

**U.S Food and Drug Administration  
Center for Tobacco Products  
Substantial Equivalence Reports for Tobacco Products  
0910-0673  
RIN 0910-AG89**

**SUPPORTING STATEMENT PART A**

**Terms of Clearance:** None

**A. Justification**

1. Circumstances Making the Collection of Information Necessary

On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 111-31) was signed into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by adding, among other things, a chapter granting FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. In May 2016, the FDA issued a final rule that deemed all tobacco products meeting the statutory definition of “tobacco product” be subject to the FD&C Act, except accessories of these deemed tobacco products.

The FD&C Act requires FDA to issue an order under section 910(c)(1)(A)(i) (order after review of a premarket application, see section 910(b) of the FD&C Act) before a new tobacco product may be commercially marketed. An order under section 910(c)(1)(A)(i) is not required, however, if a manufacturer submits a report under section 905(j)(1)(A)(i) for the new tobacco product and FDA issues an order finding that the tobacco product is (1) substantially equivalent to a tobacco product commercially marketed in the United States as of February 15, 2007, and (2) in compliance with the requirements of the FD&C Act. Manufacturers of these tobacco products may submit a report under section 905(j)(1)(A)(i) demonstrating that a new tobacco product is “substantially equivalent, within the meaning of section 910, to a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007, or to a tobacco product that the Secretary has previously determined, pursuant to subsection (a)(3) of section 910, is substantially equivalent and that it is in compliance with the requirements of this Act” (section 905(j)(1)(A)(i) of the FD&C Act). The comparison product chosen by the tobacco product manufacturer is referred to by FDA as the predicate tobacco product. (In addition to the premarket application under section 910(b) and a report under 905(j)(1)(A)(i), certain new tobacco products may use the exemption premarket pathway, see 21 CFR 1107.1.)

For the purposes of 905(j)(1)(A)(i) substantial equivalence reports (SE Reports), the new tobacco product is compared to a predicate tobacco product in determining substantial equivalence (section 910(a)(3)(A) of the FD&C Act). FDA interprets this to mean that a single predicate tobacco product should be used for comparison purposes, as FDA

believes that a meaningful scientific comparison intended to determine whether the characteristics of the products are the same or are different but present no different questions of public health cannot be made between a new tobacco product and multiple predicate products.

The Food and Drug Administration (FDA) is now issuing a rule that establishes requirements for the content and format of SE Reports intended to establish the substantial equivalence of a tobacco product. The rule establishes the information an SE Report must include so that FDA may make a substantial equivalence determination. In addition, the rule establishes the general procedures FDA intends to follow when evaluating SE Reports, including procedures that address communications with the applicant and the confidentiality of data in an SE Report.

2. Purpose and Use of the Information Collection

This rule establishes requirements related to the content and format of SE Reports, including the information that SE Reports must contain. FDA is basing this rule on the experience the Agency has in reviewing thousands of SE Reports since 2010. The respondents to this collection of information are private sector business and other for-profit institutions that manufacture tobacco products and submit SE Reports.

3. Use of Improved Information Technology and Burden Reduction

The rule requires that respondents submit an SE Report in an electronic format, unless a waiver from this requirement is requested by the applicant and granted by FDA. FDA created two new forms for submission: FDA 3964 Tobacco Amendment and General Correspondence Report and FDA 3965 Tobacco Substantial Equivalence Report Submission. FDA estimates that based on its experience with submittal of this type of information, approximately 85 percent of the respondents will submit the information in an electronic format. Although FDA believes most respondents will submit electronically, to be conservative we estimate that 15% of applicants may submit a waiver to submit by paper.

