The Food and Drug Administration Deems Tobacco Products to be Subject to the Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations Restricting the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Product Packages and Advertisements

Final Rule

0910-0768
0910 AG38

ABSTRACT FOR USE IN ICRAS

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The Food and Drug Administration (FDA) issued a final rule to deem products meeting the statutory definition of “tobacco product” to be subject to the Federal Food, Drug, and Cosmetic Act (FD&C Act). The FD&C 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. This final rule extends the Agency’s “tobacco product” authorities 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. 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. FDA is taking this action to reduce the death and disease from tobacco products.

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SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

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 (44 U.S.C. 3501-3520).

The Food and Drug Administration (FDA) issued a final rule to deem products meeting the statutory definition of "tobacco product" to be subject to the Federal Food, Drug, and Cosmetic Act (FD&C Act). The FD&C 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.

The Tobacco Control Act, enacted on June 22, 2009, amended the Food, Drug, & Cosmetic Act (FD&C Act) and provided FDA with the authority to regulate tobacco products (Pub. L. 111-31; 123 Stat. 1776). Specifically, section 101(b) of the Tobacco Control Act amended the FD&C Act by adding chapter IX that provides FDA with tools to regulate tobacco products. Section 901 of the FD&C Act states that 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 order to extend FDA's "tobacco product" authorities to other tobacco products not specifically enumerated in the statute, FDA must issue a regulation deeming them to be subject to Chapter IX of the FD&C Act. Section 201(rr) of the FD&C Act (21 USC 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)" that is not a drug, device, or combination product under the FD&C Act. This final rule extends FDA's "tobacco product" authorities under Chapter IX to all tobacco products that meet the statutory definition of "tobacco product" in section 201(rr) of the FD&C Act.

Section 906(d) of the FD&C Act allows FDA to promulgate a restriction on the sale and distribution of a tobacco product, including restrictions on the access to, and the advertising and promotion of, a "tobacco product," if the Agency determines that "such regulation would be appropriate for the protection of the public health." The finding as to whether "such regulation would be appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account—(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and (B) the increased or decreased likelihood that those who do not use tobacco products will start using such products."

With this final rule, FDA is extending the Agency's "tobacco product" authorities 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.

Health Concerns Regarding Cigars and Other Tobacco Products

In the "Findings" section of the Tobacco Control Act (section 2), Congress proclaimed that the "use of tobacco products by the Nation's children is a pediatric disease of considerable proportions that results in new generations of tobacco-dependent children and adults," and that a "consensus exists within the scientific and medical communities that tobacco products are inherently dangerous and cause cancer, heart disease, and other serious adverse health effects." In enacting the Tobacco Control Act, Congress found that providing FDA with authority to regulate tobacco products, including the advertising and promotion of such products, would result in significant benefits to the American public in human and economic terms. Virtually all new users of tobacco products are minor children and a reduction in tobacco use by this population alone could significantly reduce tobacco-related death and disease in the United States.

The information collection provisions for which we are seeking OMB approval to collect in this final rule have either **(1)** existing burdens associated with tobacco products currently subject to Chapter IX of the FD&C Act (i.e., cigarettes, cigarette tobacco, RYO tobacco, and smokeless tobacco) with approved OMB control numbers; **(2)** burdens associated with tobacco products currently subject to Chapter IX of the FD&C Act, but have not yet been approved by OMB; or **(3)** a new burden that would apply only to newly deemed covered tobacco products.

Descriptions of Information Collections

For this information collection only #2 and #3 above will be submitted for approval under this OMB Control number 0910-0768. The existing burdens associated with currently regulated products (#1) will be submitted to OMB under their existing control numbers as revisions.

(1) Tobacco Products Currently Subject to Chapter IX of the FD&C Act

This section describes existing collections of information currently approved by OMB under the Paperwork Reduction Act of 1995 (PRA) for tobacco products subject to Chapter IX of the FD&C Act (i.e., cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco). FDA solicited public comment since they are being revised in this final rule to include newly deemed tobacco products.

