist small tobacco product manufacturers and retailers in complying with the law. FDA recognizes that the issuance of this final deeming rule, including the clarifying information noting that ENDS retail establishments are manufacturers subject to this rule, may result in many additional small tobacco product entities contacting OSBA for assistance. Accordingly, FDA intends to hire additional OSBA staff to provide assistance to small tobacco product entities wherever possible.

X. Regulation of Other Categories of Products

FDA is finalizing this rule to deem all products that meet the definition of tobacco product in section 201(rr) of the FD&C Act (except accessories of newly deemed tobacco products) to be subject to FDA's tobacco product authorities. In addition, as stated in the NPRM, any future tobacco product that meets the definition in section 201(rr) (except accessories of newly deemed tobacco products) will also be subject to FDA's authorities under chapter IX of the FD&C Act. Regulation of the newly deemed tobacco products is intended to address the public health concerns related to these products. A summary of the comments regarding dissolvables, gels, pipe tobacco, waterpipe tobacco, other alternative products, and future tobacco products is discussed as follows. FDA's responses to the comments are also included.

A. Nicotine in Newly Deemed Products

Comments were split as to the health risks of nicotine and its impact on adult tobacco product users.

(Comment 179) Many comments stated that nicotine is addictive, and all products containing nicotine pose a health threat to youth. Some also stated that nicotine can have detrimental effects on the cardiovascular system and promotes lung carcinomas (Refs. 15, 205). Other comments noted that it is generally accepted that nicotine is not directly responsible for tobacco-related

death and disease (Ref. 206) and that the Surgeon General has stated that it is the toxic substances in tobacco products (not the nicotine) that cause almost all tobacco-related death and disease (Ref. 9).

(Response) FDA agrees that nicotine is the primary addictive substance in tobacco products, as stated in the proposed deeming rule (79 FR 23142 at 23180). The Surgeon General has long recognized that nicotine is the primary pharmacologic agent of tobacco that can be absorbed into the bloodstream and cause addiction (Ref. 1 at 6–9). In addition, the Surgeon General has stated that addiction to nicotine is the ''fundamental reason that individuals persist in using tobacco products, and this persistent use contributes to many diseases'' (Ref. 2 at 105). While nicotine does not directly cause most smoking-related diseases, addiction to the nicotine in tobacco products sustains tobacco use, leading to the ingestion of the toxic substances in combusted tobacco products and tobacco smoke (Ref. 14). However, nicotine, in low doses, is given in different routes of administration as nicotine replacement therapies to help consumers to stop smoking, when approved for such purposes.

While the inhalation of nicotine (*i.e.,* nicotine without the products of combustion) is of less risk to overall public health than the inhalation of nicotine delivered by smoke from combusted tobacco products, limited data suggests that the pharmacokinetic properties of inhaled nicotine can be similar to nicotine delivered by combusted tobacco products. Thus, inhaled nicotine from a non-combustible product may be as addictive as inhaled nicotine delivered by combusted tobacco products. Researchers recognize that the effects from nicotine exposure by inhalation are likely not responsible for the high prevalence of tobacco-related death and disease in this country (Refs. 10, 11). Although nicotine has not been shown to cause the chronic disease associated with tobacco use, the 2014 Surgeon General's report noted that there are risks associated with nicotine (Ref. 9 at 111). For example, nicotine at high enough doses has acute toxicity (id.). Nicotine exposure during fetal development has lasting adverse consequences for brain development (id.). Nicotine also adversely affects maternal and fetal health during pregnancy, contributing to multiple adverse outcomes such as preterm delivery and stillbirth (id.). Further, data in animal models suggest that nicotine exposure during adolescence may have lasting adverse consequences for brain development (id.). Some studies also have found that nicotine can have detrimental effects on the cardiovascular system and potentially disrupt the central nervous system (Refs. 14, 15). (See also section VIII.C discussing the increase in poisoning due to accidental nicotine ingestion.)

(Comment 180) FDA received a large number of comments discussing the addictive nature of nicotine and the impact of nicotine on adolescents. Several comments stated that research indicates that the adolescent brain is more vulnerable to nicotine addiction than the adult brain. The comments noted that researchers have found that, ''most likely owing to its ongoing development, the adolescent brain is more vulnerable to the effects of nicotine than the adult brain. Adolescents progress faster to nicotine dependence than adults, find nicotine more rewarding, underestimate the risks of smoking, and are more influenced by smoking behavior in their social milieu.'' (Refs. 207, 208). One comment noted that animal research showing the adolescent brain is particularly vulnerable to nicotine addiction, and that adolescents are also less susceptible to withdrawal symptoms, creating an all-reward, no-regret system for psychostimulant use (Refs. 209, 210, 211). Another comment noted that the U.S. Surgeon General has found that key symptoms of nicotine dependence—such as withdrawal and tolerance—develop in adolescents following even minimal exposure to nicotine. Additionally, the comment stated that the Surgeon General's 2012 report cites one study following occasional adolescent smokers that found that a large proportion experienced at least one symptom of nicotine dependence upon quitting, even in the first 4 weeks after initiating monthly smoking (at least two cigarettes within a 2-month period) (Ref. 49 at 24, citing Ref. 212).

(Response) FDA agrees that given their developmental stage, and the fact that brain maturation continues into the mid-twenties, adolescents and young adults are more uniquely susceptible to biological, social, and environmental influences to use and become addicted to tobacco products. If individuals do not start using cigarettes by age 26, they are unlikely ever to smoke (Ref. 3). Research shows that 87 percent of established adult smokers began smoking before the age of 18 (Ref. 9). An analysis by the 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. 213).

In addition, FDA agrees that there are data suggesting that the adolescent brain is more vulnerable to developing nicotine dependence than the adult brain and that there is evidence to suggest that these brain changes are permanent (Refs. 49, 214). The Surgeon General reported that ''most people begin to smoke in adolescence and develop characteristic patterns of nicotine dependence before adulthood'' (Ref. 3). 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. 4). Additionally, youth and young adults generally ''underestimate the tenacity of nicotine addiction and overestimate their ability to stop smoking when they choose'' (Ref. 5). For example, one survey revealed that ''nearly 60 percent of adolescents believed that they could smoke for a few years and then quit'' (Ref. 7). Research conducted in animal models have indicated that exposure to substances such as nicotine can disrupt adolescent brain development and may 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. 8). This exposure to nicotine can also have long-term results on decreasing attention performance and increasing impulsivity which could in turn promote the maintenance of nicotine use behavior (id.).

B. Dissolvables

FDA noted in the NPRM that it was proposing to deem certain dissolvable 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 because they do not contain cut, ground, powdered, or leaf tobacco and instead contain nicotine extracted from tobacco). We explained that 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. We also noted that certain dissolvable smokeless tobacco products, given their candy-like appearance, have the potential for unintended poisonings. FDA deems these dissolvable products with this final rule.

(Comment 181) Comments stated that FDA should not rely on a study investigating flavored tobacco products in young adults as evidence that dissolvables are more attractive to children. They indicated that this study is inapplicable because it only looked at behaviors of people 18 years or older.

(Response) The cited study (Ref. 54) assessed the prevalence of flavored tobacco products (including dissolvables) in individuals 18 and older, which encompasses both young adults and adults. The study stated that the products' packaging looks like candy packaging and the products often are sold next to candy. FDA believes that these factors cause confusion regarding the safety of these novel tobacco products for adult consumers as well as children (Ref. 215). In addition, this study cited an additional study that concluded that sugar preference is greater in youth and young adults (Ref. 53). Accordingly, FDA believes it was appropriate to cite to this study as evidence supporting FDA's concerns with certain dissolvable products.

(Comment 182) Some comments expressed concerns regarding possible confusion between dissolvable tobacco products and candy and the possibility of inadvertent poisonings.

(Response) FDA agrees that the candy-like appearance of some dissolvable products may result in accidental poisonings. As FDA discussed in the NPRM, 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. 215). Although 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.).

(Comment 183) Some comments mentioned that dissolvable tobacco products may be easily confused with NRTs and, therefore, should be regulated.

(Response) The Agency finds that FDA regulation of all dissolvable products under chapter IX of the FD&C Act will help to alleviate potential confusion about the safety and use of these products. Products that contain nicotine derived from tobacco, are intended for human consumption, and are not marketed for therapeutic purposes, are subject to FDA's tobacco product authorities under chapter IX of the FD&C Act.

(Comment 184) Comments provided unpublished data (Ref. 216) indicating that dissolvable tobacco products deliver nicotine levels sufficient to promote and sustain addiction. They also indicated that dissolvable tobacco products have a higher average pH than other tobacco products, increasing the amount of absorbable nicotine.

(Response) FDA acknowledges that information about harmful or potentially harmful constituents in such products is sparse, but studies indicate that the level of nicotine in dissolvable products may differ from cigarettes and may lead to nicotine addiction (Ref. 217). These studies support the public health need to regulate all dissolvable tobacco products.

(Comment 185) Comments stated that dissolvable tobacco products are safer than other tobacco products and have lower levels of nitrosamines than snus or snuff and just slightly higher levels than some NRTs (Ref. 218). They also provided information that evaluated plasma nicotine levels, heart rates, and reduction in cigarette cravings, and found that the levels in certain dissolvables were similar to the levels in NRTs (Ref. 219).

(Response) While a continuum of nicotine-delivering products exists, deeming all tobacco products will enable the Agency to collect information about the ingredients and the health and behavioral effects of these products. These products are ''tobacco products'' with the potential to addict users and harm children, particularly given their candy-like appearance, and are subject to FDA's tobacco control authorities upon the effective date of this final rule. FDA also notes that NRTs are regulated products and subject to premarket review by FDA.

C. Gels

As proposed, FDA is deeming nicotine gels with this final rule.

(Comment 186) Some comments agreed that nicotine gels should be subject to FDA's chapter IX authorities under the FD&C Act. In support of their argument, they provided studies showing that children and young adults are more susceptible than adults to nicotine poisoning through the skin (Ref. 220).

(Response) With this final rule, FDA is finalizing its proposal to deem all ''tobacco products'' including nicotine gels, which are absorbed through the skin. In addition to meeting the definition of ''tobacco product,'' nicotine gels can be addictive and lead to use of other tobacco products that have well-documented risks of tobacco-related death and disease. Regulating these products also will help, among other things, to address consumers' unsubstantiated beliefs that non-cigarette tobacco products are safe alternatives to cigarettes.

D. Pipe Tobacco

FDA proposed to cover pipe tobacco with this deeming rule. FDA indicated that pipe tobacco smokers have a risk of tobacco-related disease similar to the risk of those who inhale cigar smoke or smoke cigarettes (Ref. 221). The Surgeon General also found that pipe and cigar smokers experience oral and laryngeal cancer risks similar to that of cigarette smokers (Ref. 222). FDA is deeming pipe tobacco with this final rule.

(Comment 187) A few comments provided suggestions as to how FDA should define pipe tobacco in this final rule to differentiate it from roll-your-own tobacco. For example, comments suggested FDA define pipe tobacco to include the moisture measured at the time of packing, the amount of reducing sugars, and the fact that it does not use reconstituted sheet tobacco or expanded leaf tobacco as part of the blend. Others suggested FDA define the term based on the ''consumer's reasonable perception of the product'' or include language stating that it is ''suitable for use and likely to be offered to, or purchased by, consumers as tobacco to be smoked in a pipe.'' Comments also requested that FDA enforce against the misuse of pipe tobacco as roll-your-own tobacco, regardless of whether it defines pipe tobacco, because mislabeled pipe tobacco already meets the definition of cigarette tobacco or roll-your-own tobacco.

(Response) FDA disagrees. The Agency finds that it is not necessary to define pipe tobacco in this rule. FDA also notes that it has issued Warning Letters for products bearing the package description of ''pipe tobacco,'' but that are sold or distributed for use as cigarettes for the purposes of chapter IX of the FD&C Act due to the fact that, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, it is suitable for use and likely to be offered to consumers as cigarettes, and/or likely to be purchased by consumers for making cigarettes or intended for use in cigarettes. FDA will continue to do so as circumstances warrant.

(Comment 188) Comments stated that when consumers use pipe tobacco for its intended use, it does not have the same public health concerns as other tobacco products. They also stated that pipe tobacco users are only a small percentage of adults and that only 0.2 percent of minors indicate that they are dual users of pipe tobacco and cigarettes (Ref. 9). They stated that based on these differences, some of the automatic

deeming provisions should not apply to pipe tobacco. For example, they claimed premarket review requirements should not apply to pipe tobacco, because manufacturers make changes to maintain consistent taste for older populations and not to create ''new'' products.

Other comments disagreed, citing evidence of the dangers of pipe tobacco, as discussed in the NPRM (79 FR 23142 at 23156 and 23168). They also expressed concerns that extended use of pipe tobacco releases significant amounts of secondhand smoke into the environment.

(Response) FDA disagrees that pipe smoking is not a public health issue. As we stated in the NPRM, studies of pipe tobacco smokers have found that their risk of tobacco-related disease is similar to the risk in those who inhale cigar smoke or smoke cigarettes (Ref. 221). The Surgeon General also previously found that pipe and cigar smokers experience oral and laryngeal cancer risks similar to that of a cigarette smoker (Ref. 222). While the Surgeon General's report does indicate that pipe tobacco smokers may have a lower risk of developing cardiovascular disease than cigarette smokers, pipe tobacco users still are at risk for these diseases, and those who use both cigarettes and pipe tobacco may have even higher levels of risk due to their usage patterns (Ref. 9 at 428). Moreover, researchers have found that when compared with individuals who have never used tobacco, pipe smokers have an increased risk of death from cancers of the lung, oropharynx, esophagus, colorectum, pancreas, and larynx, and from coronary heart disease, cerebrovascular disease, and COPD (Refs. 32, 221).

(Comment 189) A few comments expressed concern that retailers who blend pipe tobacco would be subject to all FD&C Act requirements for manufacturers, preparers, compounders, or processors of tobacco products, such as premarket review, and registration and listing. These comments requested that retailers blending up to either 3,000 pounds or 5,000 pounds of pipe tobacco per year be exempt from the requirements of the law that apply to manufacturers.

(Response) All entities that meet the definition of ''tobacco product manufacturer'' in section 900(20) of the FD&C Act, including retail establishments that blend pipe tobacco, are subject to and must comply with all applicable statutory and regulatory requirements for tobacco product manufacturers.

E. Waterpipe Tobacco

The NPRM included waterpipe tobacco as an example of a tobacco product that would be covered under this deeming rule. We noted concerns regarding the safety of waterpipe tobacco given the nicotine and carcinogens in waterpipe tobacco smoke, and the availability of waterpipe tobacco in a variety of flavors that could be appealing to youth and young adults. FDA's final rule includes waterpipe tobacco in the scope of products subject to FDA's tobacco control authorities.

(Comment 190) One comment requested that FDA clarify whether the term ''hookah'' refers to the waterpipe or the tobacco used in the waterpipe.

(Response) In the NPRM, FDA generally used the term ''hookah'' to mean waterpipe smoking and ''hookah tobacco'' as the tobacco used in the waterpipe. Waterpipe smoking may also be referred to by other names such as shisha or narghile. To alleviate any confusion in this final rule, FDA has referred to ''waterpipe smoking'' and ''waterpipe tobacco'' to cover all types of tobacco smoking using a waterpipe.

(Comment 191) At least one comment expressed concern about the public health risk of herbal waterpipe tobacco, which they assert has the same levels of toxicant exposure but without nicotine.

(Response) FDA's tobacco product authorities under chapter IX of the FD&C Act do not extend to substances that are not made or derived from tobacco (like herbal waterpipe tobacco), because they do not meet the definition of ''tobacco product'' under section 201(rr) of the FD&C Act.

1. Dual and Polytobacco Use

(Comment 192) Many comments expressed concern about the growth in dual and polytobacco use among youth and young adults. For example, the North Carolina Public Health Association submitted a preliminary analysis of the 2013 NCYTS, which indicated that 19.1 percent of high school students reported using two or more tobacco products and that 88.4 percent of high school students who currently are using waterpipe tobacco reported using at least one other tobacco product. Some comments noted that dual use of waterpipe tobacco and cigarettes is more prevalent than exclusive waterpipe tobacco use and that waterpipe tobacco users typically smoke cigarettes with greater intensity than nonwaterpipe tobacco users (Ref. 222). In fact, dual use of waterpipe tobacco and cigarette use is one of the most common tobacco use profiles found in young adults age 18 to 24 years (*e.g.,* Ref. 223).

(Response) FDA remains concerned about the potential for dual and polytobacco use, particularly among youth and young adults. As the North Carolina research shows, a noncigarette tobacco product (like waterpipe tobacco) can be the first product used by new tobacco users and there is concern such users could continue using the initial product or transition to cigarettes or other tobacco products. There is also the concern that existing users could become dual users. Accordingly, it is critical to deem these noncigarette tobacco products and place restrictions upon them that are appropriate for the protection of the public health, including age and identification restrictions to help prevent youth use of these products.

2. Popularity

(Comment 193) Many comments expressed concern about the growing use of waterpipe tobacco, particularly among young adults. For example, they noted that the percentage of young adults aged 18 to 24 who use waterpipe tobacco (7.8 percent) is significantly higher than adult use (1.5 percent) (Ref. 224). A few comments suggested that FDA overestimated this trend.

(Response) FDA agrees with the many comments that supported regulation of waterpipe tobacco and noted the increase in use among young adults. Waterpipe tobacco use continues to increase in popularity, particularly among college students, with as many as 40 percent reporting ever using waterpipe tobacco and 20 percent reporting use (*i.e.,* use within the past 30 days) on some college campuses (Refs. 25, 26).

3. Harms

(Comment 194) Many comments supplemented the data in the NPRM regarding the dangers of smoking waterpipe tobacco. For example, they referred to several studies showing significant nicotine, carbon monoxide, and other carcinogen intake during waterpipe use (*e.g.,* Refs. 225, 226, 227, 228). Further, in studies involving the use of waterpipes in a hospital research ward, researchers found greater carbon monoxide exposure and a different pattern of carcinogen exposure for waterpipe tobacco smokers (when compared to cigarette smokers), and concluded that exposure to tobacco smoke toxicants during waterpipe use is similar qualitatively (though not quantitatively) to cigarette smoke (Refs. 229, 230). Comments concluded that waterpipe users have a significant risk of smoking-related diseases, but the

magnitude of the risk depends upon the extent of the use.

(Response) FDA agrees with this assessment and that it supports finalizing its proposal to include waterpipe tobacco in the scope of this rule.

(Comment 195) Many comments included data regarding the increased cancer risks associated with waterpipe smoking. For example, researchers identified significant associations between waterpipe tobacco use and esophageal squamous cell carcinoma and a 6-fold increase in risk of lung cancer from waterpipe tobacco use (Refs. 231, 232). In addition, the existence of tobacco-related toxicants in waterpipe tobacco smoke may place users at risk for many of the same diseases as cigarette smokers, including a risk of lung cancer and respiratory illness (*e.g.,* Refs. 233, 234, 235, 236). While some comments maintained that many of these users will use waterpipe tobacco only once in their lifetime, these products are growing in popularity with youth and young adults and cause tobacco-related death and disease.

Other comments opposed FDA's proposal to regulate waterpipe tobacco, claiming that the dangers of waterpipe tobacco use are unsupported, that FDA has not adequately reviewed scientific studies, and that FDA ignored evidence. They also believed that use of disposable mouth piece tips would alleviate the risks of spreading communicable diseases through waterpipe use. In addition, they indicated that FDA's comparison of a waterpipe smoking session to smoking a single cigarette is inherently flawed due to the different patterns of use of these tobacco products.

(Response) Although it is possible that use of disposable mouth piece tips could help alleviate the risks of spreading communicable diseases through waterpipe use, the products nevertheless present a significant risk of smoking-related diseases. Accordingly, FDA is finalizing its proposal to include waterpipe tobacco in the scope of this rule. Further, although the products have different use topographies, FDA continues to believe that a comparison between the toxicants emitted during a waterpipe session and cigarette smoking is valid and indicative of the dangers associated with waterpipe use. In fact, the WHO study group on tobacco regulation has found that a waterpipe session can be the equivalent of smoking more than 100 cigarettes (Ref. 237). Moreover, regardless of the number of waterpipe tobacco users who use waterpipe tobacco for more than 1 day, the product presents significant health risks and is appropriately included in the scope of this rule.

4. Addiction

(Comment 196) Some comments claimed that waterpipe tobacco smokers do not get addicted and, therefore, there is no need for FDA to regulate waterpipe tobacco. Others disagreed and claimed that waterpipe tobacco is addictive. These comments provided extensive data about the significant health effects (including nicotine and toxicant exposure) and the highly addictive nature of waterpipe use (*e.g.,* dual use) (*e.g.,* Ref. 233).

(Response) Waterpipe tobacco contains nicotine, which is the primary addictive chemical in tobacco products. Researchers have observed nicotine dependence characteristics in some users, including suppressed cravings to smoke and anxiousness (Refs. 238, 239, 240), with one study showing that waterpipe tobacco use suppressed withdrawal symptoms just as cigarette smoking suppresses withdrawal symptoms (Ref. 240).

5. Misunderstanding

(Comment 197) Consumers stated that waterpipe tobacco should be regulated given its appeal to youth and adolescents' belief that it is not as harmful as traditional cigarettes. They agreed that a failure to regulate the proposed deemed products could reinforce consumers' existing confusion and misinformation about these products. However, other comments stated that FDA's concerns over youth's misperception of the safety of certain tobacco products should not be a factor that FDA should consider in deciding whether to regulate them. They stated that regulation cannot remedy the fact that certain youth affirmatively disregard available safety information. Comments noted that waterpipe tobacco users perceive this product to be much less harmful that cigarette smoking (Ref. 241), because they mistakenly think that the water filters out toxicants from the smoke and the fact that waterpipe tobacco use is frequently exempted from clean indoor air laws.

(Response) While we continue to believe that alleviating misperceptions is important, we note that the potential to alleviate youth's misperception regarding the toxicity of unregulated tobacco products was only one of many public health benefits associated with deeming tobacco products, as discussed in the NPRM (79 FR 23142 at 23148 and 23149). Waterpipe smoking carries health risks similar to smoking cigarettes, and waterpipe smoke contains many of the same carcinogens and heavy metals as cigarette smoke (79 FR 23142 at 23156 and 23157). In addition, given that waterpipe tobacco smoking sessions last significantly longer than smoking a cigarette, smoking waterpipe tobacco could potentially be even more dangerous than smoking a cigarette (79 FR 23142 at 23156). Consequently, based on the various impacts on public health, FDA believes regulation of waterpipe tobacco is important.

F. Additional Novel and Future Tobacco Products

In the NPRM, FDA proposed to deem additional novel and future tobacco products if the products meet the definition of ''tobacco product'' in section 201(rr) of the FD&C Act. FDA is finalizing this proposal here.

(Comment 198) Several comments supported deeming all future tobacco products. One comment requested that the future regulated products should include products that extend beyond buccal or dermal absorption.

(Response) Future products that meet the definition of ''tobacco product'' under section 201(rr) of the FD&C Act, including the requirement that they be ''intended for human consumption,'' are deemed subject to FDA's chapter IX authorities as a result of this rule. A product may be intended for human consumption in a variety of ways, such as through the lungs or by buccal or dermal absorption. However, future accessories of newly deemed products are not deemed subject to chapter IX as a result of this rule.

(Comment 199) At least one comment cautioned FDA that regulations for future products should be based on the continuum of risk to ensure that there is continued innovation to reduce harm.

(Response) FDA recognizes the existence of a continuum of nicotine-delivering products and will continue to consider this continuum in regulating future tobacco products.

(Comment 202) A few comments stated that FDA should not regulate products with de minimis amounts of nicotine derived from tobacco that may be used in cosmetics, food, animal feed, or other products, and for purposes not related to traditional tobacco use (such as protein). Additionally, they stated that these types of products should not have to bear the warning, ''This product is derived from tobacco.''

(Response) With this final rule, FDA deems all products meeting the definition of tobacco product, except for accessories of newly deemed products, to be subject to FDA's authorities under chapter IX of the FD&C Act.

Determinations about whether particular products meet this definition would be made on a case-by-case basis. However, animal feed is a veterinary product and not for human consumption and, therefore, would not be a tobacco product. Products that contain nicotine derived from tobacco meet the definition of a tobacco product under the FD&C Act and are required to bear a health warning on packages and in advertisements stating: ''WARNING: This product contains nicotine. Nicotine is an addictive chemical.'' For products that are made or derived from tobacco (but do not contain nicotine), manufacturers may submit a certification to FDA and, instead, bear the statement ''This product is made from tobacco.'' See section XVI.H for additional information regarding this certification.

(Comment 203) One comment stated that alternative nicotine products, such as nicotine toothpicks, have a net positive impact on the public health because they pose fewer health and safety risks than conventional cigarettes and could help addicted smokers transition to less toxic tobacco products. The comment argued that the regulatory burden for such products should be proportionately reduced.

(Response) While FDA recognizes the existence of a continuum of nicotine-delivering products, all tobacco products are addictive and potentially dangerous and, therefore, should be subject to FDA regulation. Therefore, FDA is deeming all tobacco products (except accessories of newly deemed tobacco products) subject to the requirements of chapter IX of the FD&C Act and requiring certain additional provisions (*i.e.,* minimum age and identification, vending machine, and health warnings) for covered tobacco products. FDA will continue to take this continuum of nicotine-delivering products into consideration as it contemplates future regulations of the newly deemed products.

XI. Additional Automatic Provisions Applicable to Newly Deemed Products

In addition to the requirement that non-grandfathered tobacco products obtain authorization through one of the three marketing pathways, several provisions in the Tobacco Control Act and its implementing regulations will automatically apply to the newly deemed products as of the effective date of this final rule (79 FR 23142 at 23148 and 23149). These provisions include:

(1) Adulteration and misbranding provisions (sections 902 and 903 of the FD&C Act);

(2) Ingredient listing and HPHC reporting requirements (sections 904 and 915 of the FD&C Act);

(3) Registration and product listing requirements (section 905 of the FD&C Act);

(4) Prohibition against the use of ''light,'' ''low,'' and ''mild'' descriptors and products with other unauthorized modified risk claims (section 911 of the FD&C Act); and

(5) Prohibition of free samples of the proposed deemed products (21 CFR 1140.16(d)).

Comments regarding these provisions, and FDA's responses to comments, are as follows.

(Comment 204) In the proposed deeming rule, FDA noted that it was taking this action to address the public health concerns associated with the use of tobacco products. Some comments stated that health policies based on tobacco use prevention and cessation are not sufficient to protect the public health.

(Response) FDA is deeming products that meet the definition of ''tobacco product,'' except accessories of newly deemed tobacco products, to address the public health concerns with these products. In the NPRM, FDA included discussion of public health benefits to better inform the public about the likely results of deeming these tobacco products. FDA intends to supplement this final rule with regulations as appropriate to protect the public health.

A. Sections 902 and 903—Adulteration and Misbranding

In the proposed deeming rule, we explained that the adulteration and misbranding provisions of sections 902 and 903 of the FD&C Act would subject all tobacco products to certain basic requirements. For example, their labeling and advertising cannot be false or misleading, which will help reduce consumer confusion and misperception. The Agency can take enforcement action against any tobacco product that did not meet these basic requirements.

(Comment 205) A large number of comments discussed the applicability of sections 902 and 903 of the FD&C Act to the newly deemed tobacco products. Most comments expressed general support for applying adulteration and misbranding provisions to the newly deemed tobacco products. Others supported the application of the provisions based on concerns that some e-cigarette manufacturers may not be producing their products in sterile conditions. Several comments cautioned that the differences between the newly deemed tobacco products might result in unwarranted restrictions if the provisions are applied mechanically across all product categories. At least one comment stated that the adulteration and misbranding provisions should not apply to e-cigarettes because there is no evidence that adulteration and misbranding currently occurs with those products or causes any harm.

(Response) The adulteration and misbranding provisions of sections 902 and 903 of the FD&C Act will automatically subject all tobacco products to certain basic requirements. For example, their labeling and advertising cannot be false or misleading, which will help reduce consumer confusion and misperception. FDA will be able to take enforcement action against any tobacco product that does not meet these basic requirements. For example, if a product is produced in insanitary conditions or is contaminated, or if its labeling contains a misleading claim, it will be subject to enforcement action, including seizure and injunction.

B. Sections 904 and 915—Ingredient Listing and Reporting of HPHCs

As stated in the NPRM, the newly deemed products will be required to comply with the ingredient listing and HPHC reporting requirements of sections 904 and 915 of the FD&C Act. FDA intends to issue a guidance regarding HPHC reporting, and later a testing and reporting regulation as required by section 915, with enough time for manufacturers to report given the 3-year compliance period for HPHC reporting. As noted elsewhere in this document, FDA does not intend to enforce the reporting requirements for newly deemed products before the close of the 3-year compliance period, even if the guidance is issued well in advance of that time.

