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

Proposed Rule

0910-NEW
0910 AG38

ABSTRACT FOR USE IN ICRAS

ABSTRACT

The Food and Drug Administration (FDA) is issuing a proposed 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 proposed rule would extend 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. This proposed rule also would prohibit the sale of tobacco products covered under the rule to individuals under the age of 18 and would require the display of health warnings on tobacco product packages and in advertisements for tobacco products covered under the rule. FDA is taking this action to address the public health concerns associated with the use of tobacco products.

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SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

This proposed 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) is issuing a proposed 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."

Tobacco use is the leading preventable cause of disease, disability, and death in the United States. When people do not use tobacco products, the positive impact on public health is great. For example, smoking declines in the last half century are responsible for nearly 40 percent of the reduction in male lung cancer deaths between 1991 and 2003. By extending FDA's "tobacco product" authorities under Chapter IX of the FD&C Act to all tobacco products meeting the statutory definition, and not limiting the reach of the Chapter IX authorities to cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco, FDA would be better able to ensure that the health risks of these products are effectively communicated to consumers and that youth do not have access to these products, thereby increasing the likelihood that existing users will quit using

tobacco products, and decreasing the likelihood that new users will initiate tobacco product use.

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 proposed rule would extend 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, the "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."

In this proposed rule, the Agency is proposing to extend FDA's "tobacco product" authorities in Chapter IX of 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. The proposed rule also would prohibit the sale of covered tobacco products to individuals under the age of 18 and prohibit the sale of covered tobacco products using the assistance of any 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, permitted to enter, at any time. Lastly, the proposed rule would require specified health warnings for covered tobacco products on tobacco product packages and advertisements.

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 comment in this proposed 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

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 is making these collections again available for public comment since they are being revised in this proposed rule to include newly deemed tobacco products.

Tobacco Product Establishment Registration and Submission of Certain Health Information (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 has issued guidance documents for currently regulated tobacco products in both the Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments (November 12, 2009, 74 FR 58298) and the Listing of Ingredients in

Tobacco Products (December 1, 2009, 74 FR 62795) to assist persons making registration and product listing and listing of ingredients in tobacco product submissions to FDA under the Tobacco Control Act. FDA is strongly encouraging electronic submission to facilitate efficiency and timeliness of data management and collection and has designed an electronic submissions application to streamline the data entry process for registration and product listing and for ingredient listing. FDA has also developed paper forms as an alternative submission tool.

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 (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 currently 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 (OMB Control Number: 0910-0684)

In a final rule published on July 5, 2011 (76 FR 38961), FDA established a pathway for manufacturers to request exemptions from the substantial equivalence requirements of the Tobacco Control Act ("SE Exemptions Final Rule"). The SE Exemptions Final Rule implements section 905(j)(3) of the FD&C Act, under which FDA may exempt tobacco products 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.

The exemption request must also contain a certification by a responsible official summarizing the supporting evidence and providing the rationale for the official's determination that the modification will not increase the product's toxicity, addictiveness, or appeal to/use by minors; and include other information justifying an exemption. There is also a procedural mechanism for rescinding an exemption where necessary to protect the public health. In general, FDA would rescind an exemption only after providing the manufacturer notice of the proposed rescission and an opportunity for an informal hearing under part 16 (21 CFR Part 16). However, FDA may rescind an exemption prior to notice and opportunity for a hearing under part 16 if the continuance of the exemption presents a serious risk to public health. In that case, FDA would provide the manufacturer an opportunity for a hearing as soon as possible after the rescission.

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 (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.

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 (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 offered for import into the United States meet the same requirements of the act as do 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), as CBP is responsible for enforcing the revenue laws covering the very same products.

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.

