

Exemptions From Substantial Equivalence Requirements for Tobacco Products

0910-0684
SUPPORTING STATEMENT

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 a chapter granting FDA important authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

The Food and Drug Administration (FDA) issued a Final rule to deem products meeting the statutory definition of “tobacco product” to be subject to the Federal Food, Drug, and Cosmetic Act (FD&C Act). The FD&C Act provides FDA authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, and any other tobacco products that the Agency by regulation deems to be subject to the law. This Final rule extends the Agency’s “tobacco product” authorities to all other categories of products that meet the statutory definition of “tobacco product” in the FD&C Act, except accessories of such newly deemed tobacco products. FDA is taking this action to reduce the death and disease from tobacco products.

CFR and FD&C Act Citations Regarding Exemptions from Substantial Equivalence Requirements

21 CFR 1107.1(b). Section 1107.1(b) states that a request for exemption under section 905(j)(3) of the FD&C Act may be made only by the manufacturer of a legally marketed tobacco product for a minor modification to that tobacco product. The manufacturer must submit the request and all information supporting the request to FDA to support the exemption. The request must be made in an electronic format that the FDA can process, review, and archive, or a written request must be made by the manufacturer explaining in detail why the company cannot submit the request in an electronic format and requesting an alternative means of submission to the electronic format.

An exemption request must contain:

- (1) The manufacturer’s address and contact information;
- (2) Identification of the tobacco product(s);
- (3) A detailed explanation of the purpose for the modification;

- (4) A detailed description of the modification, including a statement as to whether the modification involves adding or deleting a tobacco additive, or increasing or decreasing the quantity of the existing tobacco additive;
- (5) A detailed explanation of why the modification is a minor modification of a tobacco product that can be sold under the FD&C Act;
- (6) A detailed explanation of why a report under section 905(j)(1) of the FD&C Act intended to demonstrate substantial equivalence is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for protection of the public health;
- (7) A certification (i.e., a signed statement by a responsible official of the company) summarizing the supporting evidence and providing the rationale for the official's determination that the modification does not increase the tobacco product's appeal to or use by minors, toxicity, addictiveness, or abuse liability;
- (8) Other information justifying an exemption; and
- (9) An environmental assessment under 21 CFR part 25 prepared in accordance with the requirements of § 25.40.

21 CFR 1107.1(c). Section 1107.1(c) states that FDA will review the information submitted and determine whether to grant or deny an exemption based on whether the criteria in section 905(j)(3) of the FD&C Act are met. FDA may request additional information if necessary to make a determination, and may consider the exemption request withdrawn if the information is not provided within the requested timeframe.

21 CFR 25.40. The National Environmental Policy Act (NEPA) (42 U.S.C. 4321-4347), states national environmental objectives and imposes upon each Federal agency the duty to consider the environmental effects of its actions. Section 102(2)(C) of NEPA requires the preparation of an environmental impact statement (EIS) for every major Federal action that will significantly affect the quality of the human environment.

The FDA NEPA regulations are contained in 21 CFR part 25. All applications for exemption from substantial equivalence require the submission of an environmental assessment (EA). An EA provides information that is used to determine whether an FDA action could result in a significant environmental impact. Section 25.40(a) and (c) specifies the content requirements for EAs for nonexcluded actions.

Section 905(j)(1)(A)(ii) of the FD&C Act. Section 905(j)(1)(A)(ii) of the FD&C Act states that if an exemption has been requested and granted, the manufacturer must submit to FDA a report that demonstrates that the tobacco product is modified within the meaning of section 905(j)(3), the modifications are to a product that is commercially marketed and in compliance with the requirements of the FD&C Act, and all of the modifications are covered by exemptions granted by the Secretary pursuant to section 905(j)(3).

2. Purpose and Use of the Information Collection

The information collected under these provisions of the FD&C Act and FDA's regulations is needed for FDA to determine whether to grant or deny an exemption request based on whether the criteria in section 905(j)(3) of the FD&C Act are met. The potential respondents to this collection of information are tobacco manufacturers.

If the information were not collected, FDA would be unable to determine if an exemption could be granted under section 905(j)(3) of the FD&C Act.

This collection of information will be requested of private sector, for-profit businesses.

3. Use of Improved Information Technology and Burden Reduction

The collection of information requires that the exemption request and supporting information be submitted in an electronic format that FDA can process, review, and archive. FDA intends to provide and update information on its Web site on how manufacturers may provide the electronic submission to FDA (e.g., information on electronic media and methods of transmission). The collection of information also requires that the exemption request be legible (FDA must be able to read the document) and in English. These requirements ensure that FDA can review the exemption request expeditiously and appropriately.

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 an exemption request and supporting information in a non-electronic format. However, a company that is not able to submit an exemption request in an electronic format may submit a written request to the Center for Tobacco Products explaining in detail why the company cannot submit the request in an electronic format and requesting an alternative format. FDA estimates that based on its past experience with submittal of information, approximately 99 percent of the respondents will submit the information electronically.

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 allows the submission of requests for exemption from the requirements of section 905(j) demonstrating that a tobacco product is substantially equivalent to a predicate tobacco product. The FDA is the only Federal agency responsible for the collection of such 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 respondents to the initial collection of information and respondents to the follow up collection of information are businesses who manufacture tobacco products. The information submission requirements in this collection of information do not fall disproportionately upon small businesses, as the FD&C Act allows for the submission of this information from all manufacturers of tobacco products. FDA is also allowing for the alternative submittal of requests for exemption from the requirements relating to demonstration of substantial equivalence 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.