(Comment 206) A couple of comments urged FDA not to require newly deemed products to comply with the ingredient and HPHC listing requirements. One comment argued that such reports are useless for educating consumers, who will invariably use them in an attempt to determine the relative risk of each product. Another comment claimed that the HPHC and ingredient listing requirements should be abandoned because they are not helpful and the cost of producing these reports would destroy industry.

(Response) FDA disagrees with these comments. Ingredient and HPHC reporting assist FDA in better understanding the contents of regulated products. This information will assist FDA in assessing potential health risks and determining if future regulations to

address these health risks would be appropriate. The FD&C Act directs FDA to make certain HPHC information publicly available, but it must do so in a way that is understandable and not misleading to lay persons.

(Comment 207) Several comments discussed ingredient and HPHC listing requirements in the context of small businesses and particular products. A few comments urged FDA to exempt small businesses that manufacture e-cigarettes from the HPHC reporting requirement because the testing would impose a large financial burden on them and would likely drive them out of business. One comment countered these arguments, urging FDA to require manufacturers of all products to comply with the ingredient and HPHC listing requirements and not provide an exemption for small businesses. The comment argued that the size of a business does not change a product's potential health impact and that the health benefits of regulation far exceed the costs.

Other comments focused on ingredient and HPHC listing requirements for specific product categories. At least one comment expressed concern that HPHC testing would disproportionately affect the premium cigar industry, which has a high number of low-volume products, and requested that the requirements not apply to small batch or special release products. One comment claimed that many of the new tobacco products on the market, such as e-cigarettes, are virtually identical with the exception of flavoring and nicotine levels and recommended that FDA allow for these products to be grouped together for the purposes of HPHC testing.

(Response) With respect to HPHC testing of similar products, FDA recognizes that some manufacturers of newly deemed products sell products in various flavors or with varying levels of nicotine. Manufacturers of these products will be required to test each variation for HPHCs, even where the products are otherwise the same. At this time, there is little known about the constituents of some newly deemed products. HPHC testing will allow FDA to track the level of HPHCs across different categories of flavors and by nicotine level. FDA's compliance policies for the HPHC requirements are described elsewhere in this document.

(Comment 208) Several comments stated that FDA should establish HPHC lists and testing methodology before requiring HPHC testing. One comment requested that FDA establish an HPHC list and testing methodology for e-cigarettes in the same manner that it did for currently regulated tobacco products, including holding public workshops, requesting and considering Tobacco Products Scientific Advisory Committee recommendations, publishing draft and final lists in the **Federal Register** for public comment, and providing a reasonable compliance period for e-cigarette manufacturers. A few comments expressed the opinion that FDA should establish separate lists of HPHCs for each category of newly deemed tobacco products and not require HPHC reporting until the lists and corresponding testing methodologies are created and validated. Other comments stated that because not all deemed products are likely to have the same HPHCs as currently regulated products, testing for all of the constituents would be wasteful.

(Response) As discussed elsewhere in this document, the compliance period for HPHC reporting and testing is the effective date of this rule plus 3 years. FDA intends to issue a guidance regarding HPHC reporting, and later a testing and reporting regulation as required by section 915 of the FD&C Act, with enough time for manufacturers to report given this compliance period. As noted elsewhere in this document, FDA does not intend to enforce the reporting requirements for newly deemed products before the close of the 3-year compliance period, even if the guidance is issued well in advance of that time.

(Comment 209) Several comments suggested that manufacturers should be required under section 904 of the FD&C Act to include a statement of the ingredients and/or nicotine concentration on their product labeling as a condition of sale. These comments indicated that consumers could use this information to select e-cigarette liquids with decreasing nicotine content levels as part of a nicotine replacement therapy to quit smoking.

(Response) Sections 915(b) of the FD&C Act and 206 of the Tobacco Control Act give FDA authority to require the disclosure of nicotine and certain other information on labeling and by other means. FDA has not issued regulations for the currently regulated tobacco products and did not propose this in the proposed deeming rule. FDA will consider whether it should do so in the future. To the extent the comment is about ENDS marketed for smoking cessation, such a product would be subject to FDA's drug/device authorities and not subject to FDA's tobacco product authorities.

(Comment 210) Some comments suggested that any HPHC requirement for cigars should require analysis of HPHCs in the tobacco (rather than the smoke) in a manner similar to that for hand-rolling tobacco. They stated that HPHC smoke analysis is neither available nor readily producible for most cigars. They also stated that smoking regimens recommended for collecting HPHC data for tobacco smoke were developed for cigarettes and suggested that cigars are inherently more variable than cigarettes. Finally, they stated that the cigar smoke test method recommended by the Centre de Coopération pour les Recherches Scientifiques Relatives au Tabac in 2005 has produced more variable data than that obtained using the comparable test method for cigarettes, making it difficult to compare consistent test results for cigars.

(Response) FDA disagrees with the comments. In order to determine the HPHC deliveries that each cigar provides, it is important that manufacturers submit HPHC data on smoke yields for cigars. HPHC quantities in cigar tobacco only would not provide a complete understanding of the toxicity of each cigar. As stated by the comments, Centre de Coopération pour les Recherches Scientifiques Relatives au Tabac (CORESTA) published method 64 in 2005 that describes a smoking regimen for cigars. It is not clear that the variability in cigar HPHC yields will be greater than that for cigarette yields. Variability in HPHC smoke yields is dependent on the smoking regimen, analytical method, and batch-to-batch consistency in product composition. Therefore, it is expected that the variability in HPHC smoke yields from some cigarettes will exceed that for cigars. In any case, as with cigarettes, it is important to understand the HPHC deliveries in cigar smoke.

C. Section 905—Registration and Listing

As stated in the NPRM, manufacturers of the newly deemed products will be required to comply with section 905(b) of the FD&C Act, which requires the registration of any establishment engaged in the manufacture, preparation, compounding, or processing of a tobacco product. In addition, they must comply with section 905(i) of the FD&C Act, which requires registrants to submit a list of all tobacco products that are being manufactured, prepared, compounded, or processed for commercial distribution. FDA must issue a regulation before foreign establishments are required to comply with these requirements.

(Comment 211) Several comments stated that FDA should apply the same

requirements to both foreign and domestic manufacturers of tobacco products, including manufacturers of the newly deemed products. They expressed concern that FDA has not yet issued a proposed registration and listing rule and has not provided a timeframe for a final rule that would apply these requirements to foreign establishments. They also stated that the absence of registration and listing requirements for foreign establishments creates incentives for manufacturers of the newly deemed products to move their facilities overseas.

(Response) As indicated in the Unified Agenda of Spring 2015 (Ref. 242), FDA plans to issue a proposed registration and listing rule that would extend these requirements to foreign tobacco product establishments. In addition, upon the effective date of this final deeming rule, both foreign and domestic manufacturers will be subject to, among other things, adulteration and misbranding restrictions (sections 902 and 903 of the FD&C Act); requirements for ingredient listing and reporting of HPHCs for all tobacco products (section 904 of the FD&C Act); and premarket authorization requirements (sections 905 and 910 of the FD&C Act).

D. Section 911—Elimination of Low, Light, and Mild, and Other Unauthorized Modified Risk Claims

Section 911 of the FD&C Act is one of the automatic statutory provisions that will apply to the newly deemed products on the effective date of this regulation. The purpose of this section is to prohibit the introduction into interstate commerce of MRTPs, including products the label, labeling, or advertising of which uses ''low,'' ''light,'' or ''mild,'' or other modified risk claims unless FDA issues an order authorizing their marketing. This requirement will help consumers better understand and appreciate the health risks of the newly deemed products. In addition to any applicable premarket review under section 910 of the FD&C Act, if a manufacturer wishes to sell a MRTP, the company must submit an MRTP application under section 911 and receive an FDA order to legally market an MRTP.

(Comment 212) A number of comments discussed the application of the MRTP restrictions to the newly deemed products. Several comments argued, as a general matter, that subjecting the newly deemed products to section 911 would be an unconstitutional restriction of free speech because FDA either has no substantial interest that would be advanced by such restrictions or has not demonstrated that restricting modified risk claims for these products would advance its substantial interest in protecting the public health. A couple of comments argued that the brand names of newly deemed products that contain the descriptor ''low,'' ''light,'' or ''mild'' should be prohibited only where the descriptors specifically convey a modified risk claim. These comments stated that where ''low,'' ''light,'' or ''mild'' is used and understood by consumers to describe something other than a modified risk (such as the product's taste), restricting the use of a brand name containing one of these terms would be unconstitutional, arbitrary, and capricious because the government does not advance any substantial interest by doing so. Other comments supported the application of section 911 to all newly deemed tobacco products, with some comments maintaining that certain e-cigarette companies are currently marketing their products using unauthorized modified risk claims.

(Response) FDA disagrees with the suggestion that subjecting the newly deemed products to section 911 would be an unconstitutional restriction of free speech. The Sixth Circuit upheld the modified risk provisions against a First Amendment challenge to the facial validity of the statute in *Discount Tobacco* v. *FDA,* 674 F.3d 509, 531–37 (6th Cir. 2012). We discuss this issue in depth in section II.B.3.b. FDA has and will continue to apply section 911 of the FD&C Act consistent with the First Amendment and will take all relevant facts into account on a case-by-case basis.

FDA agrees with comments that supported the application of section 911 to all newly deemed products. Historically, certain users have initiated and continued using certain tobacco products based on unauthorized modified risk claims and consumers' unsubstantiated beliefs about the relative safety of these products. Section 911 will prevent the use of unsubstantiated modified risk claims, which may mislead consumers and lead them to initiate tobacco product use or to continue using tobacco when they would otherwise quit. This will allow for better-informed consumers and help to prevent the use of misleading marketing targeted to youth populations.

(Comment 213) Many comments stated that e-cigarette companies make direct and indirect health claims in the marketing and promotion of their products (*e.g.,* by posting customer comments and testimonials on their Web sites) and that some e-cigarette advertising implies FDA approval or endorsement (*e.g.,* use of the FDA logo on labels or statements such as ''made in an FDA-approved facility'') (Ref. 151). As a result, the comments suggested a number of different actions to curb these unsubstantiated or misleading claims, including: (1) Prohibiting direct and implied therapeutic claims that e-cigarettes are effective cessation products unless there is evidence; (2) using existing enforcement authority to prohibit therapeutic, health, and cessation claims unless there is evidence of safety and efficacy; (3) working with the FTC to prohibit such claims as false advertising until such time as there is evidence of safety and efficacy; (4) working with the FTC to introduce or strengthen disclosure rules on the Internet (*e.g.,* product reviews) to promote transparency; and (5) prohibiting explicit or implicit statements that e-cigarettes are approved or endorsed by FDA.

(Response) Under section 911 of the FD&C Act, no person may introduce or deliver for introduction into interstate commerce any MRTP without an order in effect under section 911(g). Also, a tobacco product is misbranded if its label, labeling, or advertising is false or misleading in any particular. Therefore, by deeming ENDS and other tobacco products, FDA is now authorized to take enforcement action against manufacturers who sell and distribute products with unsubstantiated MRTP claims, or false or misleading claims on their label, labeling, or advertising. Additionally, under section 301(tt) of the FD&C Act, anyone making explicit or implicit statements that a product is, among other things, ''approved'' or ''endorsed by FDA'' is committing a prohibited act. An ENDS product claiming to be an NRT or otherwise marketed for therapeutic purposes is a drug or device subject to FDA's regulations and laws for those products. Additionally, the Agency will consider these comments in the future, and, if FDA determines that it is appropriate, will issue additional regulations.

E. Section 919—User Fees

In 2014, FDA issued a final rule regarding user fees for cigarettes, snuff, chewing tobacco, and roll-your-own tobacco, including the submission of information needed to calculate and assess those user fees (79 FR 39302, July 10, 2014). In that final rule, FDA stated that if it deems cigars or pipe tobacco, FDA would respond to the NPRM comments regarding user fee provisions for cigars and pipes, and revise the user fee regulations (79 FR 39302 at 39305).

Accordingly, elsewhere in this issue of the **Federal Register**, FDA is issuing a final rule revising the current user fee regulations.

(Comment 214) Some comments supported applying the user fee provisions of the Tobacco Control Act to all tobacco products, explaining that application of user fee provisions to all products is essential to ensure uniformity and fairness across the regulated entities. They also noted that section 919(b)(3) of the FD&C Act states that no manufacturer or importer of tobacco products shall be required to pay a user fee in excess of the percentage share of such manufacturer or importer. Accordingly, they argued that FDA cannot assess user fees based on the continuum of nicotine-delivering products.

(Response) Elsewhere in this issue of the **Federal Register**, FDA is issuing a final rule regarding user fees for cigars and pipe tobacco, including the submission of information needed to calculate their user fee assessments. These comments are addressed in that rule.

F. Tobacco Control Act, Section 102—Prohibition Against Free Samples

In this final rule, FDA is not modifying the existing restriction on distributing free samples of tobacco products (21 CFR 1140.16(d)). As a result, this restriction will prohibit the distribution of free samples of newly deemed tobacco products, as required by section 102 of the Tobacco Control Act. See section II.B.3.a for discussion regarding the constitutionality of this free sample prohibition.

FDA understands concerns from some retailers about the effect that a ban on free samples would have on their ability to promote new products. FDA wishes to clarify that allowing prospective adult buyers to smell or handle one of the newly deemed products is not considered distribution of a ''free sample'' as long as the free product is not actually consumed, in whole or in part, in the retail facility and the prospective buyer does not leave the facility with a free tobacco product. For example, affording adult consumers the opportunity to handle a cigar will give them the ability to feel the resistance of the cigar's structure and allow them to clearly see the color of the product, which is an indication of the fermentation period for the tobacco. Handling the product also will allow users to capture the aroma of a cigar and the box (if the cigar is sold in a package). However, if the prospective buyer lights and draws or puffs on the cigar to keep it lit, or otherwise uses the free cigar or leaves the retail establishment with a free cigar (partially used or intact whole), this would constitute a ''free sample'' in violation of the restriction on free samples mandated by section 102 of the Tobacco Control Act. We believe that, in most circumstances, other retail facilities, including ENDS retail establishments, can similarly allow customers to touch, hold, and smell their products without violating the free sample ban. We note that nothing in this policy should be construed to alter or amend the regulation implementing the free sample ban at § 1140.16.

(Comment 215) A large number of comments discussed whether FDA should allow the continued distribution of free samples of the newly deemed tobacco products. Most comments expressed general support for the ban on free samples, citing concerns that such samples serve as a gateway for youth tobacco initiation. Several comments argued that there is no reason to believe that free samples of pipe tobacco and premium cigars encourage youth initiation because the samples are distributed almost exclusively in adult-only retail operations. One comment claimed that because epidemiological data suggest that the majority of premium cigar smokers fall into a category where there is no significant difference in the incidence of disease compared to never-smokers, banning free samples of premium cigars would have no corresponding benefit even if it did reduce youth initiation. This comment also claimed that it would similarly not help prevent youth access because they assert that, as indicated in a recent SAMHSA survey, there is no evidence that youth obtain premium cigars at all, let alone as free samples from retailers.

Several comments, referring specifically to pipe tobacco, premium cigars, and e-cigarettes, stated that, in light of the lack of evidence that youth obtain free samples of their products, banning these samples, which are a vital part of their industries, would only hurt sales and small businesses without a corresponding public health benefit. Comments referring to premium cigars and pipe tobacco stated that free samples of these products are necessary to entice adult consumers to purchase what are frequently unique and sometimes expensive products. Comments on e-cigarettes argued that, because their products are new, free samples are necessary to convince cigarette users to switch to them.

One comment argued that FDA's proposed ban on free samples impermissibly restricts commercial speech that is protected by the First Amendment. The comment stated that while the court in *Discount Tobacco City & Lottery* v. *United States* upheld the Tobacco Control Act's sampling ban on cigarettes, the evidence the court used to uphold that ban does not support the same ban for the newly deemed tobacco products. The comment argued that FDA has presented no evidence that samples of these products lead to youth initiation and, therefore, the Agency would not be advancing a legitimate government interest with this ban. Additionally, the comment suggested that even if the ban did advance a legitimate government interest, FDA could achieve the same results through less restrictive means, such as by allowing samples in qualified adult-only facilities, as FDA does with smokeless tobacco.

(Response) FDA disagrees with the assertions that the proposed ban on free samples would hurt businesses without corresponding public health benefits or that this prohibition impermissibly restricts commercial speech. This prohibition will eliminate a pathway for youth to access tobacco products, which can help reduce youth initiation and therefore short-term and long-term morbidity and mortality resulting from these products. The 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. 30). While the IOM was speaking in the context of cigarettes, FDA believes that the same rationale applies to the newly deemed products. In addition, the U.S. Court of Appeals for the Sixth Circuit held that the free sample ban as applied to cigarettes does not violate the First Amendment. The court 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 sub nom. Am. Snuff Co., LLC* v. *United States,* 133 S. Ct. 1966 (2013)). Moreover, the panel unanimously found that the ban ''embodie[d] a narrow fit between the harm articulated and the restrictions employed'' (id.). See section II.B.3.a for more detailed discussion of the constitutionality of the free sample prohibition.

FDA understands concerns from cigar retailers about the effect that a ban on free samples would have on their ability to promote new products. FDA wishes to clarify that allowing prospective adult buyers to smell or handle a cigar is not considered the distribution of a

''free sample'' as long as the product is not actually consumed, in whole or in part, in the retail facility and the prospective buyer does not leave the facility with a free tobacco product. Affording adult consumers the opportunity to handle the product will give them the ability to feel the resistance of the cigar's structure, and allow them to clearly see the color of the product, which is an indication of the fermentation period for the tobacco. It also will allow users to capture the aroma of the cigar and the box (if the cigar is sold in a package). However, if the prospective buyer lights and draws or puffs on the free cigar or otherwise uses the free cigar or leaves the retail establishment with a free cigar (partially used or intact whole), this would constitute a ''free sample'' in violation of the ban on free samples mandated by section 102 of the Tobacco Control Act. We believe that, in most circumstances, other retail facilities, including ENDS retail establishments, can similarly allow customers to touch, hold, and smell their products without violating the free sample ban.

XII. Requests for Additional Regulations Applicable to Newly Deemed Products

In the NPRM, FDA noted that certain provisions would automatically apply to the newly deemed products and that the Agency was proposing additional restrictions that also would apply to covered tobacco products. FDA also noted that after the final rule becomes effective, the Agency would have the authority to issue additional regulations applicable to the newly deemed products, including product standards under section 907 of the FD&C Act. Many stakeholders submitted comments and data regarding the need for additional requirements and restrictions for the newly deemed products. Some of these requests would require a separate NPRM, and they will help inform FDA as it considers additional regulations for newly deemed products.

A. Ban on Flavored Tobacco Products

FDA received numerous comments regarding flavored tobacco products, including comments expressing concerns regarding the impact of flavors on youth and young adults and preliminary data regarding some individuals' use of flavored ENDS products to transition away from combusted tobacco use. FDA's summary of comments and data regarding flavored tobacco products is included in section V.B of this document. FDA's responses to comments regarding a possible ban on flavored tobacco products are included below.

(Comment 216) Many comments suggested that FDA include a ban on flavored tobacco products with this final rule. Other comments suggested that FDA continue to allow the sale of fruit or candy-flavored e-cigarettes, because they aid cigarette smokers in decreasing cigarette use and in smoking cessation. These comments generally relied on a research article that found that most e-cigarette users switched between flavors on a daily basis or within the day, with former smokers switching more frequently than current smokers, and that respondents indicated that flavor variety was ''very important'' in reducing or quitting smoking (Ref. 62). This survey also noted that almost half of respondents indicated that a reduction in available flavors would ''increase craving[s] for tobacco cigarettes and would make reducing or completely substituting smoking less likely'' (id.). Therefore, they believed that FDA should not sacrifice adults' use of flavored tobacco products in an attempt to prevent children from using flavored tobacco products. These comments also noted that flavors are used in other legally marketed products including nicotine replacement therapies (NRTs), which are FDA-approved products.

(Response) FDA is not banning flavored tobacco products with this final deeming rule. To address concerns with the growing flavored cigar market and its impact on youth and young adult initiation with tobacco products, FDA is announcing here that it intends to issue in the future a proposed product standard that would prohibit characterizing flavors in all cigars, including cigarillos and little cigars.

As discussed in section VIII.F of this document, we recognize that there is evidence that some individual former smokers may now report using ENDS (Ref. 24). However, the study referred to in the comments (Ref. 62) examined self-selected research subjects who were recruited through an e-cigarette Web site. All respondents were either former smokers (91.2 percent) or current smokers (8.8 percent); both groups had smoked on average 22 years before beginning to use ENDS. The article did not consider whether either the self-selection or the demographic profile of the respondents might affect the applicability of its results to any larger population. Moreover, the study did not address the question of whether study participants would have increased cigarette use if there were no available flavored ENDS or if the variety of flavored ENDS were limited. If additional evidence emerges that flavored ENDS make it more likely that smokers switch completely to ENDS, such evidence submitted as part of a PMTA would help support that application, as part of the analysis of whether the marketing of the product is appropriate for the protection of public health.

Further, new data shows continued growth in youth and young adult usage of flavored tobacco products. FDA has balanced those concerns with preliminary data showing that some adults may potentially use flavored ENDS to transition from combusted tobacco use when developing the compliance policy for premarket review.

(Comment 217) Many comments responded to FDA's request for data, research, and information regarding the characteristics or 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 labeled as a little cigar or other noncigarette tobacco product. Several comments stated that little cigars are being marketed and used as cigarettes and, therefore, FDA should communicate that such products are subject to the cigarette flavor ban. Other comments provided information regarding the differences between cigarettes and little cigars or other noncigarette tobacco products and indicated that such products should not be subject to the cigarette flavor ban.

(Response) FDA understands and appreciates comments regarding the role that flavored little cigars, or similar products, might play on initiation of tobacco product use and dual use. FDA will continue to determine whether a product is a ''cigarette'' under the FD&C Act and subject to the statutory flavor ban on a case-by-case basis.

(Comment 218) One comment stated that section 907(d)(3) of the FD&C Act, which prohibits FDA from banning certain enumerated tobacco products, demonstrates that Congress did not intend to grant FDA the power to ban any tobacco product by any means, including by enacting a product standard that would be a tantamount ban of newly deemed products, especially when some of these products present lower risks of death and disease than the specifically enumerated ones. Some comments also referred to the difficulty in defining ''characterizing flavor'' in the context of instituting a ban on flavored newly deemed tobacco products.

(Response) If FDA decides to issue a product standard, it will do so in accordance with section 907 of the FD&C Act. Because FDA is not banning flavored tobacco products with this final deeming rule, it is not necessary to consider whether and how to define ''characterizing flavor.''

B. Additional Access Restrictions

(Comment 219) Some comments suggested that FDA require face-to-face sales for all covered tobacco products, as it does for sales of cigarettes and smokeless tobacco, as provided in § 1140.14(a)(3). For example, they suggested that FDA ban self-service displays for newly deemed tobacco products. They expressed concern that treating cigarettes and smokeless tobacco differently from other tobacco products would lead to confusion for retailers and complicate retailer training programs.

(Response) FDA will continue to monitor this issue and, if it determines that it is appropriate for the protection of public health to extend the self-service display prohibition to newly deemed tobacco products, the Agency will issue a new NPRM in accordance with the APA.

(Comment 220) Some comments suggested that we simultaneously issue this final rule with an ANPRM seeking additional information to draft a proposal that would apply the additional restrictions in part 1140 (*e.g.,* ban on self-service displays, the sale and distribution of nontobacco items, and the sponsorship of events) to newly deemed products.

(Response) FDA is taking this comment under advisement. If FDA decides to issue such a proposal, the Agency will comply with the requirements of the APA.

(Comment 221) A few comments requested that FDA regulate all dissolvables and other newly deemed products in the same manner it regulates other tobacco products, including application of all of the marketing and advertising restrictions in part 1140.

(Response) At this time, FDA is subjecting newly deemed products to the automatic requirements and covered tobacco products to the additional provisions (*i.e.,* age and identification requirements, vending machine restrictions, and health warning requirements) discussed in this final rule. However, if FDA later determines that extending such marketing and advertising restrictions to the newly deemed products is appropriate and meets the applicable standard in section 906(d), FDA will comply with the requirements of the APA when implementing such restrictions.

C. Nicotine Exposure Warnings

(Comment 222) Many comments expressed concern about the increase in nicotine poisonings due to accidental ingestion of e-liquids and offered suggestions to address this issue: (1) Set a maximum nicotine content level for e-liquids; (2) require the use of child-resistant containers; (3) require a poison warning on the packaging and point of sale for liquid-based products; and (4) set a limit on the allowable speed of flow of the product from its container (*e.g.,* by requiring a flow-restricting apparatus on the opening of the container or requiring a rigid container to prevent quick dispensing of product by squeezing the container).

(Response) FDA expressed similar concerns about the increase in nicotine poisonings in the NPRM and section VIII.D. Once this final rule becomes effective, FDA has authority to issue additional regulations to address these concerns. In addition, FDA has issued an ANPRM prior to this deeming rule, seeking comments, data, research, or other information that may inform regulatory actions FDA might take with respect to nicotine exposure warnings and the use of child-resistant packaging. Moreover, elsewhere in this issue of the **Federal Register**, FDA has made available draft guidance, which when final will describe FDA's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products, including recommendations for nicotine exposure warnings and child-resistant packaging that would help to support a showing that the marketing of a product is appropriate for the protection of the public health.

XIII. Severability

This rule is being finalized with several changes from the NPRM. Specific comments regarding proposed codified language, and FDA's responses to those comments, are included in section VII.

In accordance with section 5 of the Tobacco Control Act, FDA considers and intends the extension of its authorities over all tobacco products and the various requirements and prohibitions established by this rule to be severable. It is FDA's interpretation and position that the invalidity of any provision of this rule shall not affect the validity of any other part of this rule. In the event any court or other lawful authority were to temporarily or permanently invalidate, restrain, enjoin, or suspend any provision of this final rule, FDA would conclude that the remaining parts continue to be valid. As stated in section 5 of the Tobacco Control Act, if certain applications of this rule to persons or circumstances (discussed in the preamble or otherwise) are held to be invalid, application of such provisions to any other person or circumstance will not be affected and will continue to be enforced to the fullest extent possible. Each provision of the rule is independently supported by data and analysis as described or referenced in this preamble and, if issued separately, would remain a proper exercise of FDA authority.

XIV. Description of the Final Rule—Part 1100

In the NPRM, FDA explained that new part 1100 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. We consider and intend the extension of our authorities over tobacco products and the various requirements and prohibitions established by this rule to be severable.

A. Section 1100.1—Scope

FDA selects Option 1 with this final rule, deeming all cigars (rather than a subset), which has been applied throughout the codified text for parts 1100, 1140, and 1143. Therefore, this section now states that 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 FD&C Act, except accessories of such other tobacco products, to be subject to chapter IX of the FD&C Act. The definition of ''accessory'' is now included in § 1100.3 (as discussed in section VI.A).

B. Section 1100.2—Requirements

Because FDA selected Option 1 for the scope of the deeming rule, § 1100.2 states that cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco are subject to chapter IX of the FD&C Act and its implementing regulations. In addition, this section states that FDA has deemed all other tobacco products, except accessories of such other tobacco products, subject to chapter IX of the FD&C Act and its implementing regulations.

C. Section 1100.3—Definitions

FDA requested comment on definitions for cigar, covered cigar, and tobacco product. Because we are

selecting Option 1 deeming all cigars (rather than a subset) with this final rule, comments regarding the definition of covered cigar are no longer relevant to this rulemaking. In addition, FDA received many comments regarding components, parts, and accessories, including how they should be defined and the application of requirements to these objects. We have added definitions of ''component or part'' and ''accessory'' to this section. The discussion of this language is included in section VI.A.

XV. Description of the Final Rule—Part 1140

Currently, part 1140 generally applies to cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. FDA proposed additional provisions to apply to ''covered tobacco products'' (namely, the requirement to prohibit the sale and distribution of products to individuals under 18 years of age and the prohibition on vending machine sales except in adult-only facilities). As stated elsewhere in this document, ''covered tobacco product'' means any tobacco product deemed to be subject to the FD&C Act pursuant to § 1100.2, but excludes any component or part that is not made or derived from tobacco. FDA is finalizing these requirements without substantive change. FDA intends to update the current guidance documents for civil money penalties and frequently asked questions to reflect that violations of health warning requirements may lead to the issuance of civil money penalties. We consider and intend the extension of our authorities over tobacco products and the various requirements and prohibitions established by this rule to be severable.