Further Amendments to General Regulations of the Food and Drug Administration to Incorporate Tobacco Products (OMB No. 0910-0690)

FDA amended title 21 of the Code of Federal Regulations (CFR), to reflect the Agency's authority over tobacco products under the Tobacco Control Act. FDA added "tobacco products" to the list of products covered by § 1.21(a) and (c)(1) (21 CFR 1.21(a) and (c)(1)) and § 1.101(a) and (b) (21 CFR 1.101(a) and (b)). The agency also is revising the definition of "product" in § 7.3(f) (21 CFR 7.3(f)) to include tobacco products; and revising § 16.1(b) (21 CFR 16.1(b)) to add provisions from the Tobacco Control Act that allow for hearings.

Section 1.101(b) - Section 1.101 outlines the notification and recordkeeping requirements for exports of FDA-regulated products and states that persons exporting an article under section 801(e)(1) of the FD&C Act or an article otherwise subject to section 801(e)(1) of the Act shall maintain records demonstrating that the product meets the requirements of section 801(e)(1) of the Act. The records shall be maintained for the same period of time as required for records subject to good manufacturing practice or quality systems regulations applicable to the product, and shall be made available to FDA upon request during an inspection for review and copying by FDA. The records must demonstrate that the product meets the foreign purchaser's specifications that the product does not conflict with the laws of the importing country, that the product is labeled on the outside of the shipping package that it is intended for export, and should show that the product is not sold or offered for sale in the United States. Because section 103(l) of the Tobacco Control Act specifically amends section 801 of the FD&C Act to include "tobacco products" on the list of FDA-regulated products that may be exported under this section, this final rule amends § 1.101(b) to indicate that tobacco products exported under section 801(e)(1) of the FD&C Act also would be subject to the recordkeeping requirements of this regulation.

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 final rulemaking ensure tobacco manufacturers adhere to the regulations that apply to other FDA-regulated products, where appropriate. The approved rule requires persons who export human drugs, biologics, devices, animal drugs, cosmetics, and tobacco products that may not be sold in the United States to maintain records demonstrating their compliance with the requirements in section 801(e)(1) of the FD&C Act.

New Collections:

Establishing that a Tobacco Product was Commercially Marketed in the United States as of February 15, 2007

On April 25, 2011, FDA announced the availability of a draft guidance document entitled "Establishing that a Tobacco Product was Commercially Marketed in the United States as of February 15, 2007" (76 FR 22903). This guidance, when finalized, will provide 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 draft guidance recommended that the manufacturer provide evidence that may include dated copies of advertisements, dated catalog pages, dated promotional material, and dated bills of lading. FDA recommended that the manufacturer submit as much information as possible to demonstrate that the tobacco product was commercially marketed in the United States as of February 15, 2007. FDA has not yet finalized this draft guidance.

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

considered “grandfathered” and not subject to premarket review. This information is extremely important, as a product that is considered “grandfathered” may also serve as a predicate tobacco product.

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” (76 FR 60055). This guidance, when finalized, will provide industry with information on how to submit an application for premarket review of new tobacco products as required by section 910 of the FD&C Act. Section 910(a)(1) of the FD&C Act requires persons who either create a new tobacco product that was not commercially marketed in the United States as of February 15, 2007, or modify a tobacco product in any way after February 15, 2007, ‘‘including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery, or form of nicotine, or any other additive or ingredient,’’ to submit a premarket tobacco product application and obtain an order from FDA authorizing the marketing of the product before the product may be introduced or delivered for introduction into interstate commerce, unless the product has been shown to be substantially equivalent to a tobacco product commercially marketed in the United States as of February 15, 2007, or exempt from a substantial equivalence determination pursuant to an issued regulation.

The final guidance will explain the requirements and provide recommendations for the contents of an application for premarket review of a new tobacco product including a cover letter, an executive summary, full reports of all investigations of health risks, a full statement of all components, ingredients, additives, and properties, and of the principle or principles of operation of such tobacco product, a full description of methods of manufacturing and processing, a listing of all manufacturing, packaging, and control sites for the product, an explanation of how the product complies with applicable tobacco product standards, samples and components; and proposed labeling. As part of the application, if an applicant does not submit information on any of the previously mentioned items, they should include a statement indicating which information is not being submitted and an explanation of why the information is not being submitted.