4. Efforts to Identify Duplication and Use of Similar Information

This information collection is not duplicative. The FD&C Act is the only legislation that requires premarket review of new tobacco products and allows for the submission of reports intended to establish a new tobacco product's substantial equivalence to a predicate tobacco product. The FDA is the only Federal agency responsible for the collection of such premarket review 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 FD&C Act authorizes the submission of this information from all manufacturers of tobacco products that submit SE Reports (also “applicants”). Under the assumption that the percentage of tobacco product manufacturing establishments in the Tobacco Tax and Trade Bureau (TTB) data that are small is the same as the percentage of tobacco manufacturing firms that are small, then 164 small manufacturing establishments would be affected by this rule. Similarly, we also expect that most of the importers affected by this rule would be small. Using the proportion of tobacco and tobacco product merchant wholesalers that are small, 214 small importers would be affected by this rule. The impact on these small entities is also dependent on how many SE Reports the entity would submit, and FDA provides its reporting and recordkeeping burdens at section 12 of this document. In certain scenarios, the rule also permits a certification instead of the submission of detailed information, which may further reduce the burden for smaller entities. FDA also 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

Section 905(j)(1)(A)(i) of the FD&C Act requires the submission of SE information to the FDA if the manufacturer of a new tobacco product wishes to demonstrate substantial equivalence to an existing predicate tobacco product. In its SE Report, the applicant must show that its new tobacco product is substantially equivalent to a predicate tobacco product and that the product is also in compliance with the requirements of the FD&C Act. Collecting the information less frequently would not meet the FD&C Act premarket requirements for submission of an SE Report, and would mean that an applicant would need to submit a premarket application under section 910(b) of the FD&C Act.

Respondents to this collection of information include those applicants who wish to demonstrate that a new tobacco product is substantially equivalent to a predicate tobacco product. If this information were not collected, FDA would be unable to make the findings required by section 910(a)(2)(A)(i) of the FD&C Act for a new tobacco product to enter the market. Instead, applicants generally would need to submit premarket applications under section 910(b) of the FD&C Act.

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

This section is not applicable. There are no special circumstances for this collection of 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 April 2, 2019

(84 FR 12740). In response to the proposed rule FDA received the following PRA related comments:

(Comment) Some comments state that FDA underestimated the burden associated with collecting the information and suggest the proposed collection of information would have better utility and value if FDA went by product category. Specifically, the comments take issue with estimates of 683 SE reports filed and state that FDA failed to consider foreign manufacturers filing when the Agency used the registration and listing data to estimate the associated burden with the requirements. The comments also state that FDA has underestimated the burden of the proposed collection of information on FDA and does not reflect the level of agency resources needed to review the thousands of SE reports.

(Response) We disagree. The rule reflects estimates of the burden for the submission and review of SE Reports beginning when the rule becomes effective, which will be 30 days after the final rule publishes. These estimates reflect what we expect will be the level of submissions and burden at that time, based on our experience with SE Reports since the inception of the program. We disagree that we did not account for foreign firms. For SE purposes foreign firms are handled the same way as domestic firms. Although foreign firms are currently not required to register and list, they must still provide a U.S. agent to export import a tobacco product.

(Comment) Several comments stated that our estimate of 87 to 300 hours to prepare and submit an SE Report is too low and that this must not account for the burden associated with HPHC testing. Several comments suggest that, based on the commenters' experience, it will take approximately 900-1,000 hours to prepare an SE Report for one product, and other comments estimate that it may take 15-28 months to prepare an SE Report depending on the scientific testing required. One comment asserts that this estimate is too low because the Agency is assuming a single submission, when the commenter's experience is that multiple submissions may be made with an SE Report including the original report. In addition, the comment states that this estimate does not include the time associated with amending the SE Report or an environmental assessment. The comment states that FDA may need multiple years to review and process SE Reports for tobacco products subject to the deeming final rule ("deemed tobacco products"), such as cigars, and that FDA will likely make multiple requests to applicants for additional information. One comment states that SE Reports require extensive data that could take thousands of hours per application to prepare and submit.

(Response) Because the estimates are based on our experience with SE Reports, we are maintaining the estimates as proposed. The SE program was originally approved by OMB in 2010. Since then, FDA has reassessed the program burden each time the collection was up for extension and other related programmatic changes in between. Additionally, we have further analysis on our reporting and recordkeeping requirements that was provided in the preamble to the proposed rule and the proposed regulatory impact analysis. We note that the final rule provides more clarity on both design parameters for cigars, pipes, and other deemed tobacco products, and also when scientific testing may be needed. This information will assist applicants in understanding

the content and format of an SE report which will accelerate the process of submitting a report.

(Comment) A comment states that our estimated burden of “bundled” SE Reports is significantly lower than our estimate for a single product. The comments believe that this is wrong because the bundled applications cover multiple products and should therefore be greater than the burden associated with preparing a report for a single product.

(Response) We agree that the total time to submit a bundled SE Report is greater than the time to submit a report for a single product. Our estimates for “bundled” SE Reports were the time associated with submitting for each additional product in the bundle. Therefore, the total cost for submitting a bundle of 3 products would be the full SE burden for the first product, plus two times the burden to submit a bundled report. We have clarified this in the final analysis.

(Comment) Several commenters provided estimates for the hours needed for preparing and submitting SE Reports of between 900 hours and 28 months. Based on these hours, the commenters estimate that the cost per SE Report could be between \$250,000 and \$2,000,000, although they state there may be some economies of scale in submitting multiple reports.

(Response) We believe some commenters have confused cost estimates from the regulatory impact analysis (RIA) and burden hours from the PRA. Although these concepts are similar and account for some corresponding items, they ultimately serve different purposes and separate functions. The PRA estimates burden in hours on an annual basis generally for three years; while the regulatory impact analysis uses these estimated burden hours on an annual basis, along with an estimate of wage per hour, to estimate a cost in terms of dollars over a long-term horizon. See comment 4 of the RIA and comment 1 in the appendix of the RIA for a further discussion regarding costs and see comments 2 and 3 of the RIA for discussion on burden hours.

(Comment) A comment states that they believe our estimated burden for an environmental assessment is too high as a proportion of the time to prepare and submit an SE Report. They state that our estimate of 52 to 80 hours for an EA is potentially more than our estimated burden for an SE Report at 35 to 220 hours. Other comments suggest that the burden associated with EAs is too low.

(Response) FDA has estimated 80 hours for an environmental assessment for the SE program for many years. Based on experience with SE Reports, interactions with the industry, and information related to other regulated products we do not have evidence suggesting a different estimate and note that the range given for EAs is intended to reflect the variation that might exist depending on the specific tobacco product.

(Comment) Several comments believe that FDA has substantially underestimated the number of SE Reports it will receive annually. The comments state that FDA should expect tens of thousands of SE Reports--much higher than the proposed rule estimate of 683 standalone SE Reports and 456 bundled SE Reports each year. Additionally, the

commenter also notes that it expects to submit well over 100 reports per year as opposed to the FDA estimate of one application per year.

(Response) FDA believes our PRA estimates are accurate as we have had years of experience with the SE pathway. The SE program was originally approved by OMB in 2010. Since then FDA has reassessed the program burden each time the collection was up for extension and other related programmatic changes in between. Additionally, we have further analysis that was provided in the preamble to the proposed rule and the proposed regulatory impact analysis. As referenced in the proposed rule, many of our estimates were based on submissions being bundled. As is currently the practice, applicants may continue to bundle groups of SE Reports submitted under § 1107.18 that have the same proposed modifications (e.g., a change in ingredient supplier that results in a new tobacco product). Co-packaging two or more tobacco products may result in a new tobacco product. When groups of full or product quantity change SE Reports have identical content, they may be submitted together (bundled); when a group of similar reports are bundled, the subsequent bundled reports are expected to take less time to prepare than the initial report. Additionally, manufacturers may bundle groups of SE Reports for their new products in the same product category and subcategory where the proposed modifications are the same; when a group of similar SE Reports are bundled, the reporting burden for the initial SE Report is expected to take the same amount of time as a stand-alone SE Report. However, the reporting burden for subsequent bundled SE Reports is expected to be lower than the initial SE Report.

Section 1107.18, paragraphs (b) and (c) include requirements that the applicant use the forms that FDA provides when submitting an SE Report. Following our consideration of the comments related to the forms, we are finalizing these requirements without change. We describe the comments to these sections and our responses next.

(Comment) At least one comment states that use of the FDA forms should be optional rather than mandatory.

(Response) We disagree. As explained in the proposed rule, the requirements in this rule, including use of these forms, are intended to provide clarity to applicants with respect to what they should submit in an SE Report and to help ensure that an SE Report provides information necessary for FDA to determine whether the new tobacco product is substantially equivalent to a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007. Additionally, use of a standardized form allows FDA to receive information in a way that allows for faster processing and uploading of the SE Report and its contents, thereby increasing efficiency of the review process.

(Comment) Another comment notes that although FDA appears to recognize that the evidence required in an SE Report depends on whether a new tobacco product has “same” characteristics as the predicate product or if the new tobacco product has “different” characteristics than the predicate product, this distinction is not reflected in either the draft of Form FDA 3965 or the rule itself.

(Response) We disagree. The form and the rule are structured to clarify both the common elements (“same” characteristics) and distinct elements (“different” characteristics) of SE Reports for both new tobacco products with the “same”

characteristics as the predicate product and for new tobacco products with “different” characteristics than the predicate product. This includes reference to and discussion of these elements in the forms and throughout the rule. Applicants should indicate that their report is a “same characteristics” report where no data is necessary to demonstrate that the new tobacco product is substantially equivalent to its predicate. The form has been revised to include a section where the applicant would distinguish whether they are submitting a “same characteristics” SE Report, or a “different characteristics” SE Report. For a “same characteristics” SE Report, an applicant must describe the modification and certify that is the only change between the new and predicate tobacco product.

(Comment) One comment believes FDA has underestimated the time needed to complete the forms and did not explain how it arrived at these estimates.

(Response) FDA conducted a thorough analysis of the current paperwork burden associated with the SE program and other similar forms and applied the most accurate burden to the forms; however, upon consideration of this comment and certain updates made to the form based on comments received and product categorization changes FDA is revising the burden associated with entering the data into the form (which includes searching existing data sources and gathering and maintaining the data needed) to be 45 minutes per individual product (rather than 30 minutes per product) on Form FDA 3965. For Form FDA 3964, FDA is revising the burden for this form to 10 minutes (from 5 minutes). This form serves several purposes from changing a point of contact (minimal burden) to providing additional substantive information for the purpose of the review of the SE Report (more burdensome). FDA notes that the comment did not provide a recommendation for the alternative estimates FDA might consider.

(Comment) One comment believes FDA has underestimated the time needed to complete the forms and did not explain how it arrived at these estimates.

(Response) We disagree with this comment. FDA conducted a thorough analysis of the current paperwork burden associated with the SE program and other similar forms, and applied the most accurate burden to the forms. Beyond entering data into the form, we believe the burden for searching existing data sources and gathering and maintaining the data needed, is accounted for in the burden charts. FDA notes that the commenter did not provide a recommendation for alternative estimates.

#### 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

Among the laws governing the disclosure of SE Reports submitted under section 905(j) (1)(A)(i) of the FD&C Act are FOIA (5 U.S.C. 552) and FDA’s implementing regulations under 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. CTP also identified privacy compliance requirements and

coordinated with FDA’s Privacy Officer to ensure responsible offices in CTP satisfy all in accordance with law and policy. CTP received HHS approval on the privacy impact assessment and was assigned PIA Unique Identifier P-7465194-382822.

11. Justification for Sensitive Questions

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

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

FDA estimates the burden as the following:

Table 1.- Existing Burden for OMB Control Number 0910-0673,  
Estimated Annual Reporting Burden<sup>1</sup>

Activity; 21 CFR Section	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Full SE 905(j)(1)(A) (i) and 910(a)	683	1	683	300	204,900
Full SE 905(j)(1)(A) (i) and 910(a) Bundled	456	1	456	90	41,040
Product Quantity Change SE Report	239	1	239	87	20,793
Product Quantity Change Bundled SE Report	192	1	192	62	11,904
Total					00

<sup>1</sup> This chart represents the currently OMB approved burden for the SE program.

Table 2.--New Burden Per the Final Rule, Estimated Annual Reporting Burden

Activity; FDA Form; 21 CFR Section	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
FDA 3965--Tobacco Substantial Equivalence Report Submission	1,570	1	1,570	.75 (45 minutes)	1,178
FDA 3964--Tobacco Amendment and General Correspondence	628	1	628	.16 (10 minutes)	100
Waiver from Electronic submission 1107.62 (b)	240	1	240	.25 (15 minutes)	60
Totals					0

Table 3.--Final Reporting Table 1 + 2 Reporting Burden, Estimated Annual Reporting Burden

Activity; FDA Form; 21 CFR Section	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
SE Report--1107.18	683	1	683	300	204,900
Bundled SE--1107.18	456	1	456	90	41,040
SE Report where applicant provides certification for identical characteristics--1107.18(g) and 1107.18(l)(2)	239	1	239	87	20,793
SE Report where applicant provides certification for some identical characteristics (bundled)--1107.18(g) and 1107.18(l)(2)	192	1	192	62	11,904
FDA 3965--Tobacco Substantial Equivalence Report Submission	1,570	1	1,570	.75 (45 minutes)	1,178
FDA 3964--Tobacco Amendment and General Correspondence Report	628	1	628	.16 (10 minutes)	100
Waiver from Electronic submission--1107.62(b)	240	1	240	.25 (15 minutes)	60
Totals					0

Table 4.- New Recordkeeping Burden Per the Final Rule, Estimated Annual Recordkeeping Burden

Activity; 21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Recordkeeping SE Report under 1107.18-1107.58	471	1	471	5	2,355

FDA’s estimates are based on experience with SE Reports, registration and listing data, interactions with the industry, and information related to other regulated products.

Utilizing registration and listing data for deemed tobacco products, the estimated annual number of SE Reports is expected to be 1,570. The expected number of reports has not changed since the proposed rule. As discussed in the rule, FDA is not finalizing the proposed SE rule with respect to “premium” cigars. As such, the estimate of the number of reports expected is likely an overestimate as it includes “premium” cigars, which are excluded from the scope of this final rule.

When groups of full SE Reports or SE Reports that each contain a certification that some characteristics have identical content, they may be bundled; when a group of similar reports are bundled, the subsequent bundled reports are expected to take less time to prepare than the initial report.

FDA has based these estimates on information it now has available from interactions with the industry, information related to other regulated products, and FDA expectations regarding the tobacco industry's use of the substantial equivalence pathway to market their products. Table 1 describes the annual reporting burden for compliance with the requirements to demonstrate substantial equivalence under the FD&C Act. We do not expect a large burden increase for this program, as, without the rule, manufacturers would routinely submit SE Reports for new tobacco products, and the Agency believes most respondents are currently practicing most of the requirements. FDA will revise this collection with the new burden.

Table 2 describes the annual reporting burden as a result of the requirements in §§ 1107.18 and 1107.19, implementing the substantial equivalence requirements of sections 905(j)(1)(A)(i) and 910(a) of the FD&C Act. This rule requires manufacturers to submit SE Reports electronically (§ 1107.62). We estimate that it would initially take about 45 minutes per product to fill out the Form FDA 3965. However, for amendments we estimate that filling out the Form FDA 3964 will take 10 minutes as applicants can copy and paste from the first submission. Section 1107.62(b) also allows for waivers from the electronic format requirement. FDA estimates that 240 respondents or 15 percent of SE Reports (1,570) will submit a waiver.

Based on updated information, FDA estimates that it will receive 683 full initial SE Reports for a new tobacco product each year under § 1107.18 that take a manufacturer approximately 300 hours to prepare. Additionally, manufacturers may bundle groups of SE Reports for their new products in the same product category and subcategory where the proposed modifications are the same; when a group of similar SE Reports are bundled, the reporting burden for the initial SE Report is expected to take the same amount of time as a stand-alone SE Report. However, the reporting burden for subsequent bundled SE Reports is expected to be lower than the initial SE Report. We expect to receive 456 bundled SE Reports under § 1107.18 (other than the initial SE Report in the bundle) at approximately 90 hours per response for a total of 41,040 hours.

In the absence of more specific information concerning SE Reports where applicants provide a certification for some identical characteristics under §§ 1107.18(g) and 1107.18(l)(2), FDA estimates receiving 239 such SE Reports at 87 hours per response for a total of 20,973 hours. We also estimate receiving 192 bundled SE Reports where applicants provide a certification for some identical characteristics under §§ 1107.18(g) and 1107.18(l)(2) (other than the initial SE Report in the bundle) at 62 hours per response for a total of 11,904 hours. Although we believe that the number of SE Reports that include a certification will increase because the rule clarifies when applicants may certify that certain characteristics are identical in the new tobacco product and the predicate tobacco product, in the absence of specific information on how many more applicants might choose to certify, we are maintaining our previous estimates at this time.

FDA has based these estimates on the full analysis of economic impacts and experience with the recently-revised existing information collection (OMB Control Number 0910-

0673) that applies to tobacco products. In addition, anyone submitting an SE Report is required to submit an environmental assessment prepared in accordance with § 25.40 under § 1107.18(k). The burden for environmental reports has been included in the burden per response for each type of SE Report.

Based on FDA’s experience with EAs for currently regulated tobacco products, we expect industry to spend 80 hours preparing an environmental assessment for a full SE Report under § 1107.18.

Generally, an applicant may withdraw its SE Report after submission (§ 1107.22), change the ownership of its SE Report (§ 1107.24), and amend its SE Report (§ 1107.20). Currently, FDA has an OMB approved information collection for SE. The information required to grant these applications is already being collected under the OMB approval, so we do not expect a change in burden to these sections. FDA estimates that 30 percent of SE Reports or 471 respondents will maintain required records related to their SE Reports at 5 hours per record for a total of 2,355 recordkeeping hours. FDA has revised the estimated burden for recordkeeping per hour from 2.5 hours per record to 5 hours. As discussed in the RIA, the first SE Report in a chain must use a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007, as a predicate product for the SE Report. Therefore, we believe that manufacturers will have records on those “original” predicate tobacco products from their initial SE Reports. Based on this assumption, this requirement could lead to manufacturers keeping records for a longer time. The final regulatory impact analysis estimates zero to 10 hours per entity each year for recordkeeping, and the PRA estimate has assumed a mid-point of that estimate.

Section 1107.40 references meetings that may be held with applicants who want to meet with FDA to discuss scientific and other issues. Additional information about how to request meetings with FDA’s CTP can be found in FDA’s guidance entitled “Meetings with Industry and Investigators on the Research and Development of Tobacco Products.” The collections of information in the guidance referenced have been approved under OMB control number 0910-0731. In addition to the premarket application under section 910(b) and a report under 905(j)(1)(A)(i) of the FD&C Act, certain new tobacco products may use the exemption premarket pathway (see § 1107.1).

12b. Annualized Cost Burden Estimate

FDA also notes that preparation of a request for substantial equivalence will involve life, physical, and social science occupations, architecture and engineering occupations, and legal occupations. FDA has estimated that the wage per hour adjusted for benefits and overhead, is \$86.20 per hour.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Tobacco product manufacturers	282,330	\$86.20	\$24,336,846.40

FDA estimates the cost to respondents is \$24,336,846. This figure was derived by multiplying the total burden hours (282,330) by an hourly rate of \$86.20. This hourly rate is based on 2,080 annual work hours and an annual salary rate of \$179,296.

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

There are no additional capital costs associated with this collection of information.

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 = \$2,320,000

Full-time Equivalents (FTEs) = 20

Annual Cost per FTE=\$116,000

Annual Cost = \$2,320,000

15. Explanation for Program Changes or Adjustments

This is a new final rule. FDA estimates that the burden for new requirements will increase this collection by 3,693 hours (1,338 reporting + 2,355 recordkeeping) and 2,909 response. The burden for the submission of substantial equivalence information is estimated to total 282,330 hours (279,975 reporting and 2,355 recordkeeping). The burden increased from the proposed rule by 1,618 hours based on increasing the burden per response for the associated forms.

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 from display of the OMB expiration date and is also not seeking OMB approval to exclude the expiration date for this information collection.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions to the certification statement were identified.