A. Section 1140.1—Scope

The NPRM offered several amendments to part 1140 in order to apply select existing sale and distribution restrictions, including age, identification, and vending machine provisions, to address youth access to the deemed tobacco products. As currently written, part 1140 generally applies to cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco products. Accordingly, FDA is finalizing this rule to add the phrase ''and covered tobacco products'' to § 1140.1(a) and (b) to ensure the products are subject to select existing restrictions and access provisions. We also have added language to § 1140.1(a) to clarify the scope of § 1140.16(d).

B. Section 1140.2—Purpose

This final rule adds ''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 restrictions in place for cigarettes and smokeless tobacco. Therefore, the final rule states that retailers of the newly deemed covered tobacco products may not sell them to individuals under 18 years of age and requires retailers of covered tobacco products to verify the purchaser's birth date by reviewing the individual's photographic identification. However, as noted in § 1140.14(b)(2)(ii), a retailer is not required to verify the age of any person who is more than 26 years of age. In addition, § 1140.14(b)(3) prohibits the sale of covered tobacco products using an electronic or mechanical device such as a vending machine, unless it is located in a facility where the retailer ensures that no person younger than 18 years of age is present, or permitted to enter, at any time. FDA does not intend for section 1140.14(b)(3) to prohibit the sale of tobacco products via the Internet, but the sale of covered tobacco products via any medium, including the Internet, must only be to persons 18 years of age or older. Therefore, any sale of covered tobacco products over the Internet must comply with the minimum age and identification requirements in this rule.

C. Section 1140.3—Definitions

In the NPRM, we sought comments on definitions of the following terms: Cigar, cigarette, cigarette tobacco, covered tobacco product, distributor, importer, nicotine, package, point of sale, retailer, smokeless tobacco, and tobacco product. FDA received many comments regarding whether e-liquids and components, parts, and accessories are tobacco products. FDA also received many comments regarding the need to define components, parts, and accessories, which resulted in the addition of definitions of ''component or part'' and ''accessory'' in § 1140.3. The discussion of this language in included in section VI.A. Further, we revised the definition of ''package'' to refer to ''package or packaging.'' We also added a definition of ''roll-your-own'' to provide further clarity to the definition of ''cigarette.''

D. Section 1140.10—General Responsibilities of Manufacturers, Distributors, and Retailers

With the selection of Option 1, § 1140.10 now provides that manufacturers, distributors, importers, and retailers are responsible for ensuring that the covered tobacco products (in addition to cigarettes and smokeless tobacco) they manufacture, label, advertise, package, distribute, import, sell, or otherwise hold for sale comply with all applicable requirements in part 1140. The revisions to §§ 1140.10 and 1140.14 clarify that the minimum age and identification requirements and vending machine restrictions apply to the newly deemed covered tobacco products.

Previously, § 1140.10 stated that each manufacturer, distributor, importer, and retailer is responsible for ensuring that its products comply with all applicable requirements under part 1140. FDA proposed to add ''and covered tobacco products'' to the existing language of this section to clarify that the provision also applies to ''covered tobacco products'' as defined in § 1140.3. In addition, FDA proposed that § 1140.10 cover importers, because 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. FDA is finalizing this section as drafted in the NPRM.

E. Section 1140.14—Additional Responsibilities of Retailers

FDA proposed to divide this section into responsibilities for retailers of cigarettes and smokeless tobacco products and responsibilities for retailers of covered tobacco products. FDA is finalizing this section as drafted in the NPRM. Therefore, upon the effective date of this final rule, § 1140.14(a)(1) through (a)(5) will provide the retailer's responsibilities for the sale of cigarettes and smokeless tobacco. Section 1140.14(b)(1) through (b)(3) will provide the retailer's responsibilities for the sale of newly deemed products.

F. Comments and Responses Regarding Minimum Age and Identification Requirements

In the NPRM, FDA sought comment regarding whether to prohibit the sale of newly deemed products to individuals under 18 years of age and to require photographic identification for individuals aged 26 and under (which are the same requirements that currently apply to cigarettes and smokeless tobacco). FDA discussed the benefits of a uniform minimum age and identification requirement, including: (1) Decreasing youth access to tobacco products in another jurisdiction with less stringent requirements; (2) addressing youth misperceptions that tobacco products without minimum age or identification requirements are safer; and (3) increasing the ease with which retailers can comply with minimum age

and identification requirements for covered tobacco products (79 FR 23142 at 23160 23162). In addition, we expressed our intention to use an aggressive nationwide enforcement program to increase compliance and deter youth consumption of tobacco products (79 FR 23142 at 23160).

Nearly all comments supported a minimum age and identification requirement for the newly deemed tobacco products. FDA is finalizing these requirements without change. FDA also intends to update the current guidance documents for civil money penalties and frequently asked questions to reflect that violation of these provisions may lead to the imposition of civil money penalties. A summary of comments regarding these provisions, and FDA's responses, is included in the following paragraphs.

(Comment 223) Many comments supported FDA's proposal due to the fact that many of the newly deemed products are easily available. For example, they noted that tobacco industry documents refer to the increased frequency with which self-service tobacco products are stolen, and some of the proposed deemed products (*e.g.,* cigars) are frequently sold in self-service displays (Ref. 243). They expressed concern that self-service displays increase the likelihood that minors will have access to tobacco products.

(Response) FDA agrees that the newly deemed tobacco products are readily available to consumers. FDA finds that the age and identification restrictions that are included in this final rule (§ 1140.14) will help to limit youth access to the newly deemed tobacco products. In the event that FDA determines that extending the prohibition on self-service displays (§ 1140.16(c)) to the newly deemed products is appropriate and meets the applicable standard in section 906(d), FDA will issue a new NPRM and seek comment.

(Comment 224) Many comments supported the minimum age and identification requirements for covered tobacco products based on increased youth use of newly deemed products and the impact of nicotine on youth. They noted that, according to the CDC, e-cigarette use among youth doubled from 2011 to 2012, with 1.78 million high school and middle school students having ever used e-cigarettes (Ref. 108). Others noted that the 2012 Surgeon General's report stated that youth are more sensitive to developing nicotine dependence than adults (Ref. 49). In addition, other comments stated that because minimum age and identification requirements for covered tobacco products vary among the states, a uniform age requirement would help prevent youth from accessing tobacco products in a neighboring state with less stringent requirements.

(Response) FDA agrees with comments supporting the implementation of minimum age and identification requirements for covered tobacco products. As we noted in the NPRM, the goal of the minimum age restriction is to limit youth access to the newly deemed tobacco products. FDA concludes that the restrictions included with this final deeming rule are appropriate for the protection of the public health because they will reduce youth access to and, therefore, likely limit use of tobacco products.

(Comment 225) Several comments recommended that FDA raise the minimum age to purchase tobacco products to 21 years old. They claimed that a higher minimum age would restrict youth access to social sources of tobacco products because minors tend to have less contact in their social network with 21-year-olds than with 18-year-olds (Ref. 244). They also suggested that the minimum age and identification requirement should mirror the minimum age requirement for alcohol and marijuana purchases in some States.

(Response) FDA has determined that minimum age and identification restrictions, which will apply to all covered tobacco products, are appropriate for the protection of public health. FDA also will continue to provide prevention and tobacco product risk awareness campaigns targeted to youth and young adults. Although section 906(d)(3)(ii) precludes FDA from raising the minimum age of sale of tobacco products, section 104 of the Tobacco Control Act required FDA to conduct a study on the public health implications of raising the minimum age of sale of tobacco products. This study's report was published (Ref. 245) and can be found at: *http://www.iom.edu/Reports/2015/TobaccoMinimumAgeReport.aspx*.

(Comment 226) Several comments discussed Internet sales of tobacco products. Some comments favored a ban on Internet sales for all tobacco products, some supported a ban on only certain tobacco products, and others opposed a ban on Internet sales of any tobacco products.

(Response) As explained elsewhere, under this rule, retailers may not sell covered tobacco products (through any medium, including the Internet) to individuals under 18 years of age. FDA will continue to actively enforce the minimum age restriction for Internet sales. FDA will consider these comments in the future and continue to assess whether additional access restrictions would be appropriate.

(Comment 227) Several comments recommended that FDA impose stiff penalties for noncompliance with minimum age and identification requirements and institute youth tobacco prevention campaigns and other actions to effectively reduce youth access to tobacco products.

(Response) As noted in the NPRM, FDA believes that combining the minimum age and identification restriction with comprehensive and consistent enforcement, both at the Federal level and in partnership with States, will decrease the likelihood of youth smoking initiation (79 FR 23142 at 23161). In addition, FDA will continue to invest in a number of public education campaigns to help educate the public—especially youth—about the dangers of tobacco products.

(Comment 228) Several comments recommended that FDA prohibit the sale of tobacco product components, parts, and accessories (not just covered tobacco products), including ENDS, to minors under 18 years of age to provide consistency across the country.

(Response) FDA disagrees. FDA concludes that the application of minimum age requirements and vending machine requirements to covered tobacco products, together with its regulation of components and parts of newly deemed products, will protect the public from the dangers of tobacco use, discourage initiation, and encourage cessation of use of such products.

(Comment 229) A few comments suggested that FDA prohibit cigar sales to individuals under 18 years of age, except for minors serving in the U.S. military. They argued that there are greater health hazards for military personnel than using tobacco products.

(Response) We disagree with the suggestion that we provide an exception for minors in the military. Military personnel face the same risk of tobacco-related death and disease as civilians. As FDA stated in the preamble, cigars can contain greater levels of nicotine than cigarettes; cigar smoking is strongly related to certain cancers; and in certain circumstances, cigars may be as harmful to a person's health as cigarettes (79 FR 23142 at 23151, 23156).

(Comment 230) Some comments suggested that retailers record and retain copies of each purchaser's unexpired driver's license (if the document includes a photo), an armed forces identification card, or a valid passport as an acceptable identification to verify a purchaser's minimum age. Other

comments recommended that FDA implement a registration requirement for mail order sale of tobacco products and require carriers to verify that the seller sending out packages is registered before accepting the packages for delivery.

(Response) The requirements for photo identification are included in § 1140.14(b)(2). Retailers may choose any method of identification verification that complies with this provision. FDA finds that these requirements are appropriate for the protection of the public health and declines to adopt the recommendations for additional requirements at this time. However, we will continue to assess whether additional requirements regarding identification are appropriate.

G. Comments and Responses Regarding Vending Machines

Consistent with the minimum age and identification provisions, FDA proposed to ban the sale of covered tobacco products in vending machines (*i.e.,* requiring face-to-face transactions in retail facilities) 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. FDA is finalizing this requirement without change in § 1140.14. Therefore, upon the effective date of this final rule, covered tobacco products, including ENDS and cigars, may not be sold in electronic or mechanical devices such as vending machines unless the device is in an adult-only facility. This restriction is appropriate for the protection of the public health because it will eliminate one more method of youth access to tobacco products.

A summary of the comments regarding these provisions, and FDA's responses to them, is included in the following paragraphs.

(Comment 231) Multiple comments supported restricting vending machines sales to adult-only facilities. They asserted that FDA's discussion of this issue demonstrates that the vending machine restriction serves the stated public health purpose of the regulation. Other comments stated that FDA's rationale for this restriction for cigarettes and smokeless tobacco also applies to the newly deemed tobacco products.

(Response) FDA agrees that there is a public health benefit to limiting vending machines to adult-only facilities. As we stated in the NPRM, studies show that youth are able to access tobacco products in vending machines (79 FR 23142 at 23162). Therefore, the vending machine restrictions are important in preventing youth from gaining access to these products.

(Comment 232) Several comments suggested that FDA prohibit all vending machine sales of all tobacco products.

(Response) FDA disagrees with prohibiting all vending machine sales of all tobacco products. Sections 1140.14(a)(3) and 1140.14(b)(3) permit the sale of cigarettes and smokeless tobacco products and covered tobacco products, respectively, in a non-face-to-face exchange with the assistance of a mechanical device as long as the retailer ensures that no person younger than 18 years of age is present, or permitted to enter, at any time. FDA is permitting adult-only facilities to sell tobacco products in a vending machine because these locations employ safeguards to prohibit entry to individuals less than 18 years of age. FDA is not seeking to ban adult access to legally marketed tobacco products.

(Comment 233) Several comments recommended that FDA subject tobacco product components, parts, and accessories (particularly e-cigarettes) to the proposed vending machine restrictions. These comments expressed concern regarding exploding tanks and nicotine poisoning due to accidental e-liquid exposure.

(Response) FDA agrees that these tobacco product components and parts can pose public health concerns. At this time, FDA has determined that it is appropriate for the protection of the public health to restrict impersonal modes of sale of nicotine-containing components and parts in vending machines. However, FDA has concluded that it is not warranted at this time to impose the vending machine restrictions on components or parts that are not made or derived from tobacco as they will only be able to deliver nicotine to users by combining them with covered tobacco products that are subject to the vending machine restriction (and, therefore, youth cannot access). Accordingly, FDA believes that the public health will be protected by applying the vending machine restrictions to components and parts that contain nicotine or tobacco in order to prevent youth access to these products.

(Comment 234) Some comments suggested that the deeming rule include a ban on Internet sales. These comments asserted that manufacturers and retailers are not enforcing age verification effectively and that youth are able to purchase tobacco products when they are not in the physical presence of the seller. Several comments also recommended that FDA require retailers to verify the age of purchasers of newly deemed tobacco products using methods similar to those found in the Prevent All Cigarette Trafficking (PACT) Act of 2009 (which ensures the collection of Federal, State, and local tobacco taxes on cigarettes and smokeless tobacco sold via the Internet or mail order sales). Other comments opined that neither the PACT Act nor State laws have been effective in preventing youth access to tobacco products.

(Response) Under this rule, retailers may not sell covered tobacco products (through any medium) to individuals under 18 years of age. FDA will continue to actively enforce the minimum age restriction for mail order sales and Internet sales. FDA will continue to assess whether additional access restrictions would be appropriate.

(Comment 235) A few comments stated that because newly deemed tobacco products are generally not sold in vending machines, there will be little impact from the proposed vending machine restrictions.

(Response) FDA disagrees. As discussed in the NPRM (79 FR 23142 at 23162), FDA expects that the vending machine restrictions will have a positive impact by preventing some youth from accessing tobacco products. Therefore, FDA concludes that this restriction is appropriate for the protection of the public health.

(Comment 236) A few comments stated that FDA should permit tobacco product sales through vending machines in all locations. They noted that technological advancements now allow for accurate non-face-to-face age verification, including electronic age and identity verification (EAIV) technology and that the PACT Act already requires retailers to verify a tobacco product purchaser's name, birth date, and address through an EAIV database prior to accepting a delivery order.

(Response) FDA disagrees. We explained in the NPRM that other types of vending machine restrictions, such as electronic locking devices on vending machines, have not sufficiently limited youth access to tobacco products (79 FR 23142 at 23162). In addition, vending machines may be located in facilities that are not as sophisticated as the common carriers or Internet sellers that are subject to the PACT Act, or these retailers may not have the financial resources to update their vending machines to incorporate EAIV technology. Therefore, FDA concludes that the vending machine restriction is appropriate for the protection of public health.

XVI. Description of the Final Rule—Part 1143

In the proposed deeming rule, FDA proposed to add part 1143, which would mandate 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. As stated throughout this document, FDA has selected Option 1 with this final rule. Therefore, these requirements apply to all newly deemed covered tobacco products, including premium and other types of cigars. We consider and intend the extension of our authorities over tobacco products and the various requirements and prohibitions established by this rule to be severable.

A. Section 1143.1—Definitions

In the NPRM, FDA sought comment on definitions for the following terms: Cigar, covered cigar, covered tobacco product, package, required warning statement, and roll-your-own tobacco. As stated throughout this document, FDA has selected Option 1 as the scope of this rule. Therefore, the definition of covered cigar is unnecessary and has been removed from this section. We also added definitions of point-of-sale, retailer, and tobacco product. These terms are used in part 1143 and were already included in parts 1100 and 1140.

FDA received many comments regarding the need to define components, parts, and accessories, which resulted in the addition of definitions of ''component or part'' and ''accessory'' in § 1140.3. The discussion of this language in included in section VI.A. In addition, we included a definition of ''cigarette tobacco'' given that the health warning requirements apply to covered tobacco products, roll-your-own tobacco, and cigarette tobacco. We also have added a definition of ''principal display panels'' to address comments suggesting that a definition was necessary to comply with this part. The term ''principal display panels'' is defined as the panels of a package that are most likely to be displayed, presented, shown, or examined by the consumer.

B. Section 1143.3—Required Warning Statement Regarding Addictiveness of Nicotine

Proposed § 1143.3 included a requirement that any person who manufactures, sells, offers to sell, distributes, or imports for sale or distribution within the United States, cigarette tobacco, roll-your-own tobacco and covered tobacco products other than cigars must include the following warning statement on each product package and in each advertisement: ''WARNING: This product contains nicotine derived from tobacco. Nicotine is an addictive chemical.'' The NPRM provided that a manufacturer could submit a certification that its tobacco product does not contain nicotine and notify FDA that it intends to use the alternative warning statement: ''This product is derived from tobacco.'' FDA also proposed size and placement requirements for the use of this warning statement on packages and in advertisements.

Upon review of the comments, FDA is revising the language of this warning to read: ''WARNING: This product contains nicotine. Nicotine is an addictive chemical.'' The alternative warning statement is also revised to read: ''This product is made from tobacco.'' This warning will be required to appear on at least 30 percent of the two principal display panels of the package and at least 20 percent of the area of the advertisement. We also added language to § 1143.3(a) to clarify that the warning statement must be printed in at least 12-point font size in order to be clear and legible.

Further, we added language to § 1143.3(a)(3)(ii) to clarify when 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 does not comply with these requirements. This final rule provides that a retailer will not be in violation if the package: (1) Contains a health warning; (2) is supplied to the retailer by a tobacco product manufacturer, importer, or distributor, who has the required state, local, or TTB-issued license or permit, if applicable (consistent with the language in § 1143.5(a)(4)(ii)); and (3) is not altered by the retailer in a way that is material to the requirements of this section.

In addition, in response to comments regarding minimum font size for advertisements, we have revised § 1143.3(b)(2)(ii) to include a 12-point minimum font size for the warnings on advertisements. We note that the warning also needs to occupy ''the greatest possible portion of the warning area set aside for the required text.'' Therefore, a print advertisement would require a much larger font size in order to comply with this requirement.

Given that comments expressed uncertainty as to how the self-certification process in § 1143.3(c) would work, we also included language in this section to further clarify this process. This section now provides that the certification statement can be submitted by the tobacco product manufacturer to FDA. FDA recommends that all data used to support the self-certification, or copies of the data, be maintained at the manufacturing facility or another location that is reasonably accessible to the manufacturer and to any officers or employees duly designated by the Secretary, which includes FDA employees. These data, including data not stored at the inspected facility, should be made readily available for copying or inspection by an officer or employee duly designated by the Secretary. Manufacturers interested in submitting a certification statement may contact CTP at 1–877–CTP–1373 for more information regarding this submission.

Further, in response to comments, we added § 1143.3(d), which states that, if a product package is too small or otherwise unable to accommodate a label with sufficient space to bear such information, it will be exempt from the requirement to place the warning statement directly on the product package if the warning appears on the outer carton or other outer container or wrapper or on a tag otherwise permanently affixed to the tobacco product package. Under this provision, the warning statement must be printed using the specifications required in § 1143.3(a)(1) and (a)(2). In these cases, the outer carton, outer container, wrapper, or tag would serve as the location for the principal display panels. If a tag is used for the principal display panels, both sides of the tag must be visible to the consumer. The warning statements must be printed on both sides of the tag to comply with § 1143.3(a)(2).

We also note that this requirement in § 1143.3 applies to cigarette tobacco, roll-your-own tobacco, and covered tobacco products other than cigars. Both cigarette tobacco and roll-your-own tobacco are defined in § 1143.1. This warning requirement does not apply to smokeless tobacco products. Smokeless tobacco products must meet the warnings requirements in CSTHEA (15 U.S.C. 4401 *et seq.*).

C. Section 1143.5—Required Warning Statements for Cigars

In § 1143.5, FDA proposed warnings for the cigars that would be covered under this final rule. In addition to the addictiveness warning, FDA proposed that all cigars (except those sold individually and not in product packages) would be required to include

the following warnings on packages and in advertisements:

- WARNING: Cigar smoking can cause cancers of the mouth and throat, even if you do not inhale.
- WARNING: Cigar smoking can cause lung cancer and heart disease.
- WARNING: Cigars are not a safe alternative to cigarettes.
- WARNING: Tobacco smoke increases the risk of lung cancer and heart disease, even in nonsmokers.

FDA also proposed size and placement requirements for the warning statements on packages and in advertisements. FDA is finalizing these warning requirements in accordance with Option 1 deeming all cigars (rather than a subset). Further, FDA is adding an additional warning statement (WARNING: Cigar use while pregnant can harm you and your baby.) with an optional alternative statement (SURGEON GENERAL WARNING: Tobacco Use Increases the Risk of Infertility, Stillbirth and Low Birth Weight) as discussed in section XVI.H.16.

Therefore, the full list of required warnings for use on cigar packages and in cigar advertisements is as follows:

- WARNING: This product contains nicotine. Nicotine is an addictive chemical.
- WARNING: Cigar smoking can cause cancers of the mouth and throat, even if you do not inhale.
- WARNING: Cigar smoking can cause lung cancer and heart disease.
- WARNING: Cigars are not a safe alternative to cigarettes.
- WARNING: Tobacco smoke increases the risk of lung cancer and heart disease, even in nonsmokers.
- WARNING: Cigar use while pregnant can harm you and your baby. (Or, as an optional alternative statement: SURGEON GENERAL WARNING: Tobacco Use Increases the Risk of Infertility, Stillbirth and Low Birth Weight.)

The health warnings are required to appear on at least 30 percent of each of the two principal display panels of the package and on at least 20 percent of the area of the print advertisements and other advertisements with a visual component. As we did for § 1143.3(a)(2)(ii) and (b)(2)(ii), we added language to § 1143.5(a)(2)(ii) and (b)(2)(ii) to clarify that the font used for warnings on packaging and advertisements must be at least 12-point font size in order to be clear and legible. We note that the warning also must occupy ''the greatest possible portion of the warning area set aside for the required text.'' Therefore, a print advertisement would require a much larger font size in order to comply with this requirement.

For packages, the six warnings for cigars (five specifically for cigars and the one addictiveness warning) will be required to 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 randomly distributed in all areas of the United States. This random display and distribution must be done in accordance with a warning plan submitted to, and approved by, FDA. For advertisements, the warnings must be rotated quarterly in alternating sequence in each advertisement for each brand of cigar in accordance with a warning plan submitted to, and approved by, FDA. Warning plans must be submitted for FDA review and approval by responsible manufacturers, distributors, importers, and retailers by 1 year after the date of publication of the final rule (however, all other part 1143 requirements shall take effect 2 years after the publication date of this final rule).

In the NPRM, FDA did not have a separate section (with its own effective date) explicitly requiring the submission of warning plans with its own effective date. Rather, the sections of part 1143 requiring random display and distribution of warning statements for packaging and quarterly rotation of warning statements for advertisements (for which FDA proposed a 2-year effective date) stated that such random display and distribution and quarterly rotation be done in accordance with a warning plan submitted to and approved by FDA. Thus, those provisions implicitly required that submission of the warning plan and approval by FDA be done prior to the 2-year effective date by which manufacturers must comply with the plan. FDA has added § 1143.5(c)(3) to specifically include the requirement to submit a proposed warning plan. (See section XVI.H.17 for additional information regarding the warning plan requirement and timeframe for submission.)

The same warning statement requirements will apply to cigars sold individually and not in product packages.[15] However, instead of being required to place warnings directly on these product packages, retailers will be required to post signage at the point of sale listing the six warnings (five specifically for cigars and one addictiveness warning) on a minimum of 8.5 x 11 inch sign. The rule requires that the sign be placed on or within 3 inches of each cash register where payment is made and the sign is unobstructed in its entirety and can be easily read by each consumer making a purchase.

D. Section 1143.7—Language Requirements for Required Warning Statements

Consistent with section 3(b) of CSTHEA (15 U.S.C. 4402(b)), FDA proposed in § 1143.7 that the warning statement appear in the English language, with two exceptions. First, under § 1143.7(a), if an advertisement appears in a non-English language publication, the required warning statement would be required to appear in the predominant language (*i.e.,* the primary language used in the nonsponsored content) of the publication. Second, under § 1143.7(b), if an advertisement is in an English language publication but the advertisement is presented in a language other than English, the required warning statement would be required to appear in the same foreign language as that principally used in the advertisement. FDA is finalizing this section as proposed in the NPRM with one change; given that FDA has noted throughout this document that the health warning requirements apply to advertisements in any medium, we have changed the references from ''publication'' to ''medium'' in this section.

E. Section 1143.9—Irremovable or Permanent Required Warning Statements

FDA proposed that the warning statements for covered tobacco products be indelibly printed on or permanently affixed to packages and advertisements. FDA is finalizing this requirement without change.

F. Section 1143.11—Does Not Apply to Foreign Distribution

FDA proposed to limit the applicability of the health warning requirements by clarifying that they 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. FDA is finalizing this requirement.

[15] 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.

G. Section 1143.13—Effective Date

In the NPRM, FDA sought comment regarding the effective date of the health warning requirements. FDA proposed that these requirements would take effect 24 months after the date that the final rule publishes in the **Federal Register** and all products manufactured on or after the effective date must include the required warning statements on their labels.

This means that:

- After the effective date, no manufacturer, packager, importer, distributor, or retailer of cigarette tobacco, roll-your-own tobacco, cigars, or other covered tobacco products may advertise any such product if the advertisement does not comply with this rule;
- After the effective date, no person may manufacture for sale or distribution within the United States any such product the package of which does not comply with this rule;
- Beginning 30 days after the effective date, a manufacturer may not introduce into domestic commerce, any such product, irrespective of the date of manufacture, if its package does not comply with this rule;
- After the effective date, a distributor or retailer may not sell, offer to sell, distribute, or import for sale or distribution within the United States any such product the package of which does not comply with this regulation, unless the covered tobacco product was manufactured prior to the effective date; and
- After the effective date, however, a retailer may sell covered tobacco products in packages of which do not have a required warning if the retailer demonstrates it falls outside the scope of this rule as described in §§ 1143.3(a)(3) and 1143.5(a)(4).

In addition to proposed § 1143.13, we added paragraph (b) indicating that the requirement to submit a warning plan pursuant to § 1143.5(c)(3), describing the random display and distribution of warning statements on cigar packages and the quarterly rotation of warning statements in cigar advertisements, will take effect 12 months after the date of publication of this final rule. FDA is establishing this effective date at 12 months before the effective date of the required warnings for cigars described under part 1143 (24 months after the publication of the final rule) because the Agency anticipates that there will be a need for communication with submitters during its review of the warning plan submissions. This submission deadline also helps FDA to ensure that its surveillance program for compliance with the warning label requirements under section 1143 is implemented as of the effective date of 24 months after the publication of the final rule. FDA intends to work with manufacturers, importers, distributors, and retailers to get an approved warning plan in place. Cigar entities may wish to contact FDA to discuss the submission of their warning plans in order to make the subsequent approval process more orderly and efficient. See section XVI.H.17 for additional information regarding the warning plan requirement.

H. Comments and Responses Regarding Required Warning Statements

1. General

(Comment 237) Several comments urged FDA to clearly define ''advertisement'' in the final rule as it is unclear what constitutes an advertisement that must contain the required warning statements. At least one comment suggested that the final rule contain language explaining that any statement regarding the availability of tobacco products in a store does not by itself constitute an advertisement.

(Response) FDA does not believe it is necessary to include a definition of ''advertisement'' in this final rule, but notes that for purposes of this rule, the term ''advertisement'' should be interpreted broadly and should be interpreted to include statements regarding the availability of tobacco products.

In addition, advertisements subject to this final rule may appear in or on, for example, promotional materials (point-of-sale or non-point-of-sale), billboards, posters, placards, published journals, newspapers, magazines, other periodicals, catalogues, leaflets, brochures, direct mail, shelf-talkers, display racks, Internet Web pages, television, electronic mail correspondence, and also include those communicated via mobile telephone, smartphone, microblog, social media Web site, or other communication tool; Web sites, applications, or other programs that allow for the sharing of audio, video, or photography files; video and audio promotions; and items not subject to the sale or distribution ban in § 1140.34. FDA intends to provide guidance on how to comply with the health warning requirements on unique types of media.