FDA also accepts requests for meetings between industry and FDA for persons who would like to discuss their investigational plan prior to distributing the product for investigational purposes. The request for a meeting would be sent in writing to the FDA and should include adequate information for FDA to assess the potential utility of the meeting and to identify FDA staff necessary to discuss proposed agenda items. Under section 902(6)(A) (21 U.S.C. 387b(6)(A)), a tobacco product is deemed adulterated if it is a new tobacco product and does not have an order in effect under section 910(c)(1)(A)(i) of the FD&C Act. Under section 301(a) of the FD&C Act (21 U.S.C. 331(a)), the introduction or delivery for introduction into interstate commerce of any adulterated tobacco product is a prohibited act. Violations of section 910 are subject to regulatory and enforcement action by FDA, including, but not limited to, seizure and injunction.

The information requested will assist FDA in reviewing manufacturer's applications for premarket review of a new tobacco product as required by section 910 of the FD&C Act. FDA needs this information under section 910 of the FD&C Act so that a market authorization order may be issued before a tobacco product may be introduced into interstate commerce when the tobacco product is new or modified in any way.

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

Exemption from the Required Warning Statement Requirement

This proposed rule contains a new information collection that pertains to an exemption process related to the requirement to include the warning statement in proposed section 1143.5(a)(1). Proposed section 1143.5(c) would provide an exemption to the manufacturer of a covered tobacco product that otherwise would be required to include the warning statement in proposed section 1143.5(a)(1) on its packages and in its advertisements (i.e., "WARNING: This tobacco product contains nicotine. Nicotine is an addictive chemical."). In order to obtain this exemption, such a manufacturer would be required to certify to FDA that its product does not contain nicotine and that the company has data to support that assertion; and, therefore, the product does not warrant the proposed addictiveness warning. For any product that obtains this exemption, the proposed section requires that the product still bear the message: "This is a tobacco product." The parties that package and label such covered tobacco products would share responsibility for ensuring that this alternative statement is included on product packages and in advertisements. While FDA is not aware of any currently marketed covered tobacco products that do not contain nicotine, the proposed rule would permit companies to obtain an exemption from this warning requirement in the event that such tobacco products are developed in the future.

FDA requires this information to effectively assist them in regulating tobacco products which do not contain nicotine.

Accessories

Under proposed section 1100.3, FDA defines "accessory" to be "any item intended or expected to be used by consumers in the consumption, storage, personal possession, or alteration of any tobacco product unless it has no intended or foreseeable effect on public health." FDA researched accessories and discovered that there is an extremely wide range of tobacco products that could be considered an accessory, including items such as carrying cases, hookah pipes, and oils used to clean humidors. However, the determination of whether an accessory would be covered under this proposed rule is whether it has an "intended or foreseeable effect on public health." FDA does not have sufficient information at this time to determine how many accessories would be covered under this proposed rule, and is requesting comment on calculating the number of accessories that would be subject to Chapter IX provisions among the three categories of

cigar, pipe, and other tobacco products. FDA will then update the applicable burden tables to include accessories.

This information collection is not related to the American Recovery and Reinvestment Act of 2009 (ARRA).

2. Purpose and Use of the Information Collection

The proposed rule, when finalized, 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. The information to be collected under this proposed rule will be used by the FDA to determine if promulgating a restriction on the sale and distribution of a tobacco product, including restrictions on the access to, and the advertising and promotion of, the tobacco product is proper if the Agency determines that such regulation would be appropriate for the protection of the public health, with respect to the risks and benefits to the population as a whole.

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 proposed to be collected 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 which 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 an exemption request in an electronic

format may request to submit the request 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 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 proposed rule that published in the FEDERAL REGISTER of (month) (day), 201x (xx FR xxxxx).

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 proposed 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

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 proposed rule.