Tobacco Product Establishment Registration and Submission of Certain Health Information Revision submitted under (OMB No. 0910-0650)

Section 905(b) of the FD&C Act (21 U.S.C. 395(b)) 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 "shall, at the time of registration under any such subsection, file with [FDA] a list of all tobacco products which are being manufactured, prepared, compounded, or processed by that person for commercial distribution," along with certain accompanying consumer information, such as all labeling and a representative sampling of advertisements.

Section 904(a)(1) of the FD&C Act requires each tobacco product manufacturer or importer, or agent thereof, to submit "a listing of all ingredients, including tobacco, substances, compounds, and additives that are * * * added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product by brand and by quantity in each brand and subbrand." Section 904(c) of the FD&C Act also requires submission of information whenever additives, or the quantities of additives, are changed.

FDA issued guidance documents on both (1) Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments (74 FR 58298, November 12, 2009) and (2) Listing of Ingredients in Tobacco Products (74 FR 62795, December 1, 2009) to assist persons making these submissions to FDA under the FD&C Act. Although electronic submission of registration, 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 Unified Registration and Listing System (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.The information collected under these provisions of the FD&C Act will help FDA meet inspection requirements, and will inform FDA's development of good manufacturing practices and review standards for new tobacco products.

Tobacco Health Document Submission Revision submitted under (OMB No. 0910-0654)

Section 904(a)(4) of the FD&C Act requires each tobacco product manufacturer or importer, or agent thereof, to submit to FDA all documents developed after June 22, 2009 "that relate to health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents (including smoke constituents), ingredients, components, and additives" ("tobacco health documents"). Information required under section 904(a)(4) was due to FDA beginning December 22, 2009, for tobacco products already subject to Chapter IX of the FD&C Act. FDA is collecting this information submitted pursuant to section 904(a)(4) through an electronic portal and through a paper form for those individuals who choose not to use the electronic portal.

The information collected under this provision of the FD&C Act will inform FDA's development of good manufacturing practices, review standards for new tobacco products, and regulation of modified risk tobacco products.

Exemptions from Substantial Equivalence Requirements Revisions submitted under (OMB Control Number: 0910-0684)

In a final rule published on July 5, 2011 (76 FR 38961), FDA established procedures for manufacturers to request exemptions from the substantial equivalence requirements of the Tobacco Control Act ("SE Exemptions Final Rule"). The SE Exemptions Final Rule implements section 905(j)(3) of the FD&C Act, which provides that FDA may exempt tobacco products from substantial equivalence requirements that are modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive, if FDA determines that: (1) The modification would be a minor modification of a tobacco product that can be sold under the FD&C

Act, (2) a report is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for protection of the public health, and (3) an exemption is otherwise appropriate.

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

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

There is also a procedural mechanism for rescinding an exemption where necessary to protect 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.

This information will enable FDA to determine whether the exemption request would be appropriate for the protection of the public health.

Reports Intended to Demonstrate the Substantial Equivalence of a New Tobacco Product Revision submitted under (OMB No. 0910-0673)

Section 905(j)(1) of the FD&C Act authorizes FDA to establish the form and manner for the submission of information related to substantial equivalence (21 U.S.C. 387e(j)(1)). In a level 1 guidance document issued under the Good Guidance Practices regulation (21 CFR 10.115), FDA provided recommendations intended to assist persons submitting reports under section 905(j) of the FD&C Act, and explains, among other things, FDA's interpretation of the statutory sections related to substantial equivalence.

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 substantial equivalence 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 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 Center for Tobacco Products estimates that it will take less time to prepare those shorter substantial equivalence reports.

The information collected under these provisions of the FD&C Act will enable FDA to determine if a new tobacco product, including a tobacco product that has been on the market since February 15, 2007, is substantially equivalent to a predicate tobacco product.