(Comment 238) Several comments noted that the proposed cigar warnings are appropriate for the protection of public health. The comments noted that the rule would enhance public health by extending the labeling requirements beyond the seven manufacturers currently required to use them under the FTC consent decrees, by providing for random display on cigar packages and rotation in advertisements, and by requiring point-of-sale warnings for cigars sold individually that are not packaged. The comment also noted that the substance of each warning is strongly supported by the available scientific evidence. However, several comments took issue with the proposed warnings for premium cigars, claiming that they lack a sound scientific basis.

(Response) FDA finds there is a strong scientific basis to require health warnings on cigar packages and in cigar advertisements (as well as on signs for unpackaged cigars), which was extensively discussed in the NPRM (79 FR 23142 at 23167 through 23170).

(Comment 239) Several comments stated that the NPRM is unclear regarding the requirement to develop and submit rotation plans for warnings signs required where cigars are sold individually and not in a product package. One comment stated that the final rule should make clear that this obligation falls on cigar manufacturers and not on retailers that sell cigars. Another comment stated that retailers should be responsible for creating and posting the point of sale signs.

(Response) To clarify, retailers of cigars sold individually and not in product packaging are not required to submit a warning plan for warnings on packages, because the warning signs posted at a retailer's point-of-sale would include all six warnings applicable to cigars, as we have noted above in our discussion of § 1143.5(c)(1). Cigar retailers would be responsible for creating and posting these signs in accordance with § 1143.5(a)(3)(i)–(iv). Therefore, there is no need to rotate these health warnings, nor is it necessary to submit a rotational warning plan for them. However, manufacturers must submit a warning plan for advertisements, as the rule requires manufacturers of *all* cigars to include warnings in advertisements that must be rotated quarterly in alternating sequence in each advertisement for each brand of cigar. Similarly, retailers who are responsible for or direct their own cigar advertising must submit a warning plan for those advertisements.

(Comment 240) One comment suggested that FDA adopt labeling rules, similar to those proposed for premium cigars, for e-cigarette products that are sold without packaging (*i.e.,* require signage at the point of sale for stores selling e-cigarettes rather than require labels on their packages).

(Response) Unlike cigars sold individually and not in product

packages, ENDS and any e-liquids containing nicotine that are sold separately are sold in some sort of packaging on which the addictiveness warning can be provided. Therefore, it is not necessary at this time to instead require warnings at the point-of-sale. The warning requirements in this final rule are appropriate for the protection of the public health because they provide information to the consumers each time they use the product.

2. Continuum of Risk

(Comment 241) Several comments asserted that different product categories should carry different health warnings relative to the health risk the products present to adult consumers. They also thought that, in view of the continuum of risk, the size of the proposed addictiveness warning on e-cigarettes and other noncombusted products is too large and the location too prominent. For example, one comment suggested that FDA require that this warning be smaller for these products than for smokeless tobacco products (*i.e.,* 20 percent of the principal display panel) and it should appear only on one of the principal display panels of the package. Another comment noted that, because of its relative size and placement, the proposed e-cigarette warning could deter combusted cigarette smokers from switching to a noncombusted product based on a misunderstanding of the relative risks of smoking versus electronic and noncombusted products. This comment suggested that the warning on e-cigarettes should be no larger or more prominently located than the currently required cigarette warnings.

(Response) FDA disagrees. As discussed in section VIII, though FDA recognizes the existence of a continuum of nicotine-delivering products, all tobacco products are addictive and potentially dangerous. There is a public health benefit to warning consumers regarding the addictiveness of nicotine, regardless of how it is delivered. Numerous studies show that the likelihood that warnings are seen and noticed depends upon their size and position. (Refs. 36, 37, 38, 39; see section II.B.4). In addition, as mentioned in section VIII.C, study results have been inconclusive about the effects of ENDS products on the population. FDA does not believe, at this time, that it has sufficient evidence about the risks of ENDS products to justify the use of different warnings sizes and to determine the appropriate size for each product category. FDA will continue to monitor research regarding the health effects of different types of ENDS.

As to the comment that e-cigarette warnings should be no larger or more prominently located than currently required for cigarettes, the final rule requires the warnings to appear on at least 30 percent of the two principal display panels of the package, and at least 20 percent of the area of advertisements. These are the same warning sizes that Congress established for smokeless tobacco in the Tobacco Control Act. 15 U.S.C. 4402(a)(2)(A), (b)(2)(A). In the same Act, Congress prescribed an even larger size for cigarette warnings: 50 percent on the front and rear panels of cigarette packaging (and the same 20 percent size for cigarette advertisements) (id. § 1333(a)(2), (b)(2)). However, the larger warning sizes required for cigarettes have not yet been implemented because the final rule was challenged in court, and on August 24, 2012, the United States Court of Appeals for the District of Columbia Circuit vacated the rule and remanded the matter to the Agency. *R.J. Reynolds Tobacco Co.,* v. *Food & Drug Administration,* 696 F.3d 1205 (D.C. Circuit 2012), *overruled on other grounds by Am. Meat Inst.* v. *U.S. Dep't of Agric.,* 760 F.3d 18, 25 (D.C. Cir. 2014) (*en banc*). On December 5, 2012, the Court denied the government's petition for panel rehearing and rehearing en banc, and FDA decided not to seek further review of the Court's ruling. FDA is conducting research that aims to support a new rulemaking consistent with the Tobacco Control Act (see Generic Clearance for the Collection of Qualitative Data on Tobacco Products and Communications (OMB Control Number 0910–0796) and Pretesting of Tobacco Communications (OMB Control Number 0910–0674)). For smokeless tobacco packaging, the warning labels must be located on the two principal display panels and cover at least 30 percent of each panel (15 U.S.C. 4402(a)(2)(A)), which is consistent with the warning labels required for newly deemed tobacco products.

(Comment 242) Several comments stated that informing consumers that tobacco products are addictive by requiring an addictiveness warning does not fulfill any useful public health goal. These comments believed that it is misleading to describe all nicotine-containing products as addictive without describing the relative risk of the products.

(Response) FDA disagrees. The addictive nature of tobacco products has been well documented. The Surgeon General has long recognized the addictive nature of tobacco products due to the presence of nicotine, which is highly addictive and can be absorbed into the bloodstream (Ref. 1). Congress also expressed concern about the addictiveness of these ''inherently dangerous products'' (section 2(2) of the Tobacco Control Act). Because the covered tobacco products are made or derived from tobacco and most (if not all) contain nicotine, they are likely addictive (Refs. 14, 246, 247, 248, 249). For products that do not contain nicotine (*i.e.,* no nicotine at detectable levels), the rule provides for an alternative warning statement, ''This product is made from tobacco.''

Consumers, especially youth and young adults, wrongly believe that many tobacco products covered by this rule are less addictive than cigarettes; 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 (79 FR at 23158–59, 23166). The addictiveness warning will help consumers understand and appreciate the consequences of using tobacco products. The addictiveness warning will help ensure that youth and young adults, who may be more susceptible to the addictiveness of nicotine, have a greater awareness of the presence of nicotine and the addictiveness of these products before they might become addicted.

Additionally, any manufacturer that wishes can submit an MRTP application to FDA to show that its product is less hazardous than another tobacco product. When the Tobacco Control Act was passed, Congress found that unless tobacco products that purport to reduce the risks to the public of tobacco use actually reduce such risks, those products can cause substantial harm to the public health (section 2(37) of the Tobacco Control Act). Furthermore, Congress noted that the dangers of products sold or distributed as MRTPs that do not in fact reduce risk are so high that FDA must ensure that statements about MRTPs are complete, accurate, and relate to the overall disease risk of the product (section 2(40) of the Tobacco Control Act). Accordingly, Congress determined that manufacturers must demonstrate that such products meet a series of rigorous criteria, and will benefit the health of the population as a whole before they may be marketed to reduce the harm or the risk of tobacco-related disease or to reduce exposures to harmful substances associated with tobacco products (section 911 of the FD&C Act (21 U.S.C. 387k)). If new research on the relative risks presented by the use of smokeless

tobacco products and ENDS products emerges, FDA may consider proposing changes to the warning label requirements. If it does, the Agency will initiate a new rulemaking in accordance with the APA.

3. Warning Requirements for Other Media

(Comment 243) Several comments stated that FDA should clarify the application of the proposed warnings to television and radio advertisements, as well as in catalogs, on Internet sites, and on social media. One comment recommended that advertisers be required to include a voiceover stating the warning out loud, in a clear, conspicuous, and neutral manner. Another comment suggested that FDA clarify in the final regulation that § 1143.3(b) applies only to print advertising and not to radio and broadcast advertising.

(Response) FDA clarifies that § 1143.3(b)(1) applies to cigarette tobacco, roll-your-own tobacco, and covered tobacco products except for cigars as they have their own warning requirements as enumerated in § 1143.5(b)(1). The FCLAA (15 U.S.C. 1331 *et seq.*), as modified by the Little Cigar Act of 1973 (Pub. L. 93–109), makes it unlawful to advertise ''cigarettes'' and ''little cigars'' on any medium of electronic communication subject to the jurisdiction of the Federal Communications Commission (15 U.S.C. 1333). In 1986, Congress enacted CSTHEA (15 U.S.C. 4401 *et seq.*), extending the broadcast ban to include advertisements for smokeless tobacco products.

FDA further clarifies that the requirements to include a warning in § 1143.3(b)(1) and § 1143.5(b)(1) apply to all forms of advertising, regardless of the medium in which it appears, for cigarette tobacco, roll-your-own tobacco, and covered tobacco products, including cigars. This final rule applies to advertisements appearing in or on, for example, promotional materials (point-of-sale and non-point-of-sale), billboards, posters, placards, published journals, newspapers, magazines, other periodicals, catalogues, leaflets, brochures, direct mail, shelf-talkers, display racks, Internet Web pages, television, electronic mail correspondence, or be communicated via mobile telephone, smartphone, microblog, social media Web site, or other communication tool; Web sites, applications, or other programs that allow for the sharing of audio, video, or photography files; video and audio promotions; and items not subject to the sale or distribution restriction in § 1140.34. Accordingly, the language of §§ 1143.3(b)(2) and 1143.5(b)(2) have been changed to clarify that the formatting requirements only apply to print advertisements and other advertisements with a visual component. FDA intends to provide guidance on how to comply with the health warning requirements on unique types of media.

4. Appropriateness of Required Warnings To Protect Public Health

(Comment 244) In response to FDA's request in the NPRM, comments included data and research regarding the effectiveness of health warnings. They submitted research indicating a need for accurate health warnings that are large enough to be readable (Refs. 3, 40) and grab the consumer's attention (Ref. 40). Comments also submitted research indicating that warning labels influence and increase awareness of the health risks associated with tobacco (Ref. 36, 37, 250) and discourage initiation in nonsmoking youth (Ref. 251). One comment cited other research which found that novel information presented to smokers was associated with greater relevance of the message and motivation to quit (Ref. 252).

(Response) FDA agrees that health warnings are an effective means to help consumers understand and appreciate the risks of using tobacco products.

(Comment 245) Many comments supported the requirement for all tobacco products to contain health warnings. For example, one comment cited WHO's 2011 report on the Global Tobacco Epidemic, which states that effective warning labels increase smokers' awareness of health risks and increase the likelihood they will think about reducing tobacco consumption and quitting (Ref. 253). The comment also cited a cohort study of textual warnings in the United Kingdom, before and after they were enhanced in 2003 to meet the minimum FCTC standard (Ref. 37). This study found that, after the enhanced warnings were implemented, UK smokers were more likely to think about quitting, to think about the health risks of smoking, and to be deterred from having a cigarette compared to smokers in Australia and the United States where smaller warnings did not conform to FCTC standards. Another comment stated that required warning statements on packages and advertisements should provide needed information to consumers in a conspicuous and clear manner.

(Response) FDA agrees. Health warnings on packages and advertisements help consumers to understand and appreciate the health risks of tobacco use and have 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 two most important times—when users 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. (See In re Lorillard et al., 80 FTC 455 (1972); FCLAA; CSTHEA.)

5. Staleness of Warnings

(Comment 246) Several comments noted that requiring only a single health warning for some newly deemed tobacco products does not allow for rotation and the warning will likely grow stale, resulting in little to no effect on consumers. They argued that FDA should require multiple warnings for the newly deemed products to allow for rotation and to maintain their effectiveness. Additionally, comments urged FDA to revise this warning and the other required health warnings as new evidence emerges on the health risks associated with tobacco products.

(Response) FDA acknowledges that the use of a single health warning for some newly deemed tobacco products could allow the warning to grow stale over time. While FDA declines to add additional warnings at this time, FDA issued an ANPRM prior to this deeming rule, seeking comments, data, research, or other information that may inform regulatory actions FDA might take with respect to nicotine exposure warnings. FDA also 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. FDA will use the results of this monitoring and research to help determine whether any of the warning statements should be revised, or if any additional warning statements should be added, in a future rulemaking.

6. Other Format Issues

(Comment 247) There were several comments on the general format of the health warnings. One comment stated that the warning provisions should require black text on a bright yellow background. According to the comment, researchers have found that yellow seizes attention, is the most noticeable, is the color the eye perceives fastest, and universally signals warning or danger (Refs. 254, 255). Another comment suggested that the front of the

package should include a short and explicit warning statement that is large enough to be readily visible and readable, and the back of the package should contain a warning large enough to more fully develop the basis for the front warning statement. The comment noted that the combination of short and salient health claims on the front of the package with more fully developed health information on the back would produce better consumer awareness and understanding, and greater believability of the health claim in the mind of the consumer. Finally, several comments stated that newly deemed products should be required to display large graphic warnings.

(Response) FDA declines to make these suggested changes at this time. The format requirements included with this final rule are similar to those included in a 2001 EU directive, which have been shown to increase the effectiveness of health warnings. 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 finalizing here (*i.e.,* the EU required health warnings comprise 30 percent of the area on the front of package and 40 percent on the back of the package; are in black Helvetica bold type on a white background; occupy the greatest possible proportion of the warning area set aside for the text required; and messages are centered in the warning area and surrounded by a black border of 3 to 4 millimeters (mm) in width). Before the 2001 Directive, warnings in most EU countries were very small and general. In one study conducted for the European Commission, a majority of respondents stated that the Directive's new warning format was more effective and more credible than the previous format (Ref. 256). 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. 257). Additionally, studies showed that the requirement that the warnings appear in black text on a white background or white text on a black background improved the legibility and noticeability of the warnings (Refs. 7, 38).

FDA believes that the prescribed format of the health warnings will be effective in helping consumers better understand and appreciate the risks of these products. However, 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. If FDA determines that modification of the format requirements is appropriate, we will consider changing these requirements in a future rulemaking.

(Comment 248) FDA received a large number of comments regarding the size of the required health warnings. Several comments agreed with the format requirements proposed in the rule. One comment cited a study concluding that youth and adults are more likely to recall larger warnings, rate larger warnings as having greater impact, and often equate the size of the warning with the magnitude of the risk (Ref. 36). The comment also stated that requiring health warnings that cover at least 30 percent of the front and back of cigarette packages is consistent with the FCTC.

Several comments argued that the required health warnings are too large. One comment stated that if the warnings are too large, they could have the unintended effect of making consumers numb to the warning message or otherwise lead to consumers ignoring the warning. Another comment stated that the size of FDA's proposed addictiveness warning should be evaluated in the context of the other information that already appears on the packaging of noncombusted tobacco products. This comment asserted that packaging for certain newly deemed products includes detailed warnings and other information important to reduce risks from inappropriate use or handling of the product and that such information may not fit on the package if the proposed health warning occupies 30 percent of the principal display.

Several comments stated that the proposed warning statement should not be required on cigars sold individually and not in product packages. One cigar retailer stated that requiring warnings on 30 percent of the principal display panels would be excessive. The comment believed that a health warning covering 30 percent of each cigar box would be excessive when there are multiple boxes, particularly when combined with the requirement for a warning sign at the point of sale. Another comment asserted that the size of the proposed health warnings would be inconsistent with the First Amendment.

Other comments argued that FDA should require larger health warnings. One comment stated that numerous studies show that youth and adults are more likely to recall larger warning messages and rate larger messages as having a greater impact (Ref. 37). Another comment stated that the FCTC suggests that warnings should cover 50 percent or more of a pack's principal surface, a standard adopted by a number of countries.

(Response) FDA finds that the required size of the health warnings is appropriate for the protection of public health. 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 a larger size and that appear on the front/major surfaces of the tobacco package (Ref. 7). The 30-percent warning label area requirement for product packages is also consistent with the size requirements for similar text-only warnings for smokeless tobacco mandated by Congress in CSTHEA (15 U.S.C. 4402(a)(2)(A)). FDA does not believe that the 30-percent warning label area requirement will make consumers numb to the warning message. Rather, FDA believes that the size of the warnings will be effective in helping consumers better understand and appreciate the critical information presented by the health warning.

FDA also believes that the 30-percent warning label area requirement is consistent with the First Amendment (as discussed in section II.B). Although the warning will occupy at least 30 percent of the packaging, there will remain sufficient space for additional warnings, manufacturer instructions, and branding. However, FDA intends to conduct research and keep abreast of scientific developments regarding the efficacy of the health warnings in the final rule and the ways in which their efficacy could be improved. If FDA determines that larger warnings would be more effective for these newly deemed products, the Agency will issue a new NPRM in accordance with the APA.

(Comment 249) Comments stated that FDA should not require manufacturers to use a font size that occupies the greatest possible proportion of the warning area because that would leave limited, if any, white space and may prove to be illegible. These comments suggested that FDA reduce the font size requirement to be consistent with smokeless tobacco warnings, which are required to take up 60 to 70 percent of the warning area.

(Response) FDA disagrees. Newly deemed tobacco products are sold in a variety of packaging sizes. By requiring the font size to be at least 12-point font, FDA is ensuring that the required warning statement will be noticed by consumers regardless of the package size. Further, FDA believes that this requirement will leave adequate background space so that the warning is

legible. The format requirements are similar to those included in a 2001 EU directive (requiring warnings to occupy the greatest possible portion of the warning area set aside for the required text), which have been shown to increase the effectiveness of health warnings, as further discussed in this section of the document. FDA is not aware of any legibility issues with the EU health warnings and does not expect any legibility issues with the health warnings included in this final rule.

The size of the warning clearly matters, as recall increases significantly with font size (Ref. 258). In a study on 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 font size for the warning to a 20-point font increased recall from 63 percent to 76 percent representing a 20 percent improvement in recall (id.). Research on cigarette package warnings confirms that larger warnings are better noticed and more likely to be recalled (Ref. 7 at App. C–3; Refs. 38, 49). These studies support FDA's conclusion that requiring the proposed warnings to appear in at least 12-point font size will improve their noticeability.

(Comment 250) At least one comment believed that requiring warnings to occupy at least 20 percent of the area of an advertisement would result in warning statements that, while visible, are more likely to be ignored. This comment suggested that appropriate warning statements be presented in a minimum font size (*e.g.,* no smaller than 11-point type).

(Response) FDA is unaware of any evidence stating that a health warning occupying at least 20 percent of the area of an advertisement is likely to be ignored. Nevertheless, to ensure that the statements are visible and effectively conveying information, FDA is finalizing §§ 1143.3(b)(2)(ii) and 1143.5(b)(2)(ii) to require a minimum 12-point font size for the health warnings on advertisements. Moreover, the requirement that the warning statement occupy at least 20 percent of the area of the advertisement is the same as the statutory requirement for press and poster advertisements for smokeless tobacco products (section 3(b)(2)(B) of CSTHEA (15 U.S.C. 4402(b)(2)(B))).

(Comment 251) At least one comment expressed concern with the font requirements of the labeling provisions because they require businesses to purchase a software package that provides either or both of the prescribed fonts (Helvetica and Arial), and these are proprietary fonts.

(Response) FDA disagrees. Both Helvetica and Arial fonts are included in common printing software. Thus, the requirement that manufacturers use Helvetica or Arial font should not cause them to incur any additional costs. However, we also have included language throughout part 1143, which allows manufacturers to use other similar sans serif fonts in order to provide additional flexibility while still ensuring that the warnings are conspicuous and legible to consumers.

(Comment 252) Many comments argued for different formatting requirements for the health warnings. Some suggested that they should be consistent with the current FTC Consent Decree, which requires that health warnings be clear and conspicuous in relation to the other communications on the packaging and be presented in a black box format to attract consumer attention. One comment stated that FDA should accept alternative warning sizes, placements, and font sizes for different packaging sizes and configurations, as long as the warning is clear and conspicuous. This comment urged FDA to be flexible about the size and placement of the warnings on deemed products, some of which are offered in packaging sizes and configurations very different from cigarette and smokeless tobacco packaging. This comment also noted that it can be difficult to identify the two principal display panels.

(Response) FDA disagrees. FDA has concluded that the formatting requirements for the health warnings, which are similar to the requirements for smokeless products and similar to those suggested by FCTC, are appropriate for the protection of the public health. In addition, we have added language to this final rule which recognizes that if a product package is too small to bear the required warning statement, the manufacturer of the product can include the warning statement on the outer carton or on a hang tag attached to the product package.

To clarify how to determine the principal display panels, FDA is defining ''principal display panels'' of a product package as the panels of a package that are most likely to be displayed, presented, shown or examined by the consumer. In addition, the principal display panels should be large enough to accommodate all mandatory label information in a clear and conspicuous manner. The principal display panels may be on an outer carton for small vials holding e-liquids.

7. Waterpipe Tobacco

(Comment 253) One comment argued that the required warning should not be applied to hookah (or waterpipe tobacco) because there is a lack of substantial scientific evidence of the addictiveness of this product. The comment expressed the belief that the majority of waterpipe tobacco smokers in the United States use the product once a week or less. Another comment asserted that studies of noncigarette products, including waterpipe tobacco, show that these products are perceived to present less risk of harm and addictiveness, thereby encouraging use among young adults. The comment added that strong warnings regarding the addictiveness of all tobacco products may reduce trial and use in vulnerable populations (Ref. 259).

(Response) FDA disagrees that the addictiveness warning should not be applied to waterpipe tobacco. Waterpipe tobacco contains nicotine, which is the primary addictive chemical in tobacco products. Researchers have observed nicotine dependence characteristics in some users (Refs. 238, 239, 240), with one study showing that waterpipe tobacco use suppressed withdrawal symptoms just as cigarette smoking suppresses withdrawal symptoms (Ref. 240). 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) likely exposes users to more nicotine than smoking a cigarette (which typically takes 5 to 7 minutes). Indeed, 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 in a single cigarette.

FDA agrees that there is consumer confusion about the addictiveness of waterpipe tobacco. Whereas studies have shown that cigarette and waterpipe tobacco smoking deliver similar nicotine levels, one study showed that 46.3 percent of high school students wrongly believed that waterpipe tobacco is less addictive or less harmful than cigarettes, and one-third of these students wrongly believed that the product had less nicotine, no nicotine, or was generally less addictive than cigarettes (Ref. 260). Mistaken beliefs that waterpipe tobacco smoking is ''safer or less addictive than cigarettes'' were more prevalent among those who had ever used waterpipe tobacco (78.2 percent) compared to nonusers (31.6 percent) (Ref. 260). A study of nearly 2,000 university students found that waterpipe tobacco was considered by

those students to be less addictive than e-cigarettes, marijuana, cigar products, smokeless tobacco, and cigarettes (Ref. 261). Research found that college students who had used waterpipes within the past 30 days considered them less addictive and less harmful than never-users did (Ref. 26). Similarly, another study found that ''[freshmen college] students who used waterpipes and cigars perceived them as less harmful than regular cigarettes'' (Ref. 262). Moreover, research has shown that such false beliefs about product risks can be a significant predictor of subsequent use behavior (Refs. 263, 264). For instance, adolescents with the lowest perceptions of short-term risks related to smoking were 2.68 times more likely to initiate smoking (Ref. 264). We note that the Surgeon General's 2014 Report provides an objective discussion of nicotine and addiction, where ''nicotine addiction develops as a neurobiologic adaptation to chronic nicotine exposure. However, all forms of nicotine delivery do not pose an equal risk in establishing or maintaining nicotine addiction'' (Ref. 9 at 112). Thus, pattern of use is a factor in the facilitation of addiction.

(Comment 254) One comment stated that FDA should require the addictiveness warning on all components of waterpipe tobacco use, including those products without nicotine or tobacco.

(Response) FDA disagrees. FDA finds that requiring health warnings on covered tobacco products only (and not on the components and parts that are not made or derived from tobacco) is appropriate to protect the public health, because youth and young adults will not be able to use such components and parts, and potentially suffer the consequences of tobacco use, *without also* using the covered tobacco product. In the event that FDA later determines it is appropriate for the protection of the public health to extend the warning requirements to components and parts that are not made or derived from tobacco, the Agency will initiate a new rulemaking in accordance with APA requirements.

8. Dissolvable Products

(Comment 255) One comment suggested that FDA recognize all dissolvable tobacco products as smokeless tobacco products for the purpose of warning label regulation and, as a result, subject all dissolvables to the smokeless warning requirements in section 204 of the Tobacco Control Act.

(Response) ''Smokeless tobacco product'' is defined in section 900(18) of the FD&C Act and for purposes of the warning requirements in CSTHEA (as amended by the Tobacco Control Act) as ''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.'' Some dissolvable tobacco products do not meet the definition of ''smokeless tobacco product'' because they do not contain cut, ground, powdered, or leaf tobacco; instead, these products contain nicotine extracted from tobacco. These products are the dissolvable products covered by this final rule. Because they do not meet the statutory definition of a smokeless tobacco product, FDA cannot recognize them as such, as suggested by the comments. If FDA determines that the warning statements for any type of dissolvable product should be revised, or if any additional warning statements should be added to them, the Agency will initiate a new rulemaking in accordance with APA requirements.

(Comment 256) One comment stated that the use of an addictiveness warning would serve to protect the public health by more clearly identifying dissolvable products as addictive tobacco products and differentiating them from candy.

(Response) FDA agrees. Certain tobacco products have a candy-like appearance, frequently are sold next to candy, and are packaged in a way that makes them more attractive to children, which can mislead consumers to think that they are, in fact, candy (Refs. 54, 215). The addictiveness warning will clearly identify these products as tobacco products and help differentiate them from candy.

9. Premium Cigars and Unpackaged Cigars

(Comment 257) Several comments stated that not requiring warnings on premium cigars and those sold individually and without product packages would greatly diminish the effectiveness of the cigar warnings. One comment stated there are many instances where cigars are purchased as gifts and, in those instances, the recipients would not see these warnings. One comment also stated that if a purchaser receives with the premium cigar any wrapper, container, pack or bag, then FDA should require that it include a health warning. This would ensure that if the premium cigar is given for a celebratory occasion, or if a minor obtained a premium cigar from an adult and did not see the point-of-sale warning, the user would be warned of the health risks. Another comment stated that the warning labels should be permanently affixed to or inside the cellophane wrappers in which the cigars are sold and in a way that is clearly visible to potential purchasers.

(Response) FDA understands these concerns. However, for those cigars sold individually and not in a product package, the placement of warnings at the point of sale will be adequate to disseminate the required health information and is appropriate for the protection of the public health. For cigars that are sold in cellophane wrappers, these wrappers are considered packaging and, under this final rule, must include the required cigar warnings. In addition, FDA notes that youth attempting to purchase these cigars would be prohibited from doing so under the minimum age requirements included in this final rule.

(Comment 258) One comment expressed concern that the NPRM did not provide for warnings where premium cigars and cigars sold individually and without product packaging are sold online. The comment suggested that these cigars should either not be allowed to be sold individually or that individual cigars should be required to be packaged and include a warning label.

(Response) Under the Internal Revenue Code and TTB regulations, cigars that are taxpaid upon removal from the factory or release from customs custody must be in the packages in which they will be delivered to the ultimate consumer (bearing any marks or notices required by the Internal Revenue Code and TTB regulations) at the time of removal, and must remain in those consumer packages until taken from the package by the consumer or in the presence of the consumer. Removing taxpaid cigars from the package, other than in the presence of the waiting consumer, is a violation of the Internal Revenue Code. Cigars may nonetheless be sold individually, provided that the individual product packaging meets the requirements of the IRC and TTB regulations. An online retailer sending such individual cigars purchased online can comply with FDA's requirements by placing the warning statement on the box or container that is used to ship the product. In addition, FDA clarifies that the warning requirements apply to all forms of advertising, regardless of the medium in which they appear. As stated previously, advertisements subject to this final rule may appear in or on, for example, promotional materials (point-of-sale and non-point-of-sale), billboards, posters, placards, published journals, newspapers, magazines, other periodicals, catalogues, leaflets, brochures, direct mail, shelf-talkers, display racks, Internet Web pages, television, electronic mail

correspondence, or be communicated via mobile telephone, smartphone, microblog, social media Web site, or other communication tool; Web sites, applications, or other programs that allow for the sharing of audio, video, or photography files; video and audio promotions; and items subject to the sale or distribution restriction in § 1140.34. As stated in § 1143.5(b)(2), the formatting requirements only apply to advertisements with a visual component. FDA intends to provide guidance on how to comply with the health warning requirements on unique types of media.