Table 1
Total Burden Entered Into ROCIS

Reporting and Recordkeeping Burden			
Table	**IC Title**	**Response**	**Hours**
2	Tobacco Product Establishment Registration	604	1,812
2	Tobacco Product Listing	13,745	10,309
2	Obtaining a Dun and Bradstreet D-U-N-S Number	604	303
2	Tobacco Product Ingredient Listing	13,745	41,235
3	Health Document Submission	20	1,000
4	Preparation of Tobacco Product Exemption from Substantial Equivalence Request	468	5,616
4	Preparation of Additional Information for Tobacco Product Exemption from Substantial Equivalence Request	140	420
4	Preparation of an Environmental Assessment	468	5,616
4	Exemption from SE Report to Demonstrate Tobacco Product Modified Under Section 905(j)(3)	701	2,103
5	Reports Intended to Demonstrate the Substantial Equivalence of a New Tobacco Product	2,104	378,720
5	Environmental Assessments Reports Intended to Demonstrate the Substantial Equivalence of a New Tobacco Product	2,104	25,248
6	Importation of Tobacco Products	50,660	7,092
7	Further Amendments to General Regulations of	237	5,214

	the FDA to Incorporate Tobacco Products*		
8	Cigars 2 Largest Manufacturers Establishing that a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007	50	500
8	Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007	1,361	13,610
9	Obtaining an FDA Order Authorizing Marketing of Tobacco Product (the application)	27	135,000
9	Request for Meeting with CTP's Office of Science to Discuss Investigational Plan	27	108
9	Environmental Assessments Applications for Premarket Review of New Tobacco Products	27	324
10	Exemptions from the Required Warning Statement Requirement	1	20
Totals		**87,093**	**634,250**

**Table 7 (Further Amendments) contains Recordkeeping burden. All other burden is Reporting Burden.*

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

12 a. Annualized Hour Burden Estimate

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

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

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

Table 2. – Estimated Annual Reporting Burden **Registration and Product Ingredient Listing Estimated Annual Reporting Burden[1]**					
Activity	No. of Respondents	No. of Responses per Respondent[2]	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
Tobacco Product Establishment Registration (electronic and paper submission):					
Cigar Manufacturers (Including Large	121	1.0	121	3	363

and Small)					
Pipe Tobacco Manufacturers	73	1.0	73	3	219
Other Tobacco, E-cigarettes, and Nicotine Product Manufacturers	140	1.0	140	3	420
Importers of Cigars (222) and Pipes (48)who are considered manufacturers[3]	270	1.0	270	3	810
Total Tobacco Product Establishment Registration					**1,812**
Tobacco Product Listing (electronic and paper submission):					
Cigar Manufacturers (Including Large, Small, and Importers)	343	32.6	11,169	0.75 (45 minutes)	8,377
Pipe Tobacco Manufacturers	73	12.3	901	0.75 (45 minutes)	676
Other Tobacco, E-cigarettes, and Nicotine Product Manufacturers	188	8.9	1,675	0.75 (45 minutes)	1,256
Total Hours Tobacco Product Listing					**10,309**
Obtaining a Dun and Bradstreet D-U-N-S Number:					
Cigar Manufacturers (Including Large and Small)	121	1.0	121	0.5 (30 minutes)	61
Pipe Tobacco Manufacturers	73	1.0	73	0.5 (30 minutes)	37
Other Tobacco, E-cigarettes, and	140	1.0	140	0.5 (30 minutes)	70

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

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

[2]This number is estimated to be the total annual responses divided by the number of respondents, rounded to the nearest tenth.

[3] Under 21 U.S.C. 387(20), a "tobacco product manufacturer" includes any person who "imports a finished tobacco product for sale or distribution in the United States."