Electronic Importer's Entry Notice Revision submitted under (OMB No. 0910-0046)

Upon the passage of the Tobacco Control Act, section 801 of the FD&C Act was amended to add tobacco products to the inventory of FDA-regulated products. Section 801 charges the Secretary of Health and Human Services (HHS), through the FDA, with

the responsibility of assuring foreign-origin, FDA-regulated foods, drugs, cosmetics, medical devices, radiological health, and tobacco products being 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).

Until October 1995, importers were required to manually file entries on OMB-approved forms and attach 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 eliminated the paper forms effective October 1, 1995, to eliminate duplication of information and to reduce the paperwork burden both on the import community and FDA. FDA then developed and implemented an automated nationwide entry processing system, which enabled FDA to more efficiently obtain and process the information it requires to fulfill its regulatory responsibility.

Most of the information FDA requires to carry out its regulatory responsibilities under section 801 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 completed only once.

This collection of information in this section is being used by FDA to review and prevent imported products from entering the United States if the products do not meet the same requirements of the FD&C Act as domestic products.

Exports: Notification and Recordkeeping Requirements Revisions submitted under (OMB No. 0910-0482)

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.This information is needed to reflect the Agency's regulatory authority over tobacco products under the Tobacco Control Act, and the amendments approved in the conforming amendments rule ensure tobacco manufacturers adhere to the regulations that apply to other FDA-regulated products, where appropriate.

Establishing that a Tobacco Product was Commercially Marketed in the United States as of February 15, 2007 Revisions submitted under (OMB No. 0910-0775)

On September 29, 2014, FDA announced the availability of a guidance document entitled "Establishing that a Tobacco Product was Commercially Marketed in the United States as of February 15, 2007" (79 FR 58358). This guidance provides manufacturers with information on how they may demonstrate that a tobacco product was commercially marketed in the United States as of February 15, 2007, and is, therefore, a grandfathered product not subject to premarket review. The guidance recommends that the manufacturer provide evidence that may include 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 as of February 15, 2007.

The information collected under these provisions of the FD&C Act will enable FDA to respond to a manufacturer's request for an FDA determination that the product be

considered “grandfathered” and not subject to premarket review. A product that is considered “grandfathered” may also serve as a predicate tobacco product for SE determinations.

(2) 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

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 a 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 substantial equivalence.

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 Office of Science in CTP to discuss their investigational plan. The request for a meeting should be sent in writing to the Director of CTP's Office of Science and should include adequate information for FDA to assess the potential utility of the meeting and to identify FDA staff necessary to discuss 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 1.--Estimated Annual Reporting Burden

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
Obtaining an FDA Order Authorizing Marketing of Tobacco Product (the application) 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)					0 01,284,750

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

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 proposed rule 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. FDAs 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.

(3) New collections of information that apply only to newly deemed tobacco products

Exemption From the Required Warning Statement Requirement

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 2.--Estimated Annual Reporting Burden[1]

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

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)).

Submitting Warning Plans for Cigar Manufacturers, Importers, Distributors, and Retailers

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 0901-0671. 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 3.--Estimated Annual Reporting Burden

Cigar Warning Plan	No. of Respondents	No. 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					0

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 Federal Trade Commission 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.

Small-Scale Manufacturer Report

As discussed in section IV of the deeming final rule, 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 4.--Estimated Annual Reporting Burden

Activity	No. of Respondents	No. 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

2. Purpose and Use of the Information Collection

The final rule will extend FDA's tobacco product authorities to other tobacco products which meet the statutory definition of "tobacco product" in section 201(rr) of the FD&C Act.

In the Tobacco Control Act, Congress stated that the "use of tobacco products by the Nation's children is a pediatric disease of considerable proportions that results in new generations of tobacco-dependent children and adults", and that a "consensus exists within the scientific and medical communities that tobacco products are inherently dangerous and cause cancer, heart disease, and other serious adverse health effects." Congress found that providing FDA with authority under the Tobacco Control Act to regulate tobacco products would result in significant benefits to the American public in human and economic terms. The information collections in the deeming final rule will assist FDA in regulating tobacco product manufacturing and use among teens and adults.