(Comment 259) One comment stated that premium cigars sold individually should include a health warning on the cigar tube, if applicable, or FDA should require retailers to provide a paper warning to the purchaser or put cigars in bags that are pre-printed with the warning labels.

(Response) It is unclear exactly how this comment intends to affix the warning to the premium cigar. If this comment is referring to affixing a warning to the cigar tube, this may damage the cigar and, therefore, is impractical. If this comment is seeking to add the warning to the tube that packages some individual cigars, FDA does not believe this is appropriate. Cigars sold individually in product packages, including cigars sold in tubes, must comply with the warning statement requirements for packaging. For cigars sold individually and not in product packages, the required warning statements must instead be posted at the retailer's point of sale. FDA believes that the point of sale signage requirement will ensure that premium cigar purchasers, as well as purchasers of other individual cigars, receive the required health warnings while allowing persons selling or distributing the cigars to maintain existing business practices.

(Comment 260) One comment expressed concern about retailers having to forfeit counter space for the placement of health warnings for cigars sold individually and not in product packages. The comment stated that this space is reserved for some of the most profitable items for sale in convenience stores. The comment also stated that the U.S. Circuit Court of Appeals for the District of Columbia struck down a similar, judicially imposed warning requirement that required retailers to set aside valuable retail space to display a point-of-sale sign. (*United States* v. *Philip Morris USA Inc.,* 566 F.3d 1095 (D.C. Cir. 2009).)

(Response) FDA believes that the point-of-sale warnings are necessary and appropriate for the protection of public health. FDA notes that the requirement only applies where cigars are sold individually and unpackaged, and will ensure that consumers of these products are exposed to the same health warnings as consumers of other cigar products. FDA also believes the point-of-sale warnings are necessary to prevent manufacturers and retailers of cigars from circumventing the warning requirement by selling their products without packaging.

Moreover, the *United States* v. *Philip Morris* holding cited in the comment was not on the merits and in any event is not applicable here. That case involved corrective statements mandated in a civil Racketeer Influenced and Corrupt Organizations Act (RICO) case brought against the United States' major cigarette companies. After finding the defendants liable for racketeering and fraud, the lower court issued an injunction that required the defendants to disseminate public statements in order to prevent and restrain future fraud. The statements were required to appear in various types of media—including large-point-of-sale signs present at the checkout counter of retailers that participated in defendants' ''participating retailer'' programs. On appeal, noting that the retailers were not involved in the RICO litigation but were negatively affected by the injunctive remedy, and had not had the opportunity to present arguments against the point-of-sale location before the lower court ruled, the appellate court vacated the point-of-sale requirement on due process grounds, and remanded for further consideration by the lower court. *Philip Morris USA Inc.,* 566 F.3d at 1141–42. The appellate court did not rule on whether mandatory point-of-sale corrective statements in valuable retail space are permissible under the RICO statute, but simply ruled that before the district court could impose such a requirement, the RICO statute required ''considering the rights of third parties and existing contracts'' (id. at 1145). By contrast, these warning requirements are being issued under the Tobacco Control Act, not the RICO statute; and are the product of notice-and-comment rulemaking.

10. Cigarettes and Roll-Your-Own

(Comment 261) Some comments stated that FDA should conform the proposed health warnings for cigarette tobacco and roll-your-own tobacco to the federally mandated health warnings for cigarettes required by section 4(s) of FCLAA and to health warnings that FDA mandates for cigarettes in the future.

(Response) FDA disagrees. Cigarette tobacco and roll-your-own tobacco do not meet the definition of the term ''cigarette'' in section 3(1) of FCLAA. Because cigarette tobacco and roll-your-own tobacco are not cigarettes as defined by FCLAA, they do not need to comply with section 4 of FCLAA requiring cigarette warnings and, therefore, do not contain any warning to alert consumers of the health effects of these products. Instead, the Tobacco Control Act defines cigarette tobacco and roll-your-own tobacco in sections 900(4) and 900(15) of the FD&C Act, respectively. The lack of a warning on these tobacco products may lead consumers to believe that they are safe products. Therefore, with this final rule, FDA is requiring that manufacturers of such products comply with the addiction warning in § 1143.3 and any other future health warnings that FDA mandates for these products, where appropriate.

(Comment 262) Some comments expressed concern about the following warning as applied to pipe tobacco products: ''WARNING: This product contains nicotine derived from tobacco. Nicotine is an addictive chemical.'' They stated that this warning is not appropriate for these products because the first sentence of the warning suggests that it is targeted at e-cigarettes whose nicotine is derived from tobacco, not tobacco itself. Other comments expressed concern that the word ''derived'' would not be well understood by the majority of consumers and introduced unnecessary complexity. They also noted that the statement that the nicotine is derived from tobacco does not provide information that is relevant to the user's health. One comment suggested a number of changes to the proposed addiction warning, including a simpler alternative: ''WARNING: This product contains nicotine. Nicotine is an addictive chemical.''

(Response) FDA agrees with concerns using the word ''derived.'' FDA has concluded that the suggested warning statement ''WARNING: This product contains nicotine. Nicotine is an addictive chemical'' is a more appropriate warning label because it provides an accurate warning for both products that contain leaf tobacco and products that contain nicotine derived from tobacco. It is also clearer and does not introduce unnecessarily complex terms that may make it more difficult for consumers to understand and appreciate the risks of addiction. Similarly, FDA is revising the alternative statement to

read ''This product is made from tobacco.'' to remove use of the word ''derived,'' which may not be easily understood. However, FDA disagrees with comments stating that this warning should not be required on pipe tobacco packages because pipe tobacco contains nicotine, which is the primary addictive constituent in tobacco products.

Thus, FDA has changed § 1143.3(a)(1) to require that 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 label: ''WARNING: This product contains nicotine. Nicotine is an addictive chemical.''

11. Addictiveness Warning

(Comment 263) One comment stated that the need to inform consumers about the addictiveness of nicotine has been implicitly recognized by a number of manufacturers of e-cigarette products. The comment stated that a recent investigation by the staff of 11 U.S. Senators and Representatives of the practices of 9 of the largest e-cigarette manufacturers revealed that, although their product warning labels ''lack uniformity and may confuse consumers,'' 6 of the 9 companies included some form of nicotine warning as part of their packaging or instructions for use, in addition to the nicotine warning these companies included to satisfy California's Proposition 65 (see Ref. 31). Although the warnings are not as comprehensive as FDA's required health warnings in terms of size and prominence, they reflect the companies' own recognition that their products are addictive and that consumers should be informed of their addictive properties.

(Response) Requiring health warnings on all newly deemed tobacco products will help consumers better understand and appreciate the addictive properties of these products.

(Comment 264) Some comments questioned whether large cigars, particularly premium cigars, should be required to carry an addiction warning because users do not inhale the cigar smoke.

(Response) Regardless of whether cigar smokers inhale, they are still subject to the addictive effects through nicotine absorption (Refs. 32, 34). Cigar smoke dissolves in saliva, allowing the smoker to absorb sufficient nicotine to create dependence, even if the smoke is not inhaled (Refs. 34, 35). Therefore, consumers using premium or other cigars can become addicted to cigars given the absorption of nicotine. Accordingly, FDA finds that it is appropriate for the protection of the public health to require this warning on all cigars.

12. Alternative Statement/Certification for Products Without Nicotine: ''This Product Is Derived From Tobacco.''

(Comment 265) Several comments expressed concern about requiring a tobacco product that does not contain nicotine to have an alternate health warning stating that, ''this product is derived from tobacco.'' These comments stated that future products that are not derived from tobacco would fall outside of FDA's jurisdiction and, therefore, would not be required to include this statement on product packages.

(Response) FDA agrees. If a product is not made or derived from tobacco, it would not be required to bear the alternative statement. However, if a product is made or derived from tobacco but does not contain nicotine, the product is required to bear the alternative statement. As discussed in section XVI.B, FDA is revising this alternative statement to read ''This product is made from tobacco.''

(Comment 266) Several comments stated that FDA should not permit use of the alternate statement ''This product is derived from tobacco'' because there are studies showing instances of e-cigarette products being labeled as zero nicotine and actually containing nicotine (Refs. 20, 170).

(Response) FDA disagrees. If a tobacco product manufacturer has mislabeled its product to indicate that it does not contain nicotine when in fact it actually does, the manufacturer will be subject to enforcement action for misbranding and the product will be required to bear the addictiveness warning (instead of the alternative statement).

(Comment 267) A few comments suggested that the alternative warning statement will cause consumer confusion because most people believe nicotine causes cancer and the alternative statement suggests there is a difference in the health risks based on solely the presence of nicotine. Other comments stated that the alternative statement should not use the term ''tobacco product'' because e-cigarettes do not contain tobacco leaf. These comments also stated that the words ''tobacco product'' could also potentially cause confusion because consumers do not consider e-cigarettes to be tobacco products.

(Response) FDA disagrees that the language in the alternative statement will cause confusion. The alternative statement does not use the term ''tobacco product'' and does not state that any ENDS product contains tobacco. Instead, the alternative statement included with this final rule states: ''This product is made from tobacco.''

FDA is not aware of any currently marketed tobacco product that does not contain nicotine. If such a product is introduced in the future, FDA believes it is important that both consumers and retailers be alerted that, although it may not contain nicotine, it is nevertheless a tobacco product. From a public health perspective, FDA believes that it is important to convey this factual information to consumers because tobacco products (*i.e.,* products made or derived from tobacco) could contain other addictive chemicals (like anabasine or nornicotine) and/or dangerous toxicants and can be psychologically addictive as well. For example, users of de-nicotinized cigarettes consistently report a significant degree of subjective satisfaction (Refs. 265, 266, 267). The alternative warning statement is especially important in light of the recent proliferation of novel tobacco products (*e.g.,* dissolvables that may appear like candy) that do not resemble traditional tobacco products, and therefore, which consumers may not know are made from tobacco. As the comments noted, some consumers are not even aware that e-cigarettes are tobacco products.

FDA believes that the fact that a product without nicotine is made from tobacco is important factual information that should be conveyed to both consumers and retailers. In addition to providing consumers with significant information that could affect their health, the statement will help ensure that retailers are aware that the product is and must be treated as a tobacco product. This will result in increased retailer compliance with the minimum age and photo identification requirements, as well as other applicable requirements. FDA believes that this factual alternative statement is the simplest, least burdensome, and yet effective way to inform both consumers and retailers that, despite the absence of nicotine, the product is still a tobacco product that, like other tobacco products, may not be purchased by or sold to persons under the age of 18 and requires the presentation and examination of a photo identification card.

13. Warning: Cigars Are Not a Safe Alternative to Cigarettes

(Comment 268) A few comments noted that evidence indicates there is a widespread perception, particularly among young people, that cigars are less hazardous than cigarettes and this perception may be contributing to the increased incidence of cigar smoking. According to the comments, one study found that adult cigar smokers in general are three times more likely to believe cigars are a safe alternative to cigarettes compared to those who do not smoke cigars (Ref. 268). They also cited an online survey of college students at six colleges in the southeastern United States, which found that smokers of little cigars and cigarillos ''were more likely to report perceiving the harm of little cigars, cigarillos, and cigars to be less than that of cigarettes'' when compared to nonusers (Ref. 269). In addition, a study of middle school and high school students in Massachusetts found that 34.9 percent of current youth cigar users agreed that ''cigars are not as bad for you as cigarettes,'' while only 12.2 percent of the total study population of students agreed with the statement (Ref. 270). The comments also cited a similar study that included a focus group study of 230 middle school, high school, and college students, which found that 30 percent of teen cigar users made the statement that, compared to cigarettes, cigars are less risky, and only 10 percent of teens with no cigar experience made that statement (Ref. 271).

(Response) FDA agrees that there is an unsubstantiated perception, especially among young people, that cigars are less hazardous than cigarettes (*see* 79 FR at 23158). This warning requirement will help to consumers understand and appreciate the risks of cigars.

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

(Comment 269) The comments differed as to whether the warning ''Tobacco Smoke Increases the Risk of Lung Cancer and Heart Disease, Even in Nonsmokers'' was appropriate. Some comments thought that the health warning was appropriate. At least one noted that a causal relationship exists between secondhand smoke exposure and lung cancer among lifetime nonsmokers, and individuals living with smokers had a 20 to 30 percent increase in the risk of developing lung cancer from secondhand exposure (Ref. 272 at 445). They stated that, since all cigars produce higher levels of toxicants than cigarette smoke, the science clearly supports the proposed warning.

However, several other comments stated that the scientific evidence does not support the claim that ''secondhand smoke causes premature death and disease in youth and in adults who do not smoke.'' One of these comments stated that the epidemiological links between ''being married to a smoker'' and increased disease are tenuous at best. While these comments agreed that on a per-stick basis, cigars can produce larger amounts of environmental tobacco smoke than do cigarettes, they stated that it is not accurate to conclude that this exposes household members to a considerable involuntary health risk.

(Response) FDA agrees with the comments stating that this warning is appropriate for the protection of the public health. It is well established that secondhand smoke causes premature death and disease in youth and in adults who do not smoke (Ref. 272 at 445, 532). Adult exposure to secondhand smoke has immediate adverse effects on the cardiovascular system and causes lung cancer and coronary heart disease (id.). Tobacco smoke contains over 7,000 compounds, and there are more than 70 carcinogens in sidestream and mainstream smoke generated from cigars (Refs. 9, 70, 273). 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. 69 at 65). Cigar smoke ''tar'' appears to be at least as carcinogenic as cigarette smoke ''tar'' (Ref. 272). 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. 69 at 17–18; Ref. 272 at 362).

There is a causal relationship between lung cancer and secondhand smoke. Exposure of nonsmokers to secondhand smoke also 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. 69 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 (id. at 75–76). Cigar smoke also produces measurable amounts of lead and cadmium (id. 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. 69 at 81).

The Surgeon General has reiterated that there is considerable evidence that certain nitrosamines are major factors in the development of lung cancer (Ref. 272 at 30). According to the Surgeon General, the evidence is sufficient to infer a causal relationship between secondhand smoke exposure and lung cancer among lifetime nonsmokers (Ref. 272 at 434). Individuals living with smokers have a 20 to 30 percent increase in risk of developing lung cancer from secondhand exposure (id. at 445). Although data particular to cigars are not available, FDA believes it is reasonable to expect that cigar smoke would produce similar effects as cigarette smoke, given that data from the National Cancer Institute (NCI) cigar monograph shows that some carcinogens determined to cause lung cancer are present at higher levels in cigar smoke than in cigarette smoke and are present at levels comparable to other carcinogens linked to lung cancer (Ref. 69 at 76–93).

There is also a causal relationship between secondhand smoke and heart disease. The health warning statement indicating that tobacco smoke can cause heart disease is thoroughly supported by the evidence reiterated in reports from the Surgeon General. FDA believes it is reasonable to conclude 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. 272).

In a 2006 Surgeon General's report regarding the health effects of exposure to secondhand smoke, the evidence demonstrated that exposure of adults to secondhand smoke had immediate adverse effects on the cardiovascular system and caused coronary heart disease (id. 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 (id. at 519; Ref. 273 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. 272 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. 275 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 (id. 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. Thus, FDA believes the warning statement that ''Tobacco smoke increases the risk of lung cancer and heart disease, even in nonsmokers'' is appropriate for the protection of the public health.

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

(Comment 270) Several comments disagreed with FDA's rationale for the warning ''Cigar smoking can cause cancers of the mouth and throat, even if you do not inhale.'' These comments noted that the rationale depends almost exclusively on Monograph 9 from the National Cancer Institute, which did not distinguish among cigar types and, therefore, should not be required for premium cigars. They also stated that cigars are safe products if users do not inhale the smoke, as illustrated by experimental data showing minimal toxicity because cigar smokers do not inhale (Refs. 32, 74).

(Response) FDA disagrees. The fact that Monograph 9 did not distinguish among types of cigars does not mean that it only applies to certain cigar types. In fact, the statement in the Monograph applied to all types of cigars. Any cigar use exposes the mouth and throat to tobacco smoke and can cause several different types of cancer even without inhalation (Refs. 69, 104). For example, one study found an increased risk of head and neck cancers for those who do not smoke cigarettes but had previously smoked cigars (Ref. 104).

While inhaling cigar smoke poses higher risk rates than not inhaling, significant risk still exists for those who do not inhale. In addition, most cigar smokers do inhale some amount of smoke and are not aware that they are doing it, including those who do not intend to inhale (Ref. 33).

16. Reproductive Health Warning for Cigars

In the proposed deeming rule, FDA proposed to require four of the five warnings already included on most cigar packages and in most cigar advertisements as a result of settlement agreements between the FTC and the seven largest U.S. cigar manufacturers. (See, *e.g., In re Swisher International, Inc.,* Docket No. C–3964.) FDA proposed not to require the fifth warning (SURGEON GENERAL 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 stated it was not aware of studies specifically linking cigars to all three reproductive effects. FDA requested comment on its proposal to require the use of only four of the five current FTC warnings for cigars.

During the comment period, FDA received several comments encouraging FDA to reconsider its proposal and finalize the rule to include all five warnings. In response to these comments, FDA reconsidered whether to require use of the FTC reproductive health warning. While FDA agrees that FTC's general warning statement ''Tobacco Use Increases the Risk of Infertility, Stillbirth and Low Birth Weight'' is a factually correct statement and recognizes that cigar smoke is similar to cigarette smoke in both chemical content and effects, on balance, FDA prefers a warning that is specific to cigars. Therefore, FDA has reconsidered the issue and is including a fifth warning statement to read ''WARNING: Cigar Use While Pregnant Can Harm You and Your Baby.'' which is well supported by direct evidence and is appropriate for the protection of the public health. However, FDA is also allowing manufacturers to use the FTC warning, which is appropriate for the protection of the public health, as an optional alternative to the new reproductive health warning.

The FTC warning is about tobacco smoke generally, and the statement itself is well supported by scientific evidence. Researchers have confirmed that smoking causes negative effects on fertility, pregnancies, and infants and children born to women who smoke. For example, cigarette smoking increases rates of preterm delivery, shortened gestation, and orofacial clefts, and studies have indicated that women who smoke are twice as likely to have low birth weight infants as women who do not smoke (Ref. 9 at p. 499; Ref. 275 at pp. 569, 576). In addition, scientific evidence supports that women who smoke have an increased risk of infertility and stillbirth (Ref. 276). It also causes an increased risk of sudden infant death syndrome (SIDS) for infants whose mothers smoke during and after pregnancy (Ref. 275 at pp. 587 and 601). In addition, scientific evidence supports the conclusion that cigar smoke has similarly toxic effects. NCI's Monograph 9 states:

> there is no reason to expect that cigar smoke would be any less toxic for the mother or fetus. Regular cigar smoking, particularly with inhalation, should be presumed to have risks similar to that of cigarette smoking for the pregnant smoker.

(Ref. 69 at 10). On balance, FDA prefers a warning that is specific to cigars, so FDA is finalizing this rule with different warning language specifically relating to cigars that the Agency concludes is appropriate for the protection of the public health. However, given the accuracy of the original FTC warning on its face, given that cigar smoke contains and delivers the same harmful constituents as cigarette smoke, and given extensive evidence that cigar smoke has similar physiological effects on the body, it is also appropriate for the protection of the public health for FDA to allow the use of the optional alternative (SURGEON GENERAL WARNING: Tobacco Use Increases the Risk of Infertility, Stillbirth and Low Birth Weight) to the reproductive health warning.

FDA selected the new warning language for several reasons. First, FDA finds that this warning is supported by direct scientific evidence that nicotine adversely affects maternal and fetal health (Ref. 9). Second, this warning uses the term ''cigar use'' rather than ''tobacco use,'' because the warning would appear on cigars only. Third, FDA finds that this is powerful and comprehensible phrasing, which will be understandable to a wide audience. Nevertheless, FDA recognizes that many cigar manufacturers currently use FTC's truthful warning on the reproductive risks of tobacco smoke. Therefore, FDA is also allowing an optional alternative (SURGEON GENERAL WARNING: Tobacco Use Increases the Risk of Infertility, Stillbirth and Low Birth Weight) to the reproductive health warning to comply with the warning requirements for cigars. FDA expects that allowing the optional alternative will benefit entities bound by the FTC consent decrees.

(Comment 271) Comments from cigar makers contended that because the NPRM and the FTC consent orders both required five warnings, but not the same

five warnings, manufacturers would not be able to use one set of warnings to comply with both regimes. As one comment put it, ''For example, manufacturers could not ensure a random display of FDA's five warnings 'in as equal a number of times as is possible,' as required by the NPRM, while including the reproductive effects warning required by FTC in that random distribution.'' This comment went on to state that a reproductive warning for cigars is also required by California's Proposition 65, and added that in response to an inquiry from FTC at the time of the FTC consent orders, the California Attorney General agreed that ''compliance with the FTC Consent Order will result in compliance with Proposition 65.'' (Comments of Altria Client Services Inc. on behalf of John Middleton Co., FDA–2014–N–0189–79814.)

Other comments urged that there is scientific support to require a reproductive warning for cigars. For example, one comment asserted that this warning is based on data related to cigarette smoke, and given that cigarette smoke is very similar to cigar smoke, and in many cases, cigar smoke is more dangerous than cigarette smoke, it is a logical conclusion that this warning is appropriate for cigars. Another comment noted that the 2014 U.S. Surgeon General Report on tobacco use devotes an entire chapter to the health effects of nicotine and documents that nicotine crosses the placenta and concentrates in the fetus (Ref. 9). The comment also noted that nicotine constricts vessels and thus limits the amount of nutrients and oxygen delivered to the fetus.

(Response) While FDA is unaware of data directly and explicitly linking cigar smoke to such reproductive issues, FDA recognizes the similarities between cigarette smoke and cigar smoke. On balance, FDA prefers a warning specific to cigars. However, as noted previously, FDA is allowing an optional alternative (SURGEON GENERAL WARNING: Tobacco Use Increases the Risk of Infertility, Stillbirth and Low Birth Weight) to the reproductive health warning to comply with the warning requirements for cigars. FDA expects that allowing the optional alternative will benefit entities bound by the FTC consent decrees.

(Comment 272) One comment expressed concern that the exclusion of the reproductive effects warning in a final rule (*i.e.,* the FTC warning that states ''Tobacco Use Increases The Risk Of Infertility, Stillbirth And Low Birth Weight''), and the subsequent advertising and sale of cigar packages without the warning, could result in claims that the FTC consent orders have been violated. The comment requested that FDA ensure that the absence of such warning in any final rule will not result in a claim that the FTC consent orders have been violated.

(Response) In the NPRM, FDA indicated that it planned to consult with FTC ''to harmonize national requirements for health warnings on cigar product packages and in advertisements'' (79 FR 23142 at 23163). As noted previously, FDA has given careful consideration to the comments and the scientific evidence on this issue and has decided to require a reproductive health warning for cigars, and the Agency has discussed this evidence and decision with FTC. At this time, FDA is not aware of any concerns from FTC regarding the cigar warnings included with this final rule.

17. Rotation of Warnings on Advertisements

(Comment 273) Several comments stated that rotational warning requirements should be simple, streamlined, and easily administrated, especially for small businesses. One comment suggested that it should be sufficient to print equal numbers of labels containing all six warnings and rely on the randomness of market distribution patterns without the administrative burden of demonstrating to FDA in a written rotational plan, and in subsequent facility inspections, that FDA can determine that each different warning was equally displayed to each consumer for each brand during a 12-month period.

(Response) While FDA recognizes that the random display and distribution of warning statements on cigar product packages and the rotation of statements on advertisements can result in administrative and financial costs for cigar manufacturers, FDA does not believe it would be sufficient to rely on the randomness of market distribution patterns. Relying on random distribution would not ensure that the different health warning messages are reaching as many individuals as possible, and the health warnings may grow stale from overuse if repeated too many times for the same individual. Thus, FDA is requiring warning statements for cigar packages to be randomly displayed in each 12-month period in as equal a number of times as possible on each brand of cigar. The required warning statements also are required to be randomly distributed in all areas of the United States in which the product is marketed. The random display and distribution of required warning statements for cigar packages must be carried out in accordance with a warning plan submitted by the cigar manufacturer, importer, distributor, or retailer to, and approved by FDA.

FDA is also requiring 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 rotation of warning statements in cigar advertisements also must be done in accordance with a warning plan submitted to FDA by the cigar manufacturer, importer, distributor, or retailer to, and approved by FDA. As stated in § 1143.5(c)(3) of this final rule, each person required to randomly display and distribute or rotate warnings in accordance with an FDA-approved plan under this part must submit a proposed warning plan to FDA no later than either 12 months after [date of publication of final rule], or 12 months before advertising or commercially marketing a product that is subject to such requirement, whichever is later. This 12-month submission timeframe provides cigar entities time to develop and submit warning plans to FDA. FDA encourages firms to submit warning plans any time within this 12-month period, and FDA plans to begin reviewing warning plans as soon as they are received. FDA is establishing this effective date at 12 months before the effective date of the required warnings for cigars described under part 1143 (24 months after the publication of the final rule) because the Agency anticipates that there will be a need for communication with submitters during its review of the warning plan submissions. This submission effective date also helps FDA to ensure that its surveillance program for compliance with the warning label requirements under § 1143 is implemented as of the effective date of 24 months after the publication of the final rule.

FDA intends to work with manufacturers, importers, distributors, or retailers to get an approved warning plan in place. Cigar entities may wish to contact FDA to discuss the submission of their warning plans in order to make the approval process more orderly and efficient. FDA's review and approval of a warning plan enables the Agency to more effectively conduct surveillance and inspection activities to ensure compliance with the warning label requirements under § 1143, once effective, by providing a guide regarding the expected rotation of the various warnings as required by the regulation. In addition, the review and approval

process will help manufacturers, importers, distributors, and retailers understand the requirements under this part; and help cigar entities minimize potential economic loss from the commercial distribution of nonconforming products in the market.

Additionally, FDA believes that it will be able to complete its review of the submitted warning plans by the effective date of the required cigar warnings. In FDA's experience with the review of warning plans for smokeless tobacco products, no smokeless tobacco product manufacturer, importer, distributor, or retailer was delayed or prevented from advertising or distributing smokeless tobacco products due to FDA's review of its warning plan, and FDA does not anticipate a different outcome here. FDA intends to issue a guidance document within 12 months after publication of the final rule to assist the cigar industry with the requirements for the submission of warning plans. In addition, if FDA receives a higher volume of warning plans than anticipated, and determines that it will not be able to review and approve submitted warning plans by the 24-month effective date, FDA may also consider implementing a compliance policy to ensure that cigar entities are not delayed or prevented from advertising or distributing cigars due to FDA's review of their warning plans.

These requirements are consistent with those established by Congress in the Tobacco Control Act for currently regulated tobacco products. Section 3 of CSTHEA (as amended by section 204 of the Tobacco Control Act) requires the random distribution and rotation of warnings for smokeless tobacco products. Further, rotation of cigar warning statements already occurs under the FTC consent decrees. The WHO also has recognized the need to rotate health warnings for tobacco products. The WHO's FCTC, evidence of a strong worldwide consensus regarding a regulatory strategy for addressing the serious negative impacts of tobacco products, calls for warnings that are ''rotating'' and ''large, clear, visible and legible'' (WHO FCTC article 11.1(b)).

(Comment 274) One comment stated that the proposed requirement that the warning statements be permanent or irremovable is ambiguous and does not specifically address whether labels applied by manufacturers (which manufacturers intend not to be removed but technically are removable) are compliant with the rule.

(Response) Section 1143.9 requires that the health warnings be indelibly printed on or permanently affixed to packages and advertisements. If a warning statement can be removed, then it is not permanent and does not meet the requirements of § 1143.9. Removable or impermanent warnings 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.

18. Warnings for E-Liquids

(Comment 275) Several comments recommended that FDA require multiple and rotating warnings on all e-liquids that contain nicotine. They stated the potential consequences of nicotine use need to be listed explicitly, as explicit warnings are associated with greater perception of potential danger than vague or general warnings (Ref. 277). Suggestions for e-cigarette warning label content included: (1) Toxicity and potential lethality of nicotine; (2) danger to skin and eyes; (3) danger from ingestion of nicotine liquids; (4) other potential health hazards, including burns and explosions, from ENDS use; (5) keep out of reach of children; (6) information about the heating mechanism (coil) and energy source (battery); (7) information about overheating or overuse, including risk of fire (if applicable); (8) warnings or precautions about use in or near water as well as any electrical shocks; and (9) warnings and instructions about replacing components and parts.