FDA estimates that the total reporting burden hours for this section is 53,659 hours. This is estimated as follows:

Based on aggregate information for 2012 obtained from the Department of the Treasury, Taxation and Trade Bureau (TTB), FDA estimates that 194 domestic manufacturers of cigars and pipes and 270 importers of cigars and pipes would be required to register their establishments under section 905 of the FD&C Act. Based on FDA's own research, FDA

estimates another 140 manufacturers of other tobacco products (non-cigar and non-pipe) would be subject to registration requirements. FDA estimates that the submission of registration information as required by section 905 of the FD&C Act will take 3 hours per establishment, with a total of 604 establishments who would be required to register under this proposed rule, for a total of 1,812 hours (604 x 3).

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

FDA derived the product listing estimate (total annual response) for other newly deemed tobacco products (excluding cigars and pipe tobacco) using an assumption of 15 percent of the number of machine-made cigar products and Universal Product Codes (UPCs). FDA estimates that the submission of product listing information as required by section 905 of the FD&C Act will take 45 minutes per submission for 13,745 submissions for a total of 10,309 hours.

FDA estimates that obtaining a Dun and Bradstreet D-U-N-S number will take 30 minutes. FDA assumes that all the establishment facilities that would be required to register under section 905 of the FD&C Act would obtain a Dun and Bradstreet D-U-N-S number, with a total of 604 establishments who would need to obtain this number. The total burden to obtain a D-U-N-S number is expected to be approximately 303 hours.

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

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

Table 3. – Estimated Annual Reporting Burden
Tobacco Health Document Submission[1]

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
Cigar Manufacturers (Including Large and Small)	2	4	8	50	400
Pipe Tobacco Manufacturers	1	4	4	50	200

Other Tobacco, E-cigarettes, and Nicotine Product Manufacturers	1	4	4	50	200
Importers of cigars and pipes who are considered manufacturers	1	4	4	50	200
Total Hours Health Document Submission					**1,000**

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

FDA estimates that the total reporting burden hours for this section is 1,000 hours. This is estimated as follows:

FDA estimates that a tobacco health document submission for cigars, pipe tobacco, other tobacco, and importers of cigars and pipes, as required by section 904(a)(4) of the act, will take approximately 50 hours per submission based on the existing collection that applies to tobacco products currently subject to the FD&C Act and FDA experience. To derive the number of respondents for this provision, FDA assumes that very few of the respondents subject to registration requirements would have health documents to submit. Therefore, the agency estimates that approximately five submissions (two for cigar manufacturers, one for pipe tobacco manufacturers, one for other tobacco product manufacturers, and one for importers of cigars and pipe tobacco who are considered manufacturers) will be submitted on a annual basis. FDA estimates the total number of hours is 1,000 hours (5 submissions multiplied by 4 times per year multiplied by 50 average burden hours.)

Exemptions from Substantial Equivalence Requirements (OMB No. 0910-0684)

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

Table 4 – Estimated Annual Reporting Burden When Manufacturers Choose to Seek Exemptions from Substantial Equivalence[1]

21 CFR and Activity	No. of Respondents	No. of Responses per Respondent[2]	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
21 CFR 1107.1(b) Optional Preparation of Tobacco Product Exemption from Substantial Equivalence Request:					
Cigar Manufacturers (Including Large,	343	0.96	328	12	3,936

Small, and Importers)					
Pipe Tobacco Manufacturers (Including Importers)	121	0.58	70	12	840
Other Tobacco, E-cigarettes, and Nicotine Product Manufacturers	140	0.50	70	12	840
Total Hours 21 CFR 1107.1(b)					**5,616**
21 CFR 1107.1(c) Preparation of Additional Information for Tobacco Product Exemption from Substantial Equivalence Request:					
Cigar Manufacturers (Including Large, Small, and Importers)	343	0.29	98	3	294
Pipe Tobacco Manufacturers (Including Importers)	121	0.17	21	3	63
Other Tobacco, E-cigarettes, and Nicotine Product Manufacturers	140	0.15	21	3	63
Total Hours 1107.1(c)					**420**
21 CFR 25.40 Preparation of an Environmental Assessment:					
Cigar Manufacturers (Including Large, Small, and Importers)	343	0.96	328	12	3,936
Pipe Tobacco Manufacturers (Including Importers)	121	0.58	70	12	840
Other Tobacco, E-cigarettes, and Nicotine Product	140	0.50	70	12	840

Manufacturers					
Total Hours 21 CFR 25.40					**5,616**
905(j)(1)(A)(ii) If exemption granted, Report submitted to demonstrate tobacco product is modified under 905(j)(3), modifications are to a product that is commercially marketed and compliant product, and modifications covered by exemptions granted by Secretary pursuant to 905(j)(3):					
Cigar Manufacturers (Including Large, Small, and Importers)	343	1.43	491	3	1,473
Pipe Tobacco Manufacturers (Including Importers)	121	0.87	105	3	315
Other Tobacco, E-cigarettes, and Nicotine Product Manufacturers	140	0.75	105	3	315
Total Hours 905(j)(1)(A)(ii)					**2,103**
Total Hours Exemptions from Substantial Equivalence Requirements					**13,755**

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

FDA estimates that the total reporting burden hours for this section is 13,755 hours. This is estimated as follows:

The estimated average burden per response (in hours) to prepare an exemption from substantial equivalence report is based on the burdens associated with the existing information collection for exemptions from substantial equivalence that applies to tobacco products currently subject to the FD&C Act (i.e., cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco). Of an estimated 2,806 newly deemed products expected to enter the market through substantial equivalence exemptions (table 4) and substantial equivalence reports (table 5), FDA estimates that 25 percent (701) will enter through substantial equivalence exemptions. FDA estimates that exemption requests will be used for an average of 1.5 products each; therefore, 468 requests for exemption (701 products divided by 1.5 requests) are expected to be submitted annually, and take approximately 12 hours to prepare an exemption request for a total of 5,616 hours (468 x 12 hours).

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

FDA estimates that 604 manufacturers will submit 468 environmental assessments and that it will take approximately 12 hours to prepare and submit one environmental assessment under part 25 in accordance with the requirements of section 25.40, as referenced in section 1107.1(b)(9) for a total of 5,616 hours (468 x 12).

FDA estimates that 604 respondents will prepare 701 responses (604 x 1.16), and each response will take approximately 3 hours to prepare the report required by section 905(j)(1)(A)(ii) for a total of 2,103 hours (701 x 1 x 3).

This collection of information requires a manufacturer to submit a report at least 90 days prior to making an introduction or delivery into interstate commerce for commercial distribution of a tobacco product. The report should contain the manufacturer's basis that the tobacco product is modified within the meaning of the exemption provision in section 905(j)(3), the modifications are to a product that is a commercially marketed and compliant product with the FD&C Act, the modifications are covered by exemptions granted pursuant to section 905(j)(3), and a listing of actions taken to comply with any applicable requirements of section 907 of the FD&C Act.

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

Table 5. – Estimated Annual Reporting Burden
Reports Intended to Demonstrate the Substantial Equivalence of a New Tobacco Product[1]

Activity	No. of Respondents	No. of Responses per Respondent[2]	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
905(j)(1)(A)(i) and 910(a):					
Cigar Manufacturers (Including Large, Small, and Importers)	343	4.29	1,472	180	264,960
Pipe Tobacco Manufacturers (Including Importers)	121	2.61	316	180	56,880
Other Tobacco, E-	140	2.26	316	180	56,880

cigarettes, and Nicotine Product Manufacturers					
Total Hours 905(j)(1)(A)(i) and 910(a)					**378,720**
Section 25.40 environmental assessments:					
Cigar Manufacturers (Including Large, Small, and Importers)	343	4.29	1,472	12	17,664
Pipe Tobacco Manufacturers (Including Importers)	121	2.61	316	12	3,792
Other Tobacco, E-cigarettes, and Nicotine Product Manufacturers	140	2.26	316	12	3,792
Total Environmental Assessment					**25,248**
Total Hours					**403,968**