Respondents to this collection of information include members of private sector businesses who manufacture products that meet the definition of "tobacco products" under section 201(rr) of the FD&C Act and whose intended distribution is within the United States.

If the information were not collected, FDA would be unable to regulate newly deemed tobacco products to protect the public health.

3. Use of Improved Information Technology and Burden Reduction

FDA has chosen to collect the required information through an electronic portal and through a paper form for those individuals who choose not to use the electronic portal. FDA estimates that approximately 90% of the respondents will use the electronic portal to fulfill the agency's request for registration and listing, and product ingredient listing.

Electronic submission of information is consistent with the Government Paperwork Elimination Act (Public Law 105-277) requirement that Federal agencies allow individuals or entities to submit information or transact business with the agency electronically. Because of the broad availability of the Internet, FDA does not anticipate any need to submit information requested under this rule in a non-electronic format. However, a company that is not able to submit in an electronic format may submit their information in an alternative format. FDA estimates that based on its past experience with submittal of information, approximately 90% of the respondents will submit the information electronically. For the purposes of calculating burden in Item 12, 100% of respondents will be assumed to be using the electronic portal to submit this information to FDA.

4. Efforts to Identify Duplication and Use of Similar Information

This information collection is not duplicative. The FDA is the only Federal agency responsible for the collection of newly deemed tobacco product information, and the primary federal regulatory authority with respect to the manufacture, marketing, and distribution of tobacco products. Therefore, no duplication of data exists.

5. Impact on Small Businesses or Other Small Entities

The potential respondents to this collection of information are businesses who manufacture products which have been deemed to meet the definition of "tobacco products" under section 201(rr) of the FD&C Act. The information submission requirements do not fall disproportionately upon small businesses, as the Tobacco Control Act requires the submission of this information from all manufacturers of tobacco products. FDA is also allowing for the alternative submittal of this information in paper form for those individuals who are unable, or choose not to, use the electronic submission. FDA continues to pursue means of reducing the reporting burden for both small and large respondents and will continue to employ the latest technology for receiving these submissions, consistent with the intent of the legislation.

6. Consequences of Collecting the Information Less Frequently

The FD&C Act states that respondents to this collection of information generally will respond when they first enter the market, and occasionally on an "as needed" basis. When approved, this rule will allow for the collection of information from tobacco product manufacturers whose products meet the definition of tobacco products under section 201(rr) of the FD&C Act. Collecting the information less frequently would impede FDA's regulatory authority over tobacco product manufacturers and their products.

There are no legal obstacles to reduce the burden of this collection of information

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This section is not applicable. There are no special circumstances for collecting this information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

As required by section 3506(c)(2)(B) of the Paperwork Reduction Act of 1995 (PRA), FDA provided an opportunity for public comment on the information collection requirements of the final rule that published in the FEDERAL REGISTER of April 25, 2014 (79 FR 23142). FDA received approximately 1350,000 comments on this proposed rule from tobacco product manufacturers, trade associations, and individuals. Approximately 350 of those comments were related to PRA. We have grouped and summarized the comments and responses by the four areas the PRA solicits public comments.

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) 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 proposed rule, 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 of the final rule. 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) 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 substantial equivalence, 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) 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 proposed rule 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 of the final rule. 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) 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 proposed rule (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. FDA recently announced 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, 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 announced 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 of the final rule. 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) 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 proposed rule, 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 as described in the PRA section of the deeming final rule. 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) Some comments noted that the proposed rule 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 proposed rule, 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. 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) 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 proposed rule 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) 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 collection and the other associated collections detail the current estimates FDA believes to be accurate.

(Comment) 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 substantial equivalence, then the manufacturer must submit a PMTA. The requirements of a PMTA may vary based on the type and complexity of the product.

(Comment) 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) 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 proposed rule'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 substantial equivalence. 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 of the final rule. 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) 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 proposed rule 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) 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--substantial equivalence to a valid predicate product, exemption from substantial equivalence, 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 substantial equivalence, 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) 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 substantial equivalence. Per Agency experience and updates in the industry, FDA has updated the number of ENDS products we estimate will submit a PMTA.

(Comment) 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) 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 proposed rule. 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 proposed rule. 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 proposed rule was in review, and since the proposed rule 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) 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 the final rule, 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 in the final rule, 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) 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 of the final rule, 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 in the final rule, 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) 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 the final rule.

(Comment) 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) 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 substantial

equivalence (SE) and substantial equivalence 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) Several comments pointed out inconsistencies between the PRA and Analysis of Impacts sections in the proposed rule. 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) 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) 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 proposed rule. 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) 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 proposed rule and throughout the 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) 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.

9. Explanation of Any Payment or Gift to Respondents

This information collection does not provide for any payment or gift to respondents.

10. Assurance of Confidentiality Provided to Respondents

Information provided by respondents will be kept private and anonymous, except as otherwise required by law. Among the laws governing the disclosure of data submitted under this final collection of information are the Freedom of Information Act (FOIA) (5 U.S.C. 552), section 101 of the Family Smoking Prevention and Tobacco Control Act (which protects certain information from disclosure see Public Law 111-31, June 22, 2009), and FDA's implementing regulations at 21 CFR Part 20. Under FOIA, the public has broad access to agency records, unless the records (or a part of the records) are protected from disclosure by any of the law's nine exemptions.

11. Justification for Sensitive Questions

This information collection does not contain questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

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

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)).

The total burden for these new collections of information is 1,326,000 reporting hours (1,285,550 + 800 + 20 + 39,480 + 150).

ROCIS: The following table summarizes the burden in this collection of information which has been entered into OMB and GSA's ROCIS electronic information submission system. This is a summary of all reporting and recordkeeping burden information entered into ROCIS for this final rule.

Table 1
Total Burden Entered Into ROCIS

Reporting and Recordkeeping Burden			
Table	**IC Title**	**Responses**	**Hours**
1	Obtaining an FDA Order Authorizing Marketing of Tobacco Product (the application) and § 25.40 Environmental Assessments	750	1,285,550
1	Request for Meeting with CTP's Office of Science to Discuss Investigational Plan	200	800
2	Exemptions from the Required Warning Statement Requirement	1	20
3	Cigar Warning Plan	329	39,480
4	Small-Scale Manufacturer Report	75	150
Totals		**0**	**0**

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

12b. Annualized Cost Burden Estimate

The estimated cost burden for this collection of information is how much it costs the respondents to respond to FDA's request or requirement for reporting, keeping records or disclosing information. It is expected that an average wage for manufacturing staff to compile and keep this information will be $26.40, based on the Department of Labor's Bureau of Labor Statistics. The total cost, therefore, will be the salary that a company will pay an employee respond to the information collection is considered a cost burden. Include an explanation of how you estimated the cost burden, using appropriate wage rate categories. See below for total respondent costs as estimated by HHS:

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Manufacturers, etc.	1,326,000	$26.40	$35,006,400
Total			$35,006,400

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There is no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

FDA anticipates that the Federal Government will incur the following costs:

Staff Costs

Total annual cost to the Federal Government = $6,380,000

Full time Equivalents = 55; Annual Cost per FTE=$116,000

Annual Cost = $6,380,000

15. Explanation for Program Changes or Adjustments

The estimated burden from the proposed rule has increased by 691,750 (1,326,000-634,250) and the annual responses have decreased by 85,738 (87,093-1,355). The change in burden and responses is due to separating out the collections associated with currently OMB approved collections, and updated estimates for other requirements. As stated

previously, the collections associated with current OMB control numbers will be submitted to OMB as revisions.

16. Plans for Tabulation and Publication and Project Time Schedule

FDA does not intend to publish the results of this information collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA is not requesting an exemption for display of the OMB expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions to the certification statement were identified.