Another comment believed the Agency should consider requiring manufacturers of e-cigarettes to provide additional information for consumers in e-cigarette packaging, and as appropriate, for other newly deemed tobacco products. The comment suggested that this information could be presented using communication principles similar to those used in ''Drug Facts'' for over-the-counter drugs and should include information such as the nicotine addiction warning, age limits, warnings about danger to children and pets, and information about use during pregnancy and breast feeding.

(Response) At this time, FDA finds it is appropriate for the protection of the public health to require the warning regarding the addictiveness of nicotine on ENDS. However, as we have stated previously, this deeming regulation is a foundational rule, affording the Agency the ability to publish additional regulations as necessary and appropriate for the protection of the public health. FDA remains concerned about all of the health risks and hazards listed in this comment and will be focusing efforts and resources on future efforts to prevent nicotine poisoning in both users and nonusers. Therefore, FDA issued an ANPRM prior to this deeming rule, seeking comments, data, research, or other information that may inform regulatory actions FDA might take with respect to nicotine exposure warnings and the use of child-resistant packaging. In addition, elsewhere in this issue of the **Federal Register**, FDA has made available draft guidance for public comment, which when final will represent FDA's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products, including recommendations for exposure warnings and child-resistant packaging that would help to support a showing that the marketing of a product is appropriate for the protection of public health.

(Comment 276) Several comments noted that FDA should establish alternative methods for providing health warnings on tobacco products with small packages, such as e-cigarettes. One comment noted that FDA has created special rules for small food packages and small over-the-counter drug packages where the size of the package prevents the manufacturer from satisfying certain mandatory labeling requirements. This comment suggested that FDA implement similar alternatives for displaying warnings on small e-cigarette packages, and that the warning on advertising materials should not exceed 10 percent of the area of the advertisement. Another comment asserted that many e-liquids are packaged in relatively small 10 milliliter vials and that FDA should consider package size and design when mandating health warnings.

(Response) To address the issue of tobacco products with small packages, we have added § 1143.3(d) to this final rule, which states that a tobacco product that would otherwise be required to bear the warning in § 1143.3(a)(1) but is too small or otherwise unable to accommodate a label with sufficient space to bear the information is exempt from compliance with the requirement *provided* the information and specifications required under § 1143.3(a)(1) and (a)(2) appear on the carton or other outer container or wrapper if the carton, outer container, or wrapper has sufficient space to bear such information, or appears on a tag otherwise permanently affixed to the tobacco product package. In these cases, the carton, outer container, wrapper, or tag will serve as the location of the

principal display panels. For example, FDA is aware that e-liquids are frequently sold in small vials that may be unable to accommodate a label with sufficient space to bear a health warning. In addition, small boxes of replacement cartridges will be required to carry a warning if they contain nicotine or tobacco, or are otherwise made or derived from tobacco, and, therefore, are covered tobacco products. Such products also may not have sufficient space to bear a health warning. In these cases, a manufacturer could include such information on the carton or other outer container or wrapper if the carton, outer container, or wrapper has sufficient space to bear the information, or appear on a tag that is permanently affixed to the tobacco product package. With respect to the part of this comment stating that health warnings on advertising materials should not exceed 10 percent of the area of the advertisement, see the NPRM (79 FR 23142 at 23164) for additional discussion regarding the need for prominent health warnings.

XVII. National Environmental Policy Act

The Agency has carefully considered the potential environmental effects of deeming products to be subject to the FD&C Act and the 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.

FDA's responses to comments regarding the proposed Environmental Assessment are included in the following paragraphs.

(Comment 277) One comment stated that FDA erroneously relied upon the environmental impact analyses required by the National Environmental Policy Act (NEPA), suggesting that the Agency should review and analyze the total environmental impact of the rule.

(Response) FDA disagrees. The analysis of a regulation's environmental impact is governed by NEPA, which requires FDA to assess, as an integral part of its decisionmaking process, the environmental impacts of any proposed Federal action to ascertain the environmental consequences of that action on the quality of the human environment and to ensure that the interested and affected public is appropriately informed. FDA satisfied these requirements with the preparation of a proposed environmental assessment and a final environmental assessment (Ref. 278).

(Comment 278) One comment requested that FDA issue a new Environmental Assessment due to ''the loss of irreplaceable cultural historical resources that directly relate to the heritage of the [Ybor City National Historic Landmark] District, the City of Tampa, the State of Florida[, and] the United States of America.''

(Response) FDA denies this request. FDA prepared its Environmental Assessment in accordance with the requirements of 21 CFR part 25. FDA properly accounted for all potential environmental consequences of that action on the quality of the human environment. Therefore, a new Environmental Assessment is unnecessary and contrary to the requirements of NEPA (Ref. 279).

XVIII. Analysis of Impacts

We have examined the impacts of the final 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 us 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). We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. We believe that this final rule is a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. We find that the final rule will have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing ''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 $144 million, using the most current (2014) Implicit Price Deflator for the Gross Domestic Product. This final rule would result in a 1-year expenditure that meets or exceeds this amount.

This final rule finalizes Option 1 of the NPRM, which deems all products meeting the statutory definition of ''tobacco product,'' except accessories of a newly deemed tobacco product, to be subject to chapter IX of the FD&C Act. This final rule also finalizes additional provisions that would apply to certain newly 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 will apply to newly deemed products include establishment registration and product listing, ingredient listing, submissions prior to the introduction of new products, and labeling requirements. Free samples of newly deemed tobacco products will also be prohibited. The additional provisions of this final rule include minimum age and identification requirements, vending machine restrictions, and required warning statements for packages and advertisements.

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, under the final rule, all additional tobacco products that meet the statutory definition, except accessories of those newly deemed tobacco products, will be subject to chapter IX of the FD&C Act and its implementing regulations.[16] These products include cigars, pipe tobacco, waterpipe tobacco, ENDS (including e-cigarettes), and other novel tobacco products such as certain dissolvable products and gels. These products further include components and parts of the newly deemed products, including pipes, e-liquids, atomizers, batteries, cartomizers (atomizer plus replaceable fluid-filled cartridge), tank systems, flavors for e-liquids, vials that contain e-liquids, programmable software, flavor enhancers for waterpipe tobacco, waterpipe cooling attachments, water

[16] 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 under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)), a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)), or a combination product described in section 503(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)).

filtration base additives, flavored waterpipe tobacco charcoals, and waterpipe bowls, valves, hoses, and heads.

The final deeming action differs from most public health regulations in that it is an enabling regulation. In addition to directly applying the substantive requirements of chapter IX of the FD&C Act and its implementing regulations to newly deemed tobacco products, it enables FDA to issue further regulations related to such products that are appropriate for the protection of the public health. 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 require manufacturers to provide, for example, 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 newly deemed tobacco products subject to the requirements of chapter IX of the FD&C Act are difficult to quantify, and we cannot predict the size of these benefits at this time. Among other effects, new products will be subject to an evaluation to ensure they meet the appropriate public health standard for the pathway before they can be marketed, labeling cannot contain misleading statements, and FDA will be made aware of the ingredients in newly deemed tobacco products. If, without the final rule, new products would pose substantially greater health risks than those already on the market, the premarket requirements made effective by this final rule would keep such products from appearing on the market and worsening the health effects of tobacco product use. The warning statements required by this final rule will help consumers better understand and appreciate the risks and characteristics of tobacco products.

The final rule as a whole will impose costs in the form of registration, submission, and labeling requirements. Manufacturers of newly deemed products, as well as some manufacturers of currently regulated products, will need to comply with the warning label provisions, which will impose additional costs, including costs for signs with warnings at point-of-sale for cigars sold singly without packaging. There will be potential costs for removing non-compliant point-of-sale advertising and complying with vending machine restrictions.

The primary estimate for the present value of total quantified costs over 20 years is approximately $988 million at a 3 percent discount rate and $817 million at a 7 percent discount rate. The quantified costs of the final rule can also be expressed as annualized values, as shown in table 1. Unquantified costs which may be attributable to this final rule include: Some consumer costs for users of the newly deemed products due to loss of product variety or higher prices; recordkeeping costs for exporters of deemed tobacco products; compliance costs for components and parts other than complete pipes, waterpipes, and ENDS delivery systems; the cost of testing and reporting for HPHCs; the cost of any clinical testing that may potentially be conducted to support SE reports; market adjustment (friction) costs and lost producer surplus associated with product consolidation, exit of manufacturers, and the switch to pure retailing among retailers such as vape shops who currently engage in manufacturing activities.

TABLE 5—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 of Private Sector Costs	517.7	783.7	1,109.8	450.4	670.9	939.8
Present Value of Government Costs [1]	204.6	204.6	204.6	145.7	145.7	145.7
Present Value of Total Costs	722.3	988.2	1,314.4	596.1	816.5	1,085.4
Annualized Value of Private Sector Costs	34.8	52.7	74.6	42.5	63.3	88.7
Annualized Value of Government Costs [1]	13.8	13.8	13.8	13.8	13.8	13.8
Annualized Value of Total Costs	48.5	66.4	88.3	56.3	77.1	102.5

[1] FDA costs represent an opportunity cost, but this rule will not result in changes to overall FDA accounting costs, the size of the federal budget, or the total amount of tobacco industry user fees.

Because it is not possible to compare benefits and costs directly when the benefits are not quantified, we employ a breakeven approach. For the reasons provided elsewhere in this preamble and in the analysis of impacts, FDA has concluded that the benefits of the final rule justify the costs.

In addition to the benefits and costs of this final rule, we assess the benefits and costs of four different approaches. These approaches consist of regulatory alternatives (*i.e.,* alternatives to the rule) as well as enforcement options (*i.e.,* periods of time during which FDA does not intend to enforce certain requirements). First, we assess the regulatory alternative of exempting premium cigars from regulation. Second, we assess two hybrid regulatory alternatives/enforcement options of providing either a 36-month or 12-month compliance period for labeling changes. Lastly, we assess the enforcement option of not extending the premarket review compliance policy to new flavored tobacco products (other than tobacco flavored products).[17] For the sake of simplicity only, we have referred to these four approaches as ''alternatives to the rule.''

In addition to the above alternatives, comments discussed changing the grandfather date as an alternative. FDA has decided not to include this option in the analysis of alternatives because we determined that the Agency lacks the authority to change the grandfather date.

Primary estimates of the costs of the regulatory alternatives appear as present values and annualized values in table 6.

[17] Throughout the final RIA, any reference to ''flavored tobacco products'' means flavored products other than tobacco flavor.

TABLE 6—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—Exempt Premium Cigars from Regulation	959	794	64	75
2a—36-month compliance period for labeling changes	968	797	65	75
Final Rule and Compliance Period	988	817	66	77
2b—12-month compliance period for labeling changes	1,043	871	70	82
3—Do not extend the premarket review compliance policy to new flavored tobacco products	1,141	961	77	91

[1] Nonquantified benefits are described in the text.

In addition to the social costs described in this document, the final rule would lead to distributional effects, such as: Reduced revenues for firms in affected sectors, payment of user fees, and potential changes in tax revenues.

Domestic tobacco product manufacturers, tobacco product importers, and vape shops are the businesses primarily affected by this rule; most of these businesses are small. We focus the quantitative analysis of small entities on manufacturers and importers of cigars and ENDS products. We note that most pipe tobacco and waterpipe tobacco manufacturers and importers are also small, and we expect the impact on them to be similar to the impact on cigar manufacturers and importers. Even though user fees are a transfer payment and not a societal cost, they are a cost from the standpoint of the cigar and pipe manufacturers who must pay them under this final rule and have been included in the estimated burden for cigar manufacturers and importers. Estimated costs per cigar manufacturer or importer are $278,000 to $397,000 in the first year, $292,000 to $411,000 in the second year, and $235,000 to $257,000 in the third year. (The inclusion of user fees in these estimates will cause costs to be overstated for manufactures and importers who also manufacture currently regulated products. In addition, costs will vary by firm size as user fees are based on market share). Estimated costs per ENDS manufacturer or importer are $827,000 to $1.21 million in the first year, $832,000 to $1.21 million in the second year, and $22,000 to $64,000 in subsequent years. Although we do not quantitatively examine the financial effects on vape shops, we expect the proportion of vape shops that mix e-liquids may fall during the initial compliance policy period for submission and FDA receipt of PMTAs. After this initial compliance policy period, we expect that most vape shops will continue to operate but those that have not already switched pure retailing will likely do so. Regulatory alternatives that would reduce costs are analyzed as potential regulatory relief options for small businesses.

The Economic Analysis of Impacts of the final rule performed in accordance with Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act, and the Unfunded Mandates Reform Act is available at *http://www.regulations.gov* under the docket number(s) for this final rule (Ref. 204) and at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm*.

XIX. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown in the following paragraphs 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.

Title: 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; Restrictions 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 rule, the Agency is extending 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 deemed tobacco products. (Two options were presented in the NPRM. Under Option 1, all products meeting the definition of a ''tobacco product,'' except accessories of newly deemed tobacco products, would be deemed. Option 2 was the same as Option 1, except a subset of cigars known as ''premium cigars'' would be excluded. After thorough review of the comments and the scientific evidence, FDA has concluded that Option 1 more effectively protects the public health and therefore has made that the scope of the final rule.) The rule also prohibits the sale of covered tobacco products to individuals under the age of 18 and prohibits 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. The requirement that a retailer sell covered tobacco products in only a direct, face-to-face exchange without the assistance of electronic or mechanical devices is not intended to prevent the sale of tobacco products via the Internet, but the sale of covered tobacco products via any medium (including the Internet) must only be to persons 18 years of age or older.

The rule also provides that manufacturers, distributors, importers, and retailers are responsible for ensuring that the covered tobacco products (in addition to cigarettes and smokeless tobacco) they manufacture, label, advertise, package, distribute, import, sell, or otherwise hold for sale comply with all applicable requirements.

In addition, elsewhere in this issue of the **Federal Register**, FDA has made available a final guidance to provide information on how to establish and reference a Tobacco Product Master File (TPMF). TPMFs are expected to reduce the burden on applicants preparing premarket and other regulatory submissions because they can reference information in TPMFs rather than develop the information on their own.

Currently, FDA does allow for the submission and use of information to be incorporated by reference similar to master file programs for other FDA-regulated products.

A. Responses to Comments Regarding Proposed Collection of Information

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

(Comment 279) We received several comments regarding the practical utility of the information to be collected by FDA under the proposed regulations. The main concern among comments was that some of the requirements impose significant administrative burdens without generating useful information. Also, the comments believed that FDA is predicting that the paperwork burden will force almost all of the e-cigarette products to come off the market because manufacturers will go out of business.

(Response) FDA's regulation of the newly deemed products and the information the Agency is seeking will benefit the public health. As FDA discussed in the NPRM, deeming all tobacco products to be subject to chapter IX of the FD&C Act will provide FDA with critical information regarding the health risks of the products. FDA has not received any data indicating that regulation ''will destroy almost all of the e-cigarette products on the market.'' We also note that FDA is announcing a compliance policy for small-scale tobacco product manufacturers, offering them targeted relief to address concerns that small manufacturers may need additional time to comply with certain requirements of the deeming rule, as discussed in section IV.D. This compliance policy will provide small-scale tobacco product manufacturers (*i.e.,* those manufacturers with 150 employees or fewer and $5,000,000 or less in annual revenues) with additional time to submit ingredient listing information (under section 904(a)(1)) and health documents (under section 904(a)(4)). This policy also provides that, for the first 30 months following the effective date of the rule, small-scale tobacco product manufacturers may receive extensions of time for providing responses to SE deficiency letters.

(Comment 280) One comment stated that FDA's proposed regulation is unnecessary and does not address any valid need in society. It also stated that the PRA should set limits on regulations that do not provide significant return to the U.S. population. Another comment asked that FDA not stifle advertisements, nor saddle the industry with unnecessary testing and reporting standards that stifle innovation and increase costs.

(Response) FDA disagrees with comments suggesting that FDA's rule will have such effects on industry or the nation. FDA finds that deeming tobacco products and applying the automatic provisions of the FD&C Act in accordance with this final rule will result in significant public health benefits and that the additional restrictions imposed by this rule are appropriate for the protection of the public health. For example, benefits that will arise as a result of deeming ENDS, including FDA review of premarket submissions/applications for new tobacco products in the United States pursuant to sections 905 and 910 of the FD&C Act, which will result in increased product consistency. FDA expects to receive premarket submissions/applications from ENDS manufacturers that will allow the Agency to determine whether a new product is substantially equivalent to a valid predicate product, exempt from SE., or appropriate for the protection of the public health.

2. Accuracy of FDA's Estimate of the Burden of the Proposed Collection of Information, Including the Validity of the Methodology and Assumptions Used

(Comment 281) Many comments argued that their products could be driven from the market due to the paperwork reporting requirements and FDA's authorization process. The comments claimed that many companies (particularly e-cigarette companies) lack experience or the systems in place to comply with the NPRM and that the premarket requirements would discourage the development of new products. They also said that requirements like labeling and registration would be unfeasible for small producers lacking the experience of navigating this regulatory environment.

(Response) FDA expects that the greater regulatory certainty created by the premarket review process will help companies to invest in creating novel products that benefit the health of the population as a whole, with greater confidence that the improved products in which they have invested will enter the market without having to compete against equally novel products that do not have to meet the same basic requirements. We also note that FDA is announcing a compliance policy for small-scale tobacco product manufacturers, offering them targeted relief in certain areas to address concerns that small manufacturers may need additional time to comply with certain requirements of the FD&C Act, as discussed in section IV.D. This compliance policy will provide small-scale tobacco product manufacturers (*i.e.,* those manufacturers with 150 employees or fewer and $5,000,000 or less in annual revenues) with additional time to submit ingredient listing information (under section 904(a)(1)) and health documents (under section 904(a)(4)). This policy also provides that, for the first 30 months following the effective date of the rule, small-scale tobacco product manufacturers may receive extensions of time for providing responses to SE deficiency letters.

(Comment 282) Several comments stated that the PMTA process imposes a number of burdens on manufacturers, the most onerous burden being the requirement for scientific investigations.

(Response) In the NPRM (79 FR 23142 at 23176), FDA included discussion intended to supplement and clarify the requirement for scientific investigations. As we noted, FDA expects that, in some cases, it will be possible for an applicant to obtain a PMTA marketing order without conducting new nonclinical or clinical studies where there is an established body of evidence regarding the public health impact of the product. Therefore, FDA believes that certain categories of PMTAs may not require significant financial and administrative resources associated with clinical investigations. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a draft guidance, which when final will provide the Agency's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products, including the need for ''clinical studies'' for the purposes of preparing PMTAs for ENDS. In addition, elsewhere in this issue of the **Federal Register**, FDA has made available a final guidance to provide information on how to establish and reference a Tobacco Product Master File. TPMFs are expected to reduce the burden on applicants preparing premarket and other regulatory submissions.

We also note that FDA is announcing an enforcement policy for small-scale tobacco product manufacturers, offering them targeted relief in certain areas to address concerns that smaller manufacturers may have, as discussed in section IV.D. This compliance policy will provide small-scale tobacco product manufacturers (*i.e.,* those manufacturers with 150 employees or

fewer and $5,000,000 or less in annual revenues) with additional time to submit ingredient listing information (under section 904(a)(1)) and health documents (under section 904(a)(4)). This policy also provides that, for the first 30 months following the effective date of the rule, small-scale tobacco product manufacturers may receive extensions of time for providing responses to SE deficiency letters.

(Comment 283) Several comments expressed concern that FDA failed to provide any data on the number or type of e-cigarette businesses currently operating in the United States. According to the comments, there are at least 1,250 businesses. Other comments estimated that there are 14,000 to 16,000 e-cigarette retail outlets in the United States. They stated that these small manufacturing entities will not be able to participate in the PMTA process and most will go out of business.

(Response) At the time of the NPRM, FDA did not have precise estimates for ENDS products. Now that we have more data, the Agency is estimating the numbers for ENDS liquids and delivery systems elsewhere in the PRA section. As stated previously, FDA believes the TPMF process will help companies as they can reference information in TPMFs rather than develop the information on their own. Additionally, the enforcement policy for small-scale tobacco product manufacturers will assist small manufacturers. This compliance policy will provide small-scale tobacco product manufacturers (*i.e.,* those manufacturers with 150 employees or fewer and $5,000,000 or less in annual revenues) with additional time to submit ingredient reporting (under sections 904 and 915) and health documents (under section 904). This policy also provides that small-scale tobacco product manufacturers may receive extensions of time for providing responses to SE deficiency letters.

(Comment 284) Some comments noted that the NPRM made it appear that FDA would not allow any SE reports to be submitted for e-cigarette products, as there were only about a half dozen first generation e-cigarette products that were sold in the United States in February 2007 (the grandfather date), and those products are not substantially equivalent to any of today's products. Comments stated that applicants would then need to submit PMTAs and estimated that each PMTA would cost a successful applicant between $3 and $20 million.

(Response) The FD&C Act provides three pathways for obtaining FDA authorization to market a new tobacco product. Where a new product does not meet the requirements for SE exemption under section 905(j)(3) and does not have an appropriate predicate under section 905(j)(1)(A)(i) or is otherwise unable make a showing supporting a finding of SE., the manufacturer of the new product must submit a PMTA. As FDA stated in the NPRM, the Agency expects that some applicants may not need to engage in resource-intensive clinical investigations and provide long-term data to prepare and submit a complete PMTA. In addition, elsewhere in this issue of the **Federal Register**, FDA has made available draft guidance, which when final will describe FDA's current thinking regarding some appropriate means of addressing the premarket authorization requirements for newly deemed ENDS products, including the need for clinical studies for the purposes of preparing PMTAs for ENDS.

(Comment 285) Several comments argued that FDA has greatly underestimated the total number of e-liquid products that are on the market. According to one comment, there are nearly 1,700 e-cigarette and e-liquid businesses on record, which does not include the many companies that manufacture hardware components used in ARPVs. One comment stated that a recent study found that greater than 34,000 different e-liquid products alone were sold on the Internet (*i.e.* 7,764 unique brand flavors averaging 4.4 different nicotine levels per brand) not including different vegetable glycerin/propylene glycol water levels or components in 466 identified different e-cigarette brands. Several comments estimated that there are 5,000 to 15,000 e-liquid producers and e-cigarette retail establishments in the United States. Other comments projected that there are at least 100,000 e-cigarette products currently on the market.

Similarly, some commenters felt that FDA grossly underestimated the number of responses for certain proposed information collections. For example, they noted that the NPRM states that FDA expects only 25 new product applications from e-cigarette manufacturers. They claimed that FDA has either miscalculated the number of distinct brands and types of e-cigarettes on the market, or the Agency expects most manufacturers to exit the market rather than submit product applications.

(Response) We have revised our estimates to reflect the most recent information available at the time of drafting this final analysis. FDA estimates the average number of vape shops that meet the definition of a manufacturer are 4,250. FDA also estimates that there will be 186 other manufacturers and 14 importers of ENDS products.

(Comment 286) Many comments said that FDA's estimates of the burdens imposed by the rule's information collection requirements are understated. Specifically, they stated that the Agency's estimates of the number of respondents in the category of ''other tobacco, e-cigarettes, and nicotine product manufacturers,'' as well as the number of products on the market manufactured by these companies, were off by orders of magnitude.

(Response) Based on the comments and other evidence, FDA estimates there will be 186 manufacturers of ENDS products. Regarding the number of products, the number will depend on what type of submission is being sent to FDA. The burden charts in this section detail the current estimates FDA believes to be accurate.

(Comment 287) Some comments indicated that FDA equates the time and financial burden of preparing a PMTA with an SE application, but the PMTA requirements are significantly more burdensome than SE requirements, and it is completely unreasonable to allocate the same amount of man-hours needed to successfully complete a PMTA and an SE application.

(Response) The Agency has revised the estimated burden per PMTA response to an average of 1,500 hours to complete a PMTA. In reaching this average, FDA considered efficiencies achieved through manufacturer experience, application overlap, economies of scale, incorporation of evidence by reference, and other means including availability of the SE FAQ guidance. Based on this information, FDA believes an SE submission will take considerably less time and money. If the manufacturer is unable to show that its product is substantially equivalent to a predicate product or that its product is exempt from SE., then the manufacturer must submit a PMTA. The requirements of a PMTA may vary based on the type and complexity of the product.

(Comment 288) One comment said that FDA erred in its estimate of the in-house cost burdens imposed by the proposed information collections. The comment said internal costs can only be excluded when estimating the burden of an information collection if such costs are related to ''usual and customary'' activities. In this case, the comment believed FDA did not consider the types of internal costs that will be incurred by companies to comply with the information collections.

(Response) FDA disagrees with this comment. The Agency was thorough in

its identification of usual and customary activities. The Agency used various existing data sources and considered all the costs associated with the collections of information. In reaching this average cost, FDA considered efficiencies achieved through manufacturer experience, application overlap, economies of scale, incorporation of evidence by reference, and other means.

(Comment 289) A few comments stated that most of the cost burden created by paperwork requirements will fall upon consumers, as hundreds of thousands of American consumers would lose access to what the comments state are ''low-risk products'' that have allowed consumers to quit smoking. They said FDA should take into consideration small business and consumer stakeholders' suggested alternatives to minimize the NPRM's potential impact.

(Response) FDA disagrees with these comments. This final rule will prevent new products from entering the market that are not appropriate for the protection of the public health, are not substantially equivalent to a valid predicate product, or are not exempt from SE. We also note that FDA is announcing a compliance policy for small-scale tobacco product manufacturers, offering them targeted relief in certain areas to address concerns that smaller manufacturers may need additional time to comply with certain requirements of the FD&C Act, as discussed in section IV.D. This compliance policy will provide small-scale tobacco product manufacturers (*i.e.,* those manufacturers with 150 employees or fewer and $5,000,000 or less in annual revenues) with additional time to submit ingredient listing information (under section 904(a)(1)) and health documents (under section 904(a)(4)). This policy also provides that, for the first 30 months following the effective date of the rule, small-scale tobacco product manufacturers may receive extensions of time for providing responses to SE deficiency letters.

(Comment 290) Several comments stated that FDA significantly underestimated the burden on the tobacco industry. The Agency estimated that 13,745 products will be affected by the NPRM and almost 90 percent of them were cigars and pipe tobacco. They noted that FDA estimated that up to 7,869 products will submit SE reports within the first 24 months after the rule is finalized, which they believed was very low, especially given the February 15, 2007, grandfather date.

(Response) FDA used available public information to estimate the burden on the tobacco industry and the comments did not provide empirical evidence of a different number of affected products. However, based on experience with currently regulated products and changes in the industry we have revised the burden accordingly. The Agency also finds that these comments have not provided evidence as to why the grandfather date will cause applicants to submit more SE applications than FDA estimated.

(Comment 291) One comment argued that FDA has greatly underestimated the number of premium cigar products that will be subject to premarket review. According to the comment, premium cigar makers are distinct from other tobacco product manufacturers in the number of products they market and the volume of those lines. This comment stated that the average number of cigars produced for any given product in a year is 32,655, with 33.6 percent of reported annual production rates at or below 10,000 units.

Several other comments argued that the typical premium cigar manufacturer may have over 100 unique stock keeping units (SKUs) and typically will turn over about 15 percent of those SKUs in any given year. Their data indicates there are at least 10,000 and maybe as many as 20,000 unique SKUs in the United States, which would add to FDA's workload for evaluating new product applications. They also estimated that the premium hand-rolled cigar category alone could generate numbers in excess of 10,000 new product applications.

Other comments stated that the premarket application process will be costly and time consuming for cigar manufacturers and will likely result in many different kinds of newly deemed tobacco products being removed from the marketplace. The constant variation in the cigar tobacco used to make premium cigars will create significant regulatory burdens and costs for cigar manufacturers to be constantly submitting premarket applications. Comments stated that cigar manufacturers that are unable to bear the cost of applications will cease bringing new products to the marketplace.

The comments expressed similar concerns regarding e-cigarettes, stating that each e-cigarette manufacturer would need to submit a PMTA for every brand of e-cigarette currently being sold and new e-cigarettes introduced into the marketplace. Small manufacturers may not have the financial resources to submit PMTAs, which will result in the removal of e-cigarettes from the marketplace. The end result of the PMTA process will be a significant negative impact on small businesses.

(Response) The FD&C Act provides for three marketing pathways for new tobacco products—SE to a valid predicate product, exemption from SE., and PMTA. If the manufacturer is unable to show that its product is substantially equivalent to a valid predicate product or that its product is exempt from SE., then the firm must submit a PMTA. The requirements and costs of a PMTA may vary based on the type and complexity of the product. For example, where there is limited understanding of a product's potential impact on public health, several nonclinical and clinical studies may be required for market authorization. In such case, the requirements and cost of the PMTA likely would be higher than for a product in which there is already substantial scientific data on the potential public health impact.

(Comment 292) Many comments noted that FDA included a small number of PMTAs for e-cigarette products in its analysis. Some comments stated that if this is the case, FDA's estimates would probably include only a fraction of the products that are believed to be used to stop smoking cigarettes. They commented that the cost burdens of the paperwork requirements will result in an unnecessary price increase for the consumer and the PMTA requirements will limit the availability of e-cigarettes to addicted smokers trying to quit. Their concern is the burden of the paperwork would fall on both merchants and consumers.

(Response) FDA disagrees with these comments. The Agency's intention is not to impose additional costs to consumers but, instead, to prevent new products from entering the market that are not appropriate for the protection of the public health, are not substantially equivalent to a predicate product, or are not exempt from SE. Per Agency experience and updates in the industry, FDA has updated the number of ENDS products we estimate will submit a PMTA.

(Comment 293) Some comments disagreed with FDA's estimate that it expects only one ''other tobacco, e-cigarette and nicotine product manufacturers'' respondent to submit an annual health and toxicological report and its estimate that there would only be one respondent to self-certify that its product does not contain nicotine. They stated that there may be hundreds of e-liquid manufacturers self-certifying for use of the alternative statement, because it is standard industry practice to offer 0 milligram nicotine flavors in vials.

(Response) At this time, we do not have sufficient evidence to warrant revising the burden estimates.

(Comment 294) Many comments stated that FDA's estimates do not reflect the realities of the market and FDA's estimates assume that most of these small companies will be forced to exit the industry because of the high compliance and paperwork burdens envisioned by the NPRM. However, others believed that as the market evolves, many companies will continue to operate and comply with FDA's regulations.

Further, many other comments stated that, at best, FDA's estimate that there are only 140 to 188 potential respondents in the category of ''other tobacco, e-cigarettes, and nicotine product manufacturers'' is ''egregiously off target'' based on the available evidence. They believed that the entire industry will be eliminated as a result of the regulatory and paperwork burdens in the NPRM. They also noted that the reason for the difference between 140 and 188 in the Analysis of Impacts and PRA sections is unclear.

(Response) There is a high level of uncertainty in the number of manufacturers of ENDS. FDA is required to estimate burden as part of the PRA analysis. As many comments describe, the industry is ever changing; during the time that the NPRM was in review, and since the NPRM was published, the ENDS industry has grown. The comments on the number of ENDS manufacturers provided industry estimates rather than concrete data sources. In the case of non-retail manufacturers, the comment did not always specify whether the cited numbers included both domestic and foreign manufacturers, or only domestic manufactures. Therefore, considerable uncertainty remains as to the number of domestic non-retail manufacturers. Similarly, the comments did not address the number of non-retail importers. In the Regulatory Impact Analysis (RIA) for this final rule, based on logo counts from trade association Web sites and FDA listening sessions, it is estimated that there are 168 to 204 formal manufacturers of ENDS products (not including ENDS retail establishments that meet the definition of a manufacturer). For the PRA analysis, we took the average for a total of 186 manufacturers. We also estimate that there are 14 importers of ENDS products.

(Comment 295) Many comments stated that it would not be possible to complete a PMTA within 24 months after the effective date of the final rule and that it is an insufficient amount of time for manufacturers to conduct any required clinical studies in support of a PMTA.

(Response) As stated throughout this document, FDA is providing a 24-month compliance period for manufacturers to submit (and for FDA to receive) a PMTA. If manufacturers submit the appropriate applications during this compliance period, FDA will not enforce against those manufacturers continuing to market their products without FDA authorization for a certain time period. For products using the PMTA pathway, this compliance period closes 36 months after the effective date. Once the continued compliance period ends, FDA intends to actively monitor and enforce the premarket authorization requirements regarding products on the market without authorization even if the respective submission is still under review. As noted previously, FDA expects that, in some cases, it will be possible for an applicant to obtain a PMTA order without conducting any new nonclinical or clinical studies where there is an established body of evidence regarding the public health impact of the product. Therefore, FDA believes that many PMTAs may not require significant administrative resources associated with clinical investigations.

(Comment 296) Several comments noted that if FDA requires health documents from manufacturers and importers of newly deemed tobacco products, the Agency should establish a similar production timeline as it did for currently regulated products (*i.e.,* cigarettes, cigarette tobacco, smokeless tobacco, and roll-your-own tobacco) and only require production of health documents developed during the 6-month period following the effective date of the regulation.

(Response) As stated in the compliance date tables, the compliance period for manufacturers of products currently on the market to submit health documents is 6 months after the effective date of the final rule. Manufacturers of products entering the market after the effective date of the final rule must comply within 90 days before delivery of the product for introduction into interstate commerce. With this final rule, FDA also is announcing that it will extend the compliance period for an additional 6 months from the effective date to allow small-scale tobacco product manufacturers time to organize, compile, and digitize documents. Additionally, as stated elsewhere, FDA generally does not intend to take enforcement action regarding the submission of all such documents at this time so long as a specified set of documents are submitted by [the effective date plus 6 months]. FDA will publish additional guidance that specifies the scope of such documents with sufficient advance time for manufacturers and importers to prepare their submissions.

(Comment 297) Some comments stated that FDA has underestimated the number of other tobacco product manufacturers that will submit the required health documents.

(Response) FDA based this burden estimate on the existing collection that applies to tobacco products currently subject to the FD&C Act and FDA experience. The comments did not provide a basis or an estimate of other tobacco product manufacturers for FDA to utilize in its review, and the Agency is not aware of any information that warrants changing this estimate. We note that at this time, FDA intends to limit enforcement to finished tobacco products. A finished tobacco product refers to a tobacco product, including all components and parts, sealed in final packaging intended for consumer use (*e.g.,* filters, filter tubes, e-cigarettes, or e-liquids sold separately to consumers or as part of kits). FDA does not at this time intend to enforce this requirement for components and parts of newly deemed products that are sold or distributed solely for further manufacturing into finished tobacco products. However, any component or part of a newly deemed tobacco product that is sold directly to consumers as a ''finished tobacco product'' will be required to comply with the premarket review requirements discussed throughout this document.

(Comment 298) Some comments stated that e-liquid companies should be allowed to amend their ingredient lists if they add or remove ingredients or increase the maximum concentration of any of their current ingredients in any of their products, rather than submit a new ingredient list for the new product.

(Response) Ingredient listings contain important data that enable FDA to gain better understanding of the contents of regulated products. This information will assist FDA in assessing potential health risks and determining if future regulations to address these health risks are warranted. In addition, when an e-liquid manufacturer adds or removes ingredients from a product, it becomes a ''new tobacco product.''

(Comment 299) Several comments disagreed with FDA's proposed premarket review burdens for pipe tobacco manufacturers. At least one comment indicated that FDA's proposed estimate that it will receive only one

new product application for pipe tobacco products grossly underestimates the number of brands of pipe tobacco that have entered the market since 2007 or indicates that the Agency expects all but one manufacturer to voluntarily stop production of new pipe tobacco products without submitting an SE report or PTMA application. In addition, the comments stated that pipe tobacco manufacturers will incur cost and time burdens if they are required to submit PMTAs for each new blend of pipe tobacco that they manufacture, including millions of dollars per year in research to prepare the PMTAs.

(Response) At this time, FDA finds there is insufficient evidence to increase the burden estimates. FDA believes that pipe tobacco manufacturers will utilize the SE and SE exemption pathways. We believe they are manufactured similarly with few, if any, modifications and many of the ingredients and suppliers are the same as those utilized in previous years.

(Comment 300) Several comments pointed out inconsistencies between the PRA and Analysis of Impacts sections in the NPRM. They noted that the Analysis of Impacts clearly states that FDA does not have an estimate of e-cigarette entities that would register with FDA. If FDA could not estimate the number of affected entities in the Analysis of Impacts, they believed this should also be reflected in the PRA section. In addition, they stated that the estimated number of PMTAs (25) in the PRA section contradicts the number of estimated PMTAs in the Analysis of Impacts.

(Response) The RIA and PRA analyses are conducted to fulfill different purposes and must adhere to different requirements; as a result, the two analyses would rarely, if ever, be the same. For example, the time horizons for the analyses are typically different. Information collections are approved for a up to a 3-year period and are reanalyzed every time they are up for extension, whereas a prospective RIA is conducted before a rule is issued using a time horizon chosen to capture the most important effects of the rule (generally 20 years). If estimates differ from year to year, the RIA will often explicitly identify how the estimates vary, whereas the PRA analysis will most often use an average or the estimate for the current year. Regulatory impact analyses also tend to make more frequent use of ranges rather than point estimates.

As referenced previously, there is a high level of uncertainty in the number of manufacturers for ENDS. In the RIA for this final rule, based on logo counts from trade association Web sites and FDA listening sessions, it is estimated that there are 168 to 204 formal manufacturers of ENDS products. For the PRA analysis, we took the average of 168 and 204 for a total of 186 manufacturers. We also estimate that there are 14 importers of ENDS products.

(Comment 301) A number of comments also noted that FDA should be required to estimate and report the full social costs of eliminating what they considered to be beneficial products from the market where the manufacturers are unable to afford the PMTA costs.

(Response) FDA is not aware of any evidence indicating that such social costs will accrue. Nevertheless, such estimates are outside the scope of the PRA analysis.

3. Ways To Enhance the Quality, Utility, and Clarity of the Information To Be Collected

(Comment 302) One comment stated that FDA has not consulted with industry nor has the Agency audited industry recordkeeping to support the assumption that manufacturers have enough information to prepare SE reports.

(Response) FDA's proposed burden estimates are based on information available at the time of preparing the NPRM. If interested parties have evidence that warrants revising these burden estimates, they were requested to submit such evidence during the comment period for FDA to take into account when preparing final burden estimates.

(Comment 303) One comment recommended that the Office of Information and Regulatory Affairs (OIRA) should void the proposed regulations as they relate to e-cigarettes, that OIRA and FDA should urge Congress to work with FDA to create a new regulatory framework for e-cigarettes, and, at the very least, that OIRA require that FDA prepare new estimates of the paperwork burdens.

(Response) FDA disagrees with this comment. FDA has estimated the PRA burdens with the best evidence that is currently available. In addition, as stated in the NPRM and throughout this final rule, the deeming provisions are beneficial to the public health and the additional provisions are appropriate for the protection of the public health.

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

(Comment 304) One comment asserted that, under the PRA, a review of regulations should include an attempt to ensure that the paperwork is not unduly burdensome. The comment also stated that FDA appears to be ignoring the greatest cost of the paperwork burden (*i.e.,* most manufacturers will find the paperwork burden to be so great that they will abandon products or their entire businesses without attempting to comply with the requirements). They argued that FDA should follow the requirements as stated in the PRA and limit data collection to information that is useful and dependable.

(Response) FDA disagrees with this comment. FDA has faithfully complied with the all aspects of the PRA and any other applications laws and regulations.

B. 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 information collection requirements referenced in this section are amending currently approved information collections. Once the rule is finalized, the associated collections of information will be submitted to OMB for approval as revisions to the currently approved information collections. After submission to OMB, the revised collections and associated documents can be viewed at OMB's public Web site (*http://www.reginfo.gov*).

The burden estimates found in this section include existing collections that have been approved by OMB and cover tobacco products that are currently subject to the FD&C Act (*i.e.,* cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco). In developing the burden estimates for newly deemed tobacco products, FDA based the estimates on the existing collections that currently cover cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco.

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 or importers, or agents thereof, of new and currently regulated tobacco products

who are required to make submissions to FDA under section 904 of the FD&C Act, including the submission of an initial list of all ingredients in their tobacco products and the submission of information whenever additives or their quantities are changed. The respondents to this collection are also persons engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products who must register their establishments and submit a list of all tobacco products being manufactured, prepared, compounded, or processed by that person for commercial distribution at the time of registration under section 905 of the FD&C Act.

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, at the time of registration, must submit to FDA a list of all tobacco products that are being manufactured, prepared, compounded, or processed by that person for commercial distribution, along with certain accompanying consumer information and other labeling for such products and a representative sampling of advertisements.

If an ENDS retail establishment engages in these activities, it will be required to register and list their products with FDA. These requirements apply under the statute for all distinct products manufactured, and they enable FDA to assess the landscape of products manufactured by these entities. If ENDS retail establishments are custom mixing e-liquids and/or other ENDS products or components, then they will have to list each combination that they sell. For such establishments to continue to engage in mixing after this rule becomes effective, they would need to satisfy the requirements for manufacturers and the premarket authorization of new tobacco products as a result of this final rule. We note, however, that FDA does not intend to enforce the premarket authorization requirements during staggered compliance periods following the effective date, as stated previously in this preamble to this rule.

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 their quantities are changed.

As previously referenced in section IV, for small-scale tobacco product manufacturers, FDA is providing a one-time allowance of an additional 6 months after the effective date of this final rule for initial reporting of ingredients. This regulatory relief is only for small-scale tobacco product manufacturers.

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, product listing, and ingredient listing information are not required, FDA strongly encourages electronic submission to facilitate efficiency and timeliness of data management and collection. To that end, FDA designed the eSubmitter application, and then the FDA FURLS, to streamline the data entry process for registration, product listing, and ingredient listing. This tool allows for importation of large quantities of structured data, attachments of files (*e.g.,* in PDFs and certain media files), and automatic acknowledgement of FDA's receipt of submissions. FDA also developed paper forms (Form FDA 3741—Registration and Listing for Owners and Operators of Domestic Tobacco Product Establishments and Form FDA 3742—Listing of Ingredients in Tobacco Products) as alternative submission tools. Both the FURLS 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 rule as follows:

TABLE 7—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent [2]	Total annual responses	Average burden per response (in hours)	Total hours
Tobacco Product Establishment Initial First Year Registration (electronic and paper submission):					
Cigar Entities (Including Large and Small, and Importers).	221	1	221	2	442
Pipe and Waterpipe Tobacco Entities (Including Importers (22)).	96	1	96	2	192
Other Tobacco, E-Cigarettes, and Nicotine Product Entities and ENDS Products Importers (7) [3].	193	1	193	2	386
Vape shops that qualify as manufacturers [4]	4,250	1	4,250	2	8,500
Total Tobacco Product Establishment Initial First Year Registration.					9,520
Tobacco Product Establishment Recurring Registration (electronic and paper submission):					
Cigar Entities (Including Large and Small, and Importers).	221	1	221	0.20 (12 minutes)	44
Pipe and Waterpipe Tobacco Entities (Including Importers (22)).	96	1	96	0.20 (12 minutes)	19
Other Tobacco, E-Cigarettes, and Nicotine Product Entities and ENDS Products Importers (7) [3].	193	1	193	0.20 (12 minutes)	39

TABLE 7—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Activity	Number of respondents	Number of responses per respondent [2]	Total annual responses	Average burden per response (in hours)	Total hours
Vape shops that qualify as manufacturers [4]	4,250	1	4,250	0.20 (12 minutes)	850
Total Tobacco Product Establishment Recurring Registration.					952
Tobacco Product Listing Initial First Year (electronic and paper submission):					
Cigar Entities (Including Large and Small, and Importers).	221	1	221	2	442
Pipe and Waterpipe Tobacco Entities (Including Importers (22)).	96	1	96	2	192
Other Tobacco, E-Cigarettes, and Nicotine Product Entities and ENDS Products Importers (7) [3].	193	1	193	2	386
Vape shops that qualify as manufacturers [4]	4,250	1	4,250	2	8,500
Total Hours Tobacco Product Listing Initial First Year.					9,520
Tobacco Product Listing Recurring (electronic and paper submission):					
Cigar Entities (Including Large and Small, and Importers).	221	2	442	0.40 (24 minutes)	177
Pipe and Waterpipe Tobacco Entities (Including Importers (22)).	96	2	192	0.40 (24 minutes)	77
Other Tobacco, E-Cigarettes, and Nicotine Product Entities and ENDS Products Importers (7) [3].	193	2	386	0.40 (24 minutes)	154
Vape shops that qualify as manufacturers [4]	4,250	2	8,500	0.40 (24 minutes)	3,400
Total Hours Tobacco Product Listing Recurring.					3,808
Obtaining a Dun and Bradstreet (DUNS) Number:					
Cigar Entities (Including Large and Small, and Importers).	221	1	221	0.5 (30 minutes)	111
Pipe and Waterpipe Tobacco Entities (Including Importers (22)).	96	1	96	0.5 (30 minutes)	48
Other Tobacco, E-Cigarettes, and Nicotine Product Entities and ENDS Products Importers (7) [3].	193	1	193	0.5 (30 minutes)	97
Vape shops that qualify as manufacturers [4]	4,250	1	4,250	0.5 (30 minutes)	2,125
Total Hours Obtaining DUNS Number					2,381
Total Hours Registration, Product Listing, and DUNS Number.					26,181
Tobacco Product Ingredient Listing (electronic and paper submission):					
Cigar Entities (Including Large and Small, and Importers).	329	5.38	1,770	3	5,310
Pipe and Waterpipe Tobacco Entities (Including Importers (43)).	117	20.62	2,413	3	7,239
Other Tobacco, E-Cigarettes, and Nicotine Product Entities and ENDS Products Importers (7) [3].	200	11.40	2,280	3	6,840
Vape shops that qualify as manufacturers [4]	4,250	11.73	49,853	1	49,853
Total Hours Submitting Product Ingredient Listing.					69,242
Total Burden Tobacco Product Establishment Registration and Submission of Certain Health Information.					121,604

[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] Importers are included throughout this Table 7 to the extent that they engage in the manufacture, preparation, compounding, or processing of tobacco products, which includes repackaging or otherwise changing the container, wrapper, or labeling of any tobacco product package in furtherance of the distribution of the tobacco product from the original place of manufacturer to the person who makes final delivery or sale to the ultimate consumer or use.

[4] FDA assumes that vape shops will register and list only during the first two years after the rule becomes effective.

Based on aggregate information obtained from the TTB, in 2013 there were 113 domestic manufacturers of cigars, 216 importers of cigars, 74 manufacturers of pipe (including waterpipe) tobacco, and 43 importers of pipe (including waterpipe) tobacco who will be required to register under section 905 of the FD&C Act. For the purposes of this analysis, FDA estimates that the majority of the 4,250 vape shops that qualify as manufacturers will only register and list in the first two years after the rule becomes effective. In addition, FDA estimates that 186 ENDS manufacturers will be required to register under section 905 of the FD&C Act.

Product listing information is provided at the time of registration. Currently, registration and listing requirements only apply to domestic establishments engaged in the manufacture, preparation, compounding, or processing of a tobacco product. This includes importers to the extent that they engage in the manufacture, preparation, compounding, or processing of a tobacco product, including repackaging or otherwise changing the container, wrapper, or labeling of any tobacco product package.[18] Foreign establishments are not required to register and list until FDA issues regulations establishing such requirements in accordance with section 905(h) of the FD&C Act. To account for the foregoing, we include both domestic manufacturing establishments and importers in our estimates. Specifically, for the PRA analysis, we have used the midpoint between TTB permit counts for manufacturers and permit counts for manufacturers and importers as a likely overestimate of the number of entities that need to comply with registration and product listing (The Analysis of Impacts includes importers in the upper bound.)

The PRA burden estimates have been updated to fully incorporate the use of an electronic system known as FURLs for submitting registration and product listing information to FDA. With the FURLs system, manufacturers can enter information quickly and easily. For example, product label pictures can be uploaded directly and we anticipate that most, if not all companies, already have electronic versions of their labels for printing, sales, or marketing purposes. We anticipate that initial entity registration will take 2 hours and initial product listing will take an additional 2 hours per entity.

FDA estimates that the initial first year submission of registration information required by section 905 of the FD&C Act will take 2 hours per establishment, with a total of 4,760 establishments that will be required to register under this rule, for a total of 9,520 hours ($4{,}760 \times 2$).

The estimate for the number of product listing submissions for cigars is derived by using product counts from two retail Web sites: *http://www.cigarsinternational.com/* and *http://www.pipesandcigars.com/*. These two large Internet retailers had larger product offerings than other sites reviewed and sell both mass-market and specialty products. Estimates of product formulations and product-package combinations for cigars are centered over the product counts from the two Web sites. To derive the product listing count for pipe tobacco, we count the products on a Web site with a broad product offering, *http://www.pipesandcigars.com/*. We estimate formulations with the number of the product names and product-packages with the number of product-package combinations. FDA derives the product listing estimate for ENDS products by consulting experts at FDA's CTP who cataloged the ENDS products currently available on five Web sites and in scanner data from Nielsen. FDA estimates that the initial first year submission of product listing information required by section 905 of the FD&C Act will take 2 hours per submission for 4,760 submissions/annual responses for a total of 9,520 hours.

Once information is entered into FURLs, the twice yearly confirmation of annual registration and product listing updates is simplified as all information previously entered is maintained in the system. Therefore, we expect the recurring burden of subsequent years for updating registration and product listing information will take 1 hour annually per establishment (12 minutes for registration and 48 minutes for product listing). The total hours are 4,760 (952 updating registration and 3,808 product listing).

FDA estimates that obtaining a DUNS number will take 30 minutes. FDA assumes that all the establishment facilities that will be required to register under section 905 of the FD&C Act would obtain a DUNS number, with a total of 4,760 establishments that would need to obtain this number. The total burden to obtain a DUNS number is 26,181 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 56,316 ingredient listings/annual responses will be submitted annually based on the methodology used for estimating the number of product listing submissions described in this section. The total ingredient listing reporting is 69,242 hours. FDA estimates that the total burden for tobacco product establishment registration and ingredient listing reporting is 121,604 hours.

2. Tobacco Health Document Submission (OMB Control Number 0910–0654)

Description of Respondents: Respondents to this collection of information are tobacco product manufacturers or, importers, or agents thereof, who will submit all documents to FDA developed after June 22, 2009, that relate to health, toxicological, behavioral, or physiologic effects of current or future tobacco products. As stated elsewhere, however, FDA generally does not intend to take enforcement action regarding the submission of all such documents at this time so long as a specified set of documents are submitted by [the effective date plus 6 months]. FDA will publish additional guidance that specifies the scope of documents that manufacturers and importers will be required to submit by [the effective date plus 6 month], with sufficient advance time for manufacturers and importers to prepare their submissions.

Section 904(a)(4) of the FD&C Act requires each tobacco product manufacturer or importer, or agent thereof, to submit all documents to FDA 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 (tobacco health documents). To address concerns of certain small businesses relating to the tobacco health documents requirement, FDA is extending the compliance period for small-scale tobacco product

[18] Under the Internal Revenue Code, the manufacture, preparation, compounding, or processing of a tobacco product may require a permit as a manufacturer of tobacco products. As we understand TTB's permitting requirements, entities lacking a manufacturer permit, including importers, may not engage in any of the listed activities, including repackaging tobacco products after such products are released from customs custody. It is unclear whether TTB would require a manufacturer permit for *all* activities for which FDA would determine the entity must register and list; because there may be some entities with import permits for which FDA would conclude registration is necessary, FDA includes those numbers as part of its upper-bound estimate of affected entities.

manufacturers for an additional 6 months following the end of the generally applicable compliance period to allow submitters time to organize, compile, and digitize documents.

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 rule as follows:

TABLE 8—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number 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 and Waterpipe Tobacco Manufacturers	1	4	4	50	200
Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers ENDS	1	4	4	50	200
Importers of Cigars and Pipe Tobacco Who Are Considered Manufacturers	1	4	4	50	200
Importers of Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers ENDS	1	4	4	50	200
Total Hours Health Document Submission					1,200

[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 and waterpipe tobacco, other tobacco, tobacco importers, and importers of ENDS 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 manufacturers or importers, or agents thereof, would have health documents to submit. Therefore, the Agency estimates that approximately six submissions (two for cigar manufacturers, one for pipe and waterpipe tobacco manufacturers, one for other tobacco product manufacturers, and one for tobacco importers, and one for importers of ENDS who are considered manufacturers) will be submitted on an annual basis. FDA estimates the total number of hours is 1,200 hours (6 submissions multiplied by 4 times per year multiplied by 50 average burden hours).

3. Exemptions From Substantial Equivalence Requirements (OMB Control Number 0910–0684)

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

In a final rule that published on July 5, 2011, FDA established procedures for manufacturers to request exemptions from the SE requirements of the Tobacco Control Act (SE exemptions final rule). The SE exemptions final rule was issued under section 905(j)(3) of the FD&C Act, which provides that FDA may exempt from the requirements relating to the demonstration of SE 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) Such 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, including a statement as to whether the modification involves adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive;
- 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 SE 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 products appeal to or use by minors, 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.

This information will enable FDA to determine whether the exemption request is appropriate for the protection of the public health. There is also a procedural mechanism for rescinding an exemption if FDA finds the exemption is not appropriate for the protection of the public health. In general, FDA will rescind an exemption only after providing the manufacturer notice of the 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. FDA may request additional information from the manufacturer if necessary to make the determination. 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 rule as follows:

TABLE 9—ESTIMATED ANNUAL REPORTING BURDEN (WHEN MANUFACTURERS CHOOSE TO SEEK EXEMPTION FROM SUBSTANTIAL EQUIVALENCE) [1]

21 CFR Section and activity	Number of respondents	Number 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 Including § 25.40 Preparation of an Environmental Assessment					
Cigar Manufacturers (Including Large, Small, and Importers)	196	1	196	24	4,704
Pipe and Waterpipe Tobacco Manufacturers (Including Importers)	105	1	105	24	2,520
Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers (ENDS and Delivery Systems (Including Importers))	18	1	18	24	432
Total Hours (§ 1107.1(b))					7,656
§ 1107.1(c) Preparation of Additional Information for Tobacco Product Exemption From Substantial Equivalence Request:					
Cigar Manufacturers (Including Large, Small, and Importers)	59	1	59	3	177
Pipe and Waterpipe Tobacco Manufacturers (Including Importers)	32	1	32	3	96
Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers (ENDS and Delivery Systems (Including Importers))	3	1	3	3	9
Total Hours (§ 1107.1(c))					282
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)	293	1	293	3	879
Pipe and Waterpipe Tobacco Manufacturers (including importers)	156	1	156	3	468
Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers (ENDS and Delivery Systems (Including Importers))	26	1	26	3	78
Total Hours (section 905(j)(1)(A)(ii))					1,425
Total Hours Exemptions From Substantial Equivalence Requirements					9,363

[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). FDA estimates that we will receive 319 exemption requests under § 1107.1(b) for 24 hours per response including EA for a total of 7,656 hours. Since an EA is required for each § 1107.1(b) (Optional Preparation of Tobacco Product Exemption From Substantial Equivalence Request), the burden per response for EAs (12 hours) has been combined with the 12 hours for an SE request for a total of 24 hours.

FDA estimates, based on the existing information collection that applies to tobacco products currently subject to the FD&C Act, we will receive 94 submissions requiring 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 282 hours.

FDA estimates that 475 respondents will prepare 475 responses and each response will take approximately 3 hours to prepare, as required by section 905(j)(1)(A)(ii), for a total of 1,425 hours. This collection of information requires a manufacturer to submit a report at least 90 days prior to making an introduction or delivery for introduction into interstate commerce for commercial distribution of a tobacco product. Section 905(j)(1)(A)(ii) of the FD&C Act states that if an exemption has been requested and granted, the manufacturer

must submit to FDA a report that demonstrates that the tobacco product is modified within the meaning of section 905(j)(3), the modifications are to a product that is commercially marketed and in compliance with the requirements of the FD&C Act, and all of the modifications are covered by exemptions granted by the Secretary pursuant to section 905(j)(3). FDA estimated the total hours for exemptions from Substantial Equivalence Requirements would be 9,363 hours.

FDA's estimates are based on full analysis of economic impacts (Ref. 204) 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 deemed tobacco products who seek to submit a report to FDA demonstrating that a tobacco product is substantially equivalent to a valid predicate product 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 of the submission. 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 SE (see the Guidance for Industry and FDA Staff entitled ''Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products'' (76 FR 789, January 6, 2011)).

Under the recently issued guidance, which published in the **Federal Register** of September 8, 2015, entitled, ''Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions'' (Edition 2), FDA is recommending that certain modifications might be addressed in either a ''Same Characteristics SE Report'' or ''Product Quantity Change Report.'' In some circumstances manufacturers may be able to submit a shorter SE report. In particular, if a tobacco product is distinct (*e.g.,* it has a different name), but has the same characteristics as a valid predicate product, manufacturers may submit a Same Characteristics SE Report. If the only change to the tobacco product is a change to product quantity, and the per-weight composition inside the package remains identical, the manufacturer may submit a Product Quantity Change SE Report. FDA's CTP estimates that it will take less time to prepare those shorter SE reports.

When groups of full or product quantity change SE reports have identical content, they may be bundled; when a group of similar reports are bundled, the subsequent bundled reports are expected to take less time to prepare than the initial report.

FDA recognizes that many manufacturers of newly deemed products may be at the inception of their businesses. Therefore, FDA is announcing that the Agency may grant extension requests made by small-scale tobacco product manufacturers for SE Reports that need additional time to respond to deficiency letters for the first 30 months following the effective date of this rule.

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

TABLE 10—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent [2]	Total annual responses	Average burden per response (in hours)	Total hours
Full SE Initial Sections 905(j)(1)(A)(i) and 910(a) and § 25.40 Environmental Assessments:					
Cigar Manufacturers (Including Large, Small, and Importers)	168	1	168	300	50,400
Pipe and Waterpipe Tobacco Manufacturers (Including Importers)	151	1	151	300	45,300
Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers (ENDS and Delivery Systems (Including Importers))	16	1	16	300	4,800
Total Hours (sections 905(j)(1)(A)(i) and 910(a))					100,500
Full SE Bundled 905(j)(1)(A)(i) and 910(a) and § 25.40 Environmental Assessments:					
Cigar Manufacturers (Including Large, Small, and Importers)	151	1	151	90	13,590
Pipe and Water Tobacco Manufacturers (Including Importers)	83	1	83	90	7,470
Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers (ENDS and Delivery Systems (Including Importers))	16	1	16	90	1,440
Total Hours					22,500
Same Characteristics SE Report and § 25.40 Environmental Assessments:					
Cigar Manufacturers (Including Large, Small, and Importers)	285	1	285	47	13,395
Pipe and Waterpipe Tobacco Manufacturers (Including Importers)	132	1	132	47	6,204
Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers (ENDS and Delivery systems (Including Importers))	1	1	1	47	47

TABLE 10—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Activity	Number of respondents	Number of responses per respondent [2]	Total annual responses	Average burden per response (in hours)	Total hours
Total Same Characteristics					19,646
Product Quantity Change Initial and § 25.40 Environmental Assessments:					
Cigar Manufacturers (Including Large, Small, and Importers)	108	1	108	87	9,396
Pipe and Waterpipe Tobacco Manufacturers (Including Importers)	30	1	30	87	2,610
Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers (ENDS and Delivery systems (Including Importers))	1	1	1	87	87
Total Product Quantity Change Initial					12,093
Product Quantity Change Bundled and § 25.40 Environmental Assessments:					
Cigar Manufacturers (Including Large, Small, and Importers)	42	1	42	62	2,604
Pipe and Waterpipe Tobacco Manufacturers (Including Importers)	12	1	12	62	744
Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers (ENDS and Delivery systems (Including Importers))	1	1	1	62	62
Total Product Quantity Change					3,410
Total Hours (“Reports Intended to Demonstrate the Substantial Equivalence of a New Tobacco Product”)					158,149

[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. 204) 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). In addition, anyone submitting an SE report is required to submit an environmental assessment under § 25.40.

The burden for environmental reports has been included in the burden per response for each type of SE report.

FDA estimates that 335 respondents will prepare and submit 335 section 905(j)(1)(A)(i) Full SE Initial reports each year and that it will take a manufacturer approximately 300 hours per report to prepare the reports of SE and environmental assessment for a new tobacco product.

FDA estimates that we will receive 335 Full SE Initial reports for a total of 100,500 hours. We estimate 250 Full SE Bundled Reports for a total of 22,500 hours. FDA estimates that we will receive 418 Same Characteristics SE Reports for a total of 19,646 hours. FDA estimates receiving 139 Initial Product Quantity Change reports for a total of 12,093 hours. We estimate receiving 55 Product Quantity Change Bundled SE reports for a total of 3,410 hours. Based on FDA’s experience with environmental assessments (EAs) for currently regulated tobacco products, we expect industry to spend 80 hours to prepare an environmental assessment for a full SE Report, but less time to prepare an environmental assessment for shorter SE reports.

Therefore, FDA estimates the burden for submission of SE information will be 158,149 hours.

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 being imported or 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 Health and Human Services, through FDA, with the responsibility of assuring that foreign-origin, FDA-regulated foods, drugs, cosmetics, medical devices, radiological health, and tobacco products being imported or offered for import into the United States meet the same requirements of the FD&C Act as domestic products and 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). This collection of information 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. The Agency 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 rule as follows:

TABLE 11—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Importers of Cigars who are Considered Manufacturers.	216	159	34,344	0.14 (8½ minutes)	4,808
Importers of Pipe and Waterpipe Tobacco Who Are Considered Manufacturers.	43	123	5,289	0.14 (8½ minutes)	740
Importers Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers (ENDS).	14	68	952	0.14 (8½ minutes)	133
Total Hours Importation of Tobacco Products	.....	.....	.....	.....	5,681

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

FDA estimates the burden hours to be 5,681 burden hours (4,808 + 740 + 133 hours). This reflects the addition of the newly deemed tobacco products to the list of FDA's regulated products. 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 (8½ 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. Exports: Notification and Recordkeeping Requirements (OMB Control Number 0910–0482)

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, foods, 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 rule as follows:

TABLE 12—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1] [2]

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (in hours)	Total hours
21 CFR 1.101(b):					
Cigar Manufacturers (Large and Small)	57	3	171	22	3,762
Pipe and Waterpipe Tobacco Manufacturers	37	3	111	22	2,442
Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers (ENDS) ..	93	3	279	22	6,138

TABLE 12—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1] [2]—Continued

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (in hours)	Total hours
Exports: Notification and Recordkeeping Requirements					12,342

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] At publication of the NPRM, the burden for these activities were under OMB control number 0910–0690. The burden has since been transferred to OMB control number 0910–0482.

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 who have experience and information regarding tobacco product exporters. FDA estimates that 187 establishments (50 percent of all the tobacco manufacturers listed in the collection of information under OMB Control Number 0910–0046 in this document who manufacture cigars, pipe tobacco, waterpipe, other tobacco products, and ENDS) 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 12,342 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.

7. Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007 (OMB Control Number 0910–0775)

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 on February 15, 2007, and is a grandfathered product not subject to premarket review.

On September 29, 2014, FDA published the guidance document entitled ''Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007''. This guidance provides information on how a manufacturer may demonstrate that a tobacco product was commercially marketed in the United States on February 15, 2007, and is, therefore, a grandfathered product not subject to premarket review. The 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 adequate information to demonstrate that the tobacco product was commercially marketed in the United States on February 15, 2007.

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 rule as follows:

TABLE 13—ESTIMATED ANNUAL REPORTING BURDEN [1] [2]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Cigar Manufacturers (including large and small cigars and importers)	1	1	1	5	5
Pipe Tobacco Manufacturers (Including Importers)	1	1	1	5	5
Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers (Including Importers)	1	1	1	5	5
Total Hours Establishing that a Tobacco Product was Commercially Marketed in the United States as of February 15, 2007					15

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] At publication of the NPRM, this collection was not yet approved by OMB. On September 8, 2014, OMB approved the information collection for 3 years.

Based on FDA's experiences to date, and given that stand-alone grandfather submissions are purely voluntary, FDA does not anticipate that many manufacturers will make such submissions, but this option is available. As such, we assigned one respondent annually per type of product FDA estimates it will take a manufacturer approximately 5 hours to complete and submit for FDA review the evidence required by this collection of information for a total of 15 hours.

C. 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 chapter IX of the FD&C Act. However, these information collections have not yet been approved by OMB.

FDA based the estimates on the existing collections that were previously made available for comment.

• Applications for Premarket Review of New Tobacco Products

Description of Respondents: The respondents to this collection of information are manufacturers who seek a marketing authorization order under section 910(c)(1)(A)(i) of the FD&C Act.

On September 28, 2011, FDA announced the availability of a draft guidance entitled ''Applications for Premarket Review of New Tobacco Products''. This guidance, when finalized, will represent the Agency's current thinking on the topic. Section 910(a)(1) of the FD&C Act defines a ''new tobacco product'' as a tobacco product that was not commercially marketed in the United States on February 15, 2007, or 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. An order under section 910(c)(1)(A)(i) of the FD&C Act is required prior to marketing a new tobacco product. This requirement applies unless the product has been shown to be substantially equivalent to a valid predicate product or is exempt from SE.

Section 910(b) of the FD&C Act states that a PMTA shall contain 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 (which includes; 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 of the product and its components; and labeling.

FDA also encourages persons who would like to study their new tobacco product to meet with the OS in CTP to discuss their investigational plan. The request for a meeting should be sent in writing to the Director of CTP's OS and should include adequate information for FDA to assess the potential utility of the meeting and to identify FDA staff necessary to discuss 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, processing, or packing methods, facilities, or controls do not conform to good manufacturing practices issued under section 906(e) of the FD&C Act,

• the labeling is false or misleading in any particular, 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.

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

TABLE 14—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number 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) and § 25.40 Environmental Assessments:					
Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers (ENDS Liquids and ENDS Delivery Systems (Including Importers))	200	3.75	750	1,713	1,284,750
Total Hours Obtaining an FDA Order Authorizing Marketing of Tobacco Product (the application)					1,284,750
Request for Meeting with CTP's Office of Science to Discuss Investigational Plan:					
Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers (ENDS Liquids and ENDS Delivery Systems (Including Importers))	200	1	200	4	800
Total Hours Request for Meeting with CTP's Office of Science to Discuss Investigational Plan					800
Total Hours ''Applications for Premarket Review of New Tobacco Products''					1,285,550

[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 1,500 hours to prepare a PMTA seeking an order from FDA allowing the marketing of a new tobacco product. FDA also estimates that it would on average take an additional 213 hours to prepare an environmental assessment in accordance with the requirements of § 25.40, for a total of 1,713 hours per PMTA application. This average represents a wide range of hours that will be required for these applications under different circumstances, with some requiring more hours (*e.g.,* as many as 5,000 hours for early applications that involve complex products and for which the company has no experience conducting studies or preparing analysis of public health impacts, or for which reliance on master files is not possible) as well as many requiring fewer hours (*e.g.,* as few as 50 hours for applications for products that are very similar to other new products).

Although FDA has decreased the burden per each PMTA, we have increased the number of expected responses for ENDS manufacturers. We attribute this increase to the rapid growing ENDS market since the NPRM was published. FDA's estimate includes anticipated burden for the writing of an application, including intracompany edits and approvals. FDA also estimates the number of PMTAs that FDA expects to receive annually will be 750 (642 ENDS Liquids and 108 ENDS Delivery Systems).

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 randomized 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, nonclinical and clinical studies may be required for market authorization of a new product for which there is limited understanding of its potential impact on the public health. The range of hours involved to compile these two types of applications would be quite variable.

FDA anticipates that the 200 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 should 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 800 hours additional burden (200 respondents × 4 hours).

Therefore, the total annual burden for submitting PMTA applications is estimated to be 1,285,550 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.

D. New Collections of Information That Apply Only to Deemed Tobacco Products

1. Exemption From the Required Warning Statement Requirement

Description of Respondents: Respondents are manufacturers who, to obtain an exemption from the required addictiveness warning, certify to FDA that their product does not contain nicotine and that the manufacturer has data to support that assertion.

This rule contains a new information collection that pertains to an exemption process related to the requirement to include the warning statement in § 1143.3(a)(1). Section1143.3(c) will provide an exemption to the manufacturer of a product that otherwise would be required to include the warning statement in § 1143.3(a)(1) on its packages and in its advertisements, *i.e.,* ''WARNING: This product contains nicotine. Nicotine is an addictive chemical.'' This warning will be required to appear on at least 30 percent of the two principal display panels of the package and on at least 20 percent of the area of the advertisement.

To obtain an exemption from this requirement, a manufacturer would be required to certify to FDA that its product does not contain nicotine and that the manufacturer has data to support that assertion. For any product that obtains this exemption, the section requires that the product bear the statement: ''This product is made from tobacco.'' The parties that package and label such products will share responsibility for ensuring that this alternative statement is included on product packages and in advertisements. The rule will 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 rule as follows:

TABLE 15—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number 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. Although 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 to prepare and submit 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 concludes that the labeling statements in §§ 1143.3(a)(1) and 1143.5(a)(1) and the alternative statement in § 1143.3(c) (*i.e.,* ''This product is made from tobacco'') are not subject to review by OMB because they do not constitute a ''collection of information'' under the PRA (44 U.S.C. 3501–3520). Rather, these labeling statements are a ''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)).

2. Submitting Warning Plans for Cigar Manufacturers, Importers, Distributors, and Retailers

Description of Respondents: The respondents to this collection of information are manufacturers, importers, distributors, and retailers of cigar products who will be required to submit warning plans for cigars to FDA.

The requirement for submission of warning plans for cigar products, and the specific requirements relating to the random display and distribution of required warning statements on cigar

packaging and quarterly rotation of required warning statements in alternating sequence on cigar product advertising, appear in § 1143.5(c).

The six warnings for cigars (five specifically for cigars and the one addictiveness warning) will be required to 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 accordance with a warning plan submitted to and approved by FDA. For advertisements, the warning statements must be rotated quarterly in alternating sequence in each advertisement for each brand of cigar in accordance with a warning plan submitted to and approved by FDA.

For cigar products that are on the market as of the publication date of the final rule, the effective date for the requirement to submit warning plans by responsible manufacturers, distributors, importers, and retailers is 1 year after the date of publication of the final rule. FDA is establishing this effective date 1 year before the effective date of the remainder of the part 1143 requirements because the Agency anticipates that there will be a need for considerable communication with submitters during its review of the warning plan submissions. FDA will work with the submitters to ensure that the plans submitted meet the established criteria for approval under part 1143. FDA also intends to update the warning plan draft guidance and information collection, which currently pertains to smokeless tobacco products, to assist manufacturers, importers, distributors, and retailers of cigars with the submission of warning plans. The information collection in this draft guidance is approved under OMB Control Number 0910–0671. The draft guidance document discusses, among other things: The statutory requirement to submit a warning plan; definitions; who submits a warning plan; the scope of a warning plan; when to submit a warning plan; what information should be submitted in a warning plan; where to submit a warning plan; and what approval of a warning plan means.

The warning statements on cigar packaging 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 and are required to be randomly distributed in all areas of the United States in which the product is marketed in accordance with a warning plan submitted by the responsible cigar manufacturer, importer, distributor, or retailer to and approved by FDA.

To clarify, retailers of cigars sold individually and not in product packaging are not required to submit a warning plan for warnings on packages, because the warning signs posted at a retailer's point-of-sale would include all six warnings applicable to cigars, as we have noted in § 1143.5(c)(1). Therefore, it is not necessary to submit a rotational warning plan for them. However, manufacturers, distributors, and those retailers who are responsible for or direct the health warning of the advertisements of such products must submit a warning plan for their advertisements for FDA approval. The rule requires them to include warnings on advertisements, and the warnings that must be rotated quarterly in alternating sequence in each advertisement for each brand of cigar, in accordance with an FDA approved warning plan.

FDA is also requiring 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 rotation of warning statements in cigar advertisements also must be done in accordance with a warning plan submitted by the responsible cigar manufacturer, importer, distributor, or retailer to and approved by FDA.

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

TABLE 16—ESTIMATED ANNUAL REPORTING BURDEN [1]

Cigar warning plan	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Manufacturers, Importers, and Retailers	329	1	329	120	39,480
Total Cigar Warning Plan					39,480

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

The burden estimates are based on FDA's experience with smokeless warning plans and the associated information collection (OMB Control Number 0910–0671) as well as warning plans for cigarettes submitted to the FTC prior to the implementation of the Tobacco Control Act on June 22, 2009.

We estimate 329 entities will submit warning plans, and it will take an average of 120 hours per respondent to prepare and submit a warning plan for packaging and advertising for a total of 39,480 hours.

3. Small-Scale Manufacturer Report

Description of Respondents: The respondents to this collection of information are manufacturers known as ''small-scale tobacco product manufacturers.''

As discussed in section IV, FDA requested comment on the ability of smaller manufacturers of newly deemed tobacco products to fully comply with the requirements of the FD&C Act and how FDA might be able to address those concerns. Considering the comments and FDA's finite enforcement resources, the Agency's view is that those resources may not be best used in immediately enforcing the provisions of this rule against certain manufacturers that are small-scale tobacco product manufacturers and that fail to comply with certain requirements of the FD&C Act. FDA retains discretion in all cases to conduct an individualized inquiry and to consider any and all relevant facts in determining whether to bring an enforcement action.

Generally, FDA considers a ''small-scale tobacco product manufacturer'' to be a manufacturer of any regulated tobacco product that employs 150 or fewer full-time equivalent employees and has annual total revenues of $5,000,000 or less. FDA considers a manufacturer to include each entity that it controls, is controlled by, or is under common control with such manufacturer. To help make FDA's individual enforcement decisions more efficient, a manufacturer may voluntarily submit information regarding employment and revenues. FDA does not believe a large number of

manufacturers who fit the criteria of a small-scale tobacco product manufacturer would submit the voluntary information.

FDA estimates that there are approximately 75 small-scale manufacturers who will voluntarily submit information. FDA believes it will take respondents 2 hours to voluntarily submit information regarding employment and revenues for a total of 150 hours.

FDA has estimated the burden for submitting the ''small-scale tobacco product manufacturer'' annual report as follows:

TABLE 17—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Small-Scale Manufacturer Reporting	75	1	75	2	150
Total Small-Scale Manufacturer Report					150

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

The total burden for these new collections of information in this rulemaking is 1,621,212 reporting hours (121,604 + 1,200 + 9,363 + 158,149 + 5,681 + 15 + 1,285,550 + 20 + 39,480 + 150) and 12,342 recordkeeping hours for a total of 1,633,554 burden hours.

The information collection provisions in this final rule have been submitted to OMB for review as required by section 3507(d) of the Paperwork Reduction Act of 1995.

Before the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

XX. Executive Order 13132; Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

XXI. Executive Order 13175; Tribal Consultation

In accordance with Executive Order 13175, FDA has consulted with Tribal Government officials. FDA sought comment from Tribal Governments on April 25, 2014, and conducted a consultation with tribes via Webinar regarding the NPRM on May 29, 2014. FDA received one comment from a tribe stating that FDA failed to ensure meaningful and timely input from tribal officials as required by Executive Order 13175 and requesting tribal consultation in relation to existing premarket review activities for cigarettes, roll-your-own tobacco, and smokeless tobacco. In response, FDA conducted a face-to-face meeting with the tribe regarding the NPRM on January 21, 2015. FDA has determined that this final rule does not have tribal implications under Executive Order 13175, because it does not, to our knowledge, have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, nor does it impose substantial direct compliance costs.

(Comment 305) One comment stated that FDA failed to ensure meaningful and timely input from tribal officials as required by Executive Order 13175 and the HHS Consultation Policy. The comment acknowledged FDA's ''Dear Tribal Leader'' letter and Webinar and requested a face-to-face meeting between FDA and its tribe in relation to existing premarket review activities for cigarettes, roll-your-own tobacco, and smokeless tobacco.

(Response) FDA adheres to Executive Order 13175 and the HHS Consultation Policy. FDA is committed to meaningful consultation with federally recognized tribes on FDA's implementation and enforcement of the Tobacco Control Act. As a result of the tribe's inquiry, FDA participated in a face-to-face meeting.

(Comment 306) One comment encouraged FDA to respect tribal sovereignty in its enforcement of the tobacco regulation. The comment recommended that FDA provide both training and funding opportunities to tribal governments to alleviate the economic burdens stemming from enforcement of the rule. The comment urged FDA to make certain the regulatory burdens do not limit the economic viability of tribal operations.

(Response) FDA recognizes tribal sovereignty and tribal self-regulation and will work in partnership with tribal leaders to monitor compliance with this rule. As explained in this rule, FDA is implementing this rule to protect public health. However, FDA recognizes that compliance with many of the automatic provisions may be challenging at first for entities that are new to Federal public health regulation and as a result, provided compliance policies relating to provisions such as premarket authorizations and provided additional time to comply with certain requirements of the FD&C Act for small-scale tobacco manufacturers. FDA will provide training and other opportunities to tribal governments after the rule is finalized.

XXII. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m. Monday through Friday; they are also available electronically at *http://www.regulations.gov*. FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

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restrictions on the sale and distribution of covered tobacco products, and to require the use of health warning statements for cigarette tobacco, roll-your-own tobacco, and covered tobacco products.

279. Finding of No Significant Impact for Regulations (21 CFR 1100, 1140, and 1143) to deem tobacco products meeting the statutory definition of ''tobacco product'' to be subject to the Federal Food, Drug, and Cosmetic Act, to revise existing regulations to include restrictions on the sale and distribution of covered tobacco products, and to require the use of health warning statements for cigarette tobacco, roll-your-own tobacco, and covered tobacco products.

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, 21 CFR chapter I is amended as follows:

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

PART 1100—TOBACCO PRODUCTS SUBJECT TO FDA AUTHORITY

Sec.

Authority: 21 U.S.C. 387a(b), 387f(d) and Pub. L. 111–31.

§ 1100.1 Scope.

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

§ 1100.2 Requirements.

Cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco are subject to chapter IX of the Federal Food, Drug, and Cosmetic Act and its implementing regulations. FDA has deemed all other tobacco products, except accessories of such other tobacco products, subject to chapter IX of the Federal Food, Drug, and Cosmetic Act and its implementing regulations.

§ 1100.3 Definitions.

For the purposes of this part:

Accessory means any product that is intended or reasonably expected to be used with or for the human consumption of a tobacco product; does not contain tobacco and is not made or derived from tobacco; and meets either of the following:

(1) Is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product; or

(2) Is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a tobacco product but

(i) Solely controls moisture and/or temperature of a stored tobacco product; or

(ii) Solely provides an external heat source to initiate but not maintain combustion of a tobacco product.

Component or *part* means any software or assembly of materials intended or reasonably expected:

(1) To alter or affect the tobacco product's performance, composition, constituents, or characteristics; or

(2) To be used with or for the human consumption of a tobacco product. Component or part excludes anything that is an accessory of a tobacco product.

Package or *packaging* means a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane), in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers.

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 under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act, a device under 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.

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

■ 2. 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, 123 Stat. 1776.

■ 3. Revise the heading to part 1140 as set forth above.

■ 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. Section 1140.16(d) sets out restrictions on the distribution of free samples for cigarettes, smokeless tobacco, and other tobacco products (as such term is defined in section 201 of the Federal Food, Drug, and Cosmetic Act).

(b) The failure to comply with any applicable provision in this part in the sale, distribution, and use of cigarettes, smokeless tobacco, covered tobacco products, or other 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:

Accessory means any product that is intended or reasonably expected to be used with or for the human consumption of a tobacco product; does not contain tobacco and is not made or derived from tobacco; and meets either of the following:

(1) Is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product; or

(2) Is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a tobacco product but

(i) Solely controls moisture and/or temperature of a stored product; or

(ii) Solely provides an external heat source to initiate but not maintain combustion of a tobacco product.

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.

Component or *part* means any software or assembly of materials intended or reasonably expected:

(1) To alter or affect the tobacco product's performance, composition, constituents, or characteristics; or

(2) To be used with or for the human consumption of a tobacco product. Component or part excludes anything that is an accessory of a tobacco product.

Covered tobacco product means any tobacco product deemed to be subject to the Federal Food, Drug, and Cosmetic Act under § 1100.2 of this chapter, but excludes any component or part that is not made or derived from tobacco.

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 or *packaging* means a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane) in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers.

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.

Roll-your-own tobacco means any tobacco product that, 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.

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 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 under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act, a device under 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—MINIMUM REQUIRED WARNING STATEMENTS

Sec.

Authority: 21 U.S.C. 387a(b), 387f(d).

§ 1143.1 Definitions.

For purposes of this part:

Accessory means any product that is intended or reasonably expected to be used with or for the human consumption of a tobacco product; does not contain tobacco and is not made or derived from tobacco; and meets either of the following:

(1) Is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product; or

(2) Is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a tobacco product but

(i) Solely controls moisture and/or temperature of a stored tobacco product; or

(ii) Solely provides an external heat source to initiate but not maintain combustion of a tobacco product

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 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.

Component or *part* means any software or assembly of materials intended or reasonably expected:

(1) To alter or affect the tobacco product's performance, composition, constituents, or characteristics; or

(2) to be used with or for the human consumption of a tobacco product. Component or part excludes anything that is an accessory of a tobacco product.

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 is not made or derived from tobacco.

Package or *packaging* means a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane), in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers.

Principal display panels means the panels of a package that are most likely to be displayed, presented, shown, or examined by the consumer.

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.

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 that, 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.

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 under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act, a device under 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.

§ 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 package bears the following required warning statement on the package label: ''WARNING: This product contains nicotine. 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 at least 12-point font size and ensures that the required warning statement occupies the greatest possible proportion of the warning area set aside for the required text;

(iii) Be printed in conspicuous and legible Helvetica bold or Arial bold type (or other sans serif fonts) 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, 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) For cigarette tobacco, roll-your-own tobacco, and covered tobacco products other than cigars, it is unlawful for any such 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 the required warning statement specified in paragraph (a)(1) of this section.

(2) For print advertisements and other advertisements with a visual component (including, for example, advertisements on signs, shelf-talkers, Internet Web pages, and electronic mail correspondence), 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) Appear in at least 12-point font size and ensures that the required warning statement occupies the greatest

possible proportion of the warning area set aside for the required text;

(iii) Appear in conspicuous and legible Helvetica bold or Arial bold type (or other similar sans serif fonts) 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 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 appear 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 tobacco product manufacturer has submitted to FDA a confirmation statement certifying to be true and accurate that the product does not contain nicotine and that the tobacco product 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 statement ''This product is made from tobacco.'' on all packages and advertisements in accordance with the requirements of this part.

(d) *Small packages.* A tobacco product that would otherwise be required to bear the warning in paragraph (a)(1) of this section but is too small or otherwise unable to accommodate a label with sufficient space to bear such information is exempt from compliance with the requirement *provided* that the information and specifications required under paragraphs (a)(1) and (2) of this section appear on the carton or other outer container or wrapper if the carton, outer container, or wrapper has sufficient space to bear the information, or appear on a tag otherwise firmly and permanently affixed to the tobacco product package. In such cases, the carton, outer container, wrapper, or tag will serve as the location of the principal display panels.

§ 1143.5 Required warning statements for cigars.

(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 product unless the product package bears one of the following required warning statements on the package label:

(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)(A) WARNING: Cigar use while pregnant can harm you and your baby.; or

(B) SURGEON GENERAL WARNING: Tobacco Use Increases the Risk of Infertility, Stillbirth and Low Birth Weight.

(vi) WARNING: This product contains nicotine. 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) Appear in at least 12-point font size and ensure that the required warning statement occupies the greatest possible proportion of the warning area set aside for the required text;

(iii) Be printed in conspicuous and legible Helvetica bold or Arial bold type (or other similar sans serif fonts) 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) All of the warnings in paragraph (a) of this section must be placed on a sign that is a minimum of 8.5 x 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 (or other similar sans serif fonts) 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 the tobacco product 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 one of the required warning statements specified in paragraph (a)(1) of this section.

(2) For print advertisements and other advertisements with a visual component (including, for example, advertisements on signs, shelf-talkers, Internet Web pages, and electronic mail correspondence), 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) Appear in at least 12-point font size that ensures that the required warning statement occupies the greatest possible proportion of the warning area set aside for the text required;

(iii) Appear in conspicuous and legible Helvetica bold or Arial bold type (or other similar sans serif fonts) 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 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 appear 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 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) Except for cigars sold individually and not in a product package, the warning statements required for packages 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 for advertisements 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.

(3) Each person required to randomly display and distribute or rotate warnings in accordance with an FDA-approved plan under this part shall submit a proposed warning plan to FDA no later than either 12 months after May 10, 2016, or 12 months before advertising or commercially marketing a product that is subject to such requirement, whichever is later.

§ 1143.7 Language requirements for required warning statements.

The text in each 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 medium, the text in the required warning statement must appear in the predominant language of the medium whether or not the advertisement is in English, and;

(b) In the case of an advertisement that appears in an English language medium 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 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.

(a) Except as stated in paragraph (b) of this section, this part will take effect 24 months after May 10, 2016. 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.

(b) The requirement to submit a warning plan to FDA under § 1143.5(c)(3) will take effect 12 months after May 10, 2016.

Dated: May 3, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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