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

FDA estimates that the total reporting burden hours for this section is 403,968 hours. This is estimated as follows:

FDA has based the estimates for the submission of reports intended to demonstrate the substantial equivalence of a new tobacco product in this section on the full analysis of economic impacts and experience with the existing information collection that applies to tobacco products currently subject to the FD&C Act (i.e., cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco). Of an estimated 2,806 newly deemed products expected to enter the market through substantial equivalence exemptions (table 4) and substantial equivalence reports (table 5), FDA estimates that approximately 75 percent (2,104) will enter the market through substantial equivalence reporting. Therefore, FDA estimates that 604 respondents will prepare and submit 2,104 section 905(j)(1)(A)(i) substantial equivalence reports each year and that it will take a manufacturer approximately 180 hours per report to prepare the reports of substantial equivalence for a new tobacco product. Therefore, FDA estimates the burden for submission of substantial equivalence information will be 378,720 hours (2,104 responses x 180 hours = 378,720 hours.)

In addition, anyone submitting a report of substantial equivalence is also expected to submit an environmental assessment report under section 25.40. Six hundred and four respondents are expected to submit 2,104 total reports and take 12 hours to complete a single report, for a total of 25,248 burden hours (2,104 reports x 12 hours = 25,248 hours.)

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

Table 6 –Estimated Annual Reporting Burden
Electronic Importer's Entry Notice (OMB No. 0910-0046)[1]

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

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

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

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

Further Amendments to General Regulations of the Food and Drug Administration to Incorporate Tobacco Products (OMB No. 0910-0690)

Table 7. – Estimated Annual Recordkeeping Burden
Further Amendments to General Regulations of the Food and Drug Administration to Incorporate Tobacco Products[1]

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

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

FDA estimates that the total reporting burden hours for this section is 5,214 hours. This is estimated as follows:

The Agency has estimated the number of respondents and burden hours associated with the recordkeeping requirements of this section by reviewing Agency records, using Agency expert resources, and conferring with another federal agency with experience and information regarding tobacco product exporters. FDA estimates that 79 establishments (half of the 158 estimated total of all tobacco manufacturers listed in the collection of information approved under OMB No. 0910-0046 who manufacture cigars, pipe tobacco, and other tobacco products) could be involved in the exporting of all newly deemed tobacco products annually.

Based on previous recordkeeping estimates for the exporter's reporting burden in the existing OMB-approved collection of information (OMB control number 0910-0482, "Export Notification and Recordkeeping Requirements"), each establishment will maintain an average of three records per year, and it will take each recordkeeper an average of 22 hours per recordkeeper to maintain each record. The agency estimates 5,214 burden hours will be needed for tobacco product exporters to create and maintain records demonstrating compliance with section 801(e)(1) of the FD&C Act (79 recordkeepers x 3 records per year x 22 hours per record = 5,214).

Burdens associated with tobacco products currently subject to Chapter IX of the FD&C Act, but have not yet been approved by OMB

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

Establishing that a Tobacco Product was Commercially Marketed in the United States as of February 15, 2007

Table 8 – Estimated Annual Reporting Burden
Establishing that a Tobacco Product was Commercially Marketed in the United States as of February 15, 2007[1]

Activity	No. of Respondents	No. of Responses per Respondent[2]	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
Cigars – 2 largest manufacturers	2	25.0	50	10	500
Other Cigar Manufacturers (excluding 2 largest manufacturers and including large and small cigars, and importers)	341	2.8	947	10	9,470
Pipe Tobacco Manufacturers (Including Importers)	121	1.7	204	10	2,040

Other Tobacco, E-cigarettes, and Nicotine Product Manufacturers	140	1.5	210	10	2,100
Total Hours Establishing that a Tobacco Product was Commercially Marketed in the United States as of February 15, 2007					**14,110**

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

FDA estimates that the total reporting burden hours for this section is 14,110 hours. This is estimated as follows:

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

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

Each year, other tobacco manufacturers (i.e., excluding cigars and pipe tobacco) are also 0expected to submit about 1.5 grandfathered product applications each. FDA estimates that it will take these manufacturers 10 hours to complete and submit for FDA review the evidence required by this collection of information. Therefore, FDA estimates that it should take approximately 2,100 hours (210 total annual responses times 10 hours for each response) for other manufacturers to respond to this collection of information.