Consistent with the requirements of the FD&C Act, FDA intends to provide technical and other nonfinancial assistance to small tobacco product manufacturers in complying with the premarket requirements of sections 905 and 910 of the FD&C Act, along with other requirements.

6. Consequences of Collecting the Information Less Frequently

Respondents to this collection of information will respond occasionally on an as needed basis. The FD&C Act provides that FDA may exempt tobacco products that meet specific criteria from requirements relating to the demonstration that a tobacco product is substantially equivalent. The collection of information describes the process and statutory criteria for requesting an exemption and explains how FDA would review requests for exemptions. This collection of information satisfies the requirement in the FD&C Act that FDA issue regulations implementing the exemption provision. Collecting the information less frequently would hamper manufacturers' ability to use this as a pathway to market. 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.

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

In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the FEDERAL REGISTER of September 13, 2018 (83 FR 46501). Two PRA related comments were received. Along with commenting on the PRA, the comments stated that the Agency should provide additional details on exemption requests and develop categories of exemptions. FDA appreciates these comments but notes (as indicated in the comments) that such actions would need to be done pursuant to notice and comment procedures. In response to the questions related to the PRA estimates, these estimates are based on our experience. To date, the annual number of exemption requests has been lower than the estimate of 812 respondents in this notice

(<https://www.accessdata.fda.gov/scripts/fdatrack/view/track.cfm?program=ctp&id=%20CTP-OS-total-exemption-from-SE-since-Program-Inception>), but the Agency expects that the number of exemption requests could increase as applicants begin to submit such requests for tobacco products subject to the final deeming rule. The estimated number of respondents is intended to reflect that potential. As noted in the comments, the exemption request is anticipated to take less time than the other premarket applications, and FDA believes that 24 hours average burden per response reflects the experience to date.

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 data submitted under section 905 of the FD&C Act are the Freedom of Information Act (FOIA) (5 U.S.C. 552) 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

The main effect of this collection of information is a potential reduction in the costs of introducing or delivering for introduction new tobacco products into interstate commerce compared with the post-statute baseline.

12a. Annualized Hour Burden Estimate

FDA estimates the burden for this information collection as follows:

Table 1.--Estimated Annual Reporting Burden
(when manufacturers choose to seek exemption from substantial equivalence)¹

21 CFR Section and Activity	No. of Respondents	No. of Responses per Respondent ²	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
§ 1107.1(b) Optional Preparation of Tobacco Product Exemption From Substantial Equivalence Request Including § 25.40 Preparation of an Environmental Assessment					
21 CFR 1107.1(b) Preparation of tobacco product exemption from substantial equivalence request and 21 CFR 25.40 Preparation of an environmental assessment	812	1	812	24	19,488
Total Hours (§ 1107.1(b))					19,218
§ 1107.1(c) Preparation of Additional Information for Tobacco Product Exemption From Substantial Equivalence Request:					
21 CFR 1107.1(c) Preparation of additional information for tobacco product exemption from substantial equivalence request	244	1	244	3	732
Total Hours (§ 1107.1(c))					732
Section 905(j)(1)(A)(ii) of the FD&C Act: If exemption granted, report submitted to demonstrate tobacco product is modified under section 905(j)(3), modifications are to a product that is commercially marketed and compliant, and modifications covered by exemptions granted by Secretary under section 905(j)(3):					
Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers (ENDS and Delivery Systems (Including Importers))	1217	1	1217	3	3,651
Total Hours (section 905(j)(1)(A)(ii))					3651
Total Hours Exemptions From Substantial Equivalence Requirements					23,871

The estimated average burden per response (in hours) is based on the burdens associated with this existing information collection that applies to tobacco products currently subject to the FD&C Act (i.e., cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco). FDA estimates that we will receive 812 exemption requests under § 1107.1(b) for 24 hours per response including EA for a total of 19,488 hours. Since an EA is required for each § 1107.1(b) (Optional Preparation of Tobacco Product Exemption From Substantial Equivalence Request), the burden per response for EAs (12 hours) has been combined with the 12 hours for an SE request for a total of 24 hours per response.

FDA estimates, based on the existing information collection that applies to tobacco products currently subject to the FD&C Act, we will receive 244 submissions requiring additional information in support of the initial exemption request, and it is expected that it will take an average of 3 hours to prepare the additional information for a total of 732 hours.

FDA estimates that 1,217 respondents will prepare 1,217 responses and each response will take approximately 3 hours to prepare, as required by section 905(j)(1)(A)(ii), for a total of 3,651 hours.

This collection of information requires a manufacturer to submit a report at least 90 days prior to making an introduction or delivery for introduction into interstate commerce for commercial distribution of a tobacco product. Section 905(j)(1)(A)(ii) of the FD&C Act states that if an exemption has been requested and granted, the manufacturer must submit to FDA a report that demonstrates that the tobacco product is modified within the meaning of section 905(j)(3), the modifications are to a product that is commercially marketed and in compliance with the requirements of the FD&C Act, and all of the modifications are covered by exemptions granted by the Secretary pursuant to section 905(j)(3). FDA estimated the total hours for exemptions from Substantial Equivