

**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**

**OMB Control Number 0910-0768**

**SUPPORTING STATEMENT**

**A. Justification**

1. Circumstances Making the Collection of Information Necessary

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 issued 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.”

The final rule extended 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. The 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.

## **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.

### **Exemption From the Required Warning Statement Requirement**

This rule contains an information collection that pertains to an exemption process related to the requirement to include the warning statement in § 1143.3(a)(1). Section 1143.3(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.

### **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.

FDA published a final guidance in August 2018 (<https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM534739.pdf>) to assist manufacturers, importers, distributors, and retailers of cigars with the submission of warning plans. FDA will work with the submitters to ensure that the plans submitted meet the established criteria for approval under 21 CFR part 1143.

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.

### **Small-Scale Manufacturer Report**

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.

## 2. Purpose and Use of the Information Collection

The final rule extended 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 deemed tobacco products to protect the public health.

## 3. Use of Improved Information Technology and Burden Reduction

FDA collects 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

In the Federal Register of April 22, 2019 (84 FR 16673), FDA published a 60-day notice requesting public comment on the extension of collection of information “Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act.” FDA received one comment that was PRA related.

The commenter noted that they would like to see the associated collections that the deeming rule revised. FDA appreciates the comment addressing the associated deemed product information collections. FDA notes that in the Paperwork Reduction Act (PRA) section of the deeming final rule (81 FR 28973 beginning on page 29076) all the revised OMB information collection control numbers and their revised burdens were all listed. Per the comment, we have added a listing of all the collections the final rule revised.

The commenter also notes that the burdens associated with deemed products are not all included in this notice even though the notice “appears intended to present a comprehensive set of burden estimates and analyses for information collection activities associated with . . . the Deeming Rule.” FDA notes that this notice is not intended to cover all ICRs associated with the deeming rule. Instead, this notice only covers the information collections that did not already have an approved collection prior to the deeming final rule. For the collections that existed prior to the deeming final rule, FDA added the new associated deeming-related burdens to these previously approved OMB control numbers. We also note that some of the estimates from the PRA section of the deeming rule may have changed since the final rule published. If any estimates have changed, these changes have been published in the Federal Register through the process associated with renewing PRA collections.

The comment also mentions the omission of the burden associated with the submission of harmful and potentially harmful constituents (HPHC) listings. FDA notes that we have not yet sought OMB approval of the burden associated with listing and reporting HPHCs for deemed products. On March 8, 2019, FDA revised the "Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule" guidance and the related Small Entity Compliance Guide, "FDA Deems Certain Tobacco Products Subject to FDA Authority, Sales and Distribution Restrictions, and Health Warning Requirements for Packages and Advertisements." This revision extends the Harmful and Potentially Harmful Constituents (HPHCs) reporting compliance date to a date that is six months after the publication date of a final guidance regarding HPHC reporting under section

904(a)(3) and nine months after that publication date for small tobacco product manufacturers. For products entering the market after the publication date of the final guidance, manufacturers must submit their HPHC report 90 days prior to marketing the products under section 904(a)(3).

In the preamble to the final deeming rule, FDA indicated that it intends to issue guidance regarding HPHC reporting (and later a testing and reporting regulation under section 915) with enough time for manufacturers to report, given the original three-year compliance period. At this time, FDA has not published a final HPHC reporting guidance and as a result, we are providing a revised compliance date based on when a final HPHC reporting guidance is issued.

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)).

FDA estimates the annual burden for the information as follows:

Table 1.--Estimated Annual Reporting Burden<sup>1</sup>

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 21 CFR 25.40 Environmental Assessments:					
Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers (Electronic Nicotine Delivery Systems (ENDS) Liquids and 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)					001,284,750
Request for Meeting with CTP's Office of Science to Discuss Investigational Plan:					
Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers (Electronic Nicotine Delivery Systems (ENDS) Liquids and 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

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA estimates that it will take each respondent approximately 1,500 hours to prepare a PMTA seeking an order from FDA allowing the marketing of a new tobacco product. FDA also estimates that it would on average take an additional 213 hours to prepare an environmental assessment in accordance with the requirements of 21 CFR 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 a small number 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). A PMTA may require one or more types of studies including chemical analysis, nonclinical studies, and clinical studies. FDA also estimates the number of PMTAs that FDA expects to receive annually will be 750 (642 ENDS Liquids and 108 ENDS Delivery Systems).

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.

Therefore, the total annual burden for submitting PMTA applications is estimated to be 1,285,550 hours. FDA's estimates are based on the corresponding information collection estimates and an assumption that manufacturers would submit applications for the premarket review of tobacco products.

In § 1143.3(c) (21 CFR 1143.3(c)) an exemption is provided 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 is 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 is 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, 1143.3 (a)(1) 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.

Table 2.--Estimated Annual Reporting Burden<sup>1</sup>

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
Certification Statement	5	1	5	20	100
Total Exemptions From the Required Warning Statement Requirement					100

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimated average burden per response is based on currently approved information collection estimates. 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 rare and estimates that the Agency will receive on average five submissions 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)).

Table 3.--Estimated Annual Reporting Burden<sup>1</sup>

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	10	1	10	120	1,200
Total Cigar Warning Plan					1,200

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

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) are 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 in 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.

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.

FDA also requires 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.

The burden estimates are based on FDA's experience with cigar warning plans, smokeless warning plans associated information collection (OMB# 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 10 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 1,200 hours.

Table 4.--Estimated Annual Reporting Burden<sup>1</sup>

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

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

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 many 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.

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.	1,286,950	\$26.40	\$33,975,480
Total			\$33,975,480

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 Equivalentents = 55; Annual Cost per FTE=\$116,000

Annual Cost = \$6,380,000

15. Explanation for Program Changes or Adjustments

The total estimated burden for this information collection is 1,286,800 reporting hours, and 1,040 annual responses. Our estimated burden for the information collection reflects an overall decrease of 38,200 hours and a corresponding decrease of 315 responses. We attribute this adjustment to updated information in the number of submissions we received over the last few years.

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.