The total number of burden hours, therefore, is 14,110 (500 hours + 9,470 hours + 2,040 hours + 2,100 hours). FDA has based these estimates on information from interactions

with firms already subject to Chapter IX of the FD&C Act and comments received regarding the submission of reports establishing that a tobacco product was commercially marketed in the United States as of February 15, 2007 from a 60-day Federal Register Notice published on April 25, 2011 (76 FR 22903) that covered tobacco products currently subject to the FD&C Act.

Applications for Premarket Review of New Tobacco Products

Table 9. – Estimated Annual Reporting Burden Applications for Premarket Review of New Tobacco Products[1]					
Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
Obtaining an FDA order authorizing marketing of tobacco product (the application):					
Cigar Manufacturers (Including Large, Small, and Importers)	1	1	1	5000	5,000
Pipe Tobacco Manufacturers (Including Importers)	1	1	1	5000	5,000
Other Tobacco, E-cigarettes, and Nicotine Product Manufacturers	25	1	25	5000	125,000
Total Hours Obtaining an FDA order authorizing marketing of tobacco product (the application)					**135,000**
Request for Meeting with CTP's Office of Science to discuss Investigational Plan:					
Cigar Manufacturers (Including Large, Small, and Importers)	1	1	1	4	4
Pipe Tobacco Manufacturers (Including Importers)	1	1	1	4	4
Other Tobacco, E-cigarettes, and Nicotine Product Manufacturers	25	1	25	4	100
Total Hours Request for Meeting with CTP's Office of Science to discuss					**108**

Investigational Plan					
Section 25.40 environmental assessments:					
Cigar Manufacturers (Including Large, Small, and Importers)	1	1	1	12	12
Pipe Tobacco Manufacturers (Including Importers)	1	1	1	12	12
Other Tobacco, E-cigarettes, and Nicotine Product Manufacturers	25	1	25	12	300
Total Hours Section 25.40 environmental assessments					**324**
Total Hours Applications for Premarket Review of New Tobacco Products					**135,432**

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

FDA estimates that the total reporting burden hours for this section is 135,432 hours. This is estimated as follows:

FDA estimates that it will take each respondent approximately 5,000 hours to obtain an order from FDA allowing the marketing of a new tobacco product. FDA's estimate includes anticipated burden for the writing of an application, including intra-company edits and approvals, of approximately 200 hours. In addition, FDA expects that conducting the necessary scientific investigations for a new tobacco product (either in-house or via 3rd party consultant) will require, on average, 4,800 hours.

FDA also estimates the number of PMTA applications that FDA expects to receive annually will be 27 (1 each from cigar and pipe tobacco manufacturers, and 25 from other tobacco manufacturers.) Therefore, the total annual burden for submitting PMTA applications is estimated to be 135,000 hours (27 respondents x 5,000 hours).

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

include standardized clinical trials, like those conducted to support drug and device approvals.

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

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

FDA also estimates that the 27 potential respondents will take approximately 12 hours to prepare and submit an environmental assessment (for a total of 324 hours) under 21 CFR Part 25 in accordance with the requirements of section 21 CFR 25.40, as referenced in section 1107.1(b)(9).

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

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

Exemption from the Required Warning Statement Requirement

Table 10. – Estimated Annual Reporting Burden
Exemption from the Required Warning Statement Requirement[1]

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

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

FDA estimates that the total reporting burden hours for this section is 20 hours. This is estimated as follows:

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

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

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

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

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.	634,250	$26.40	$16,744,200
Total			$16,744,200

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

This is a new collection of information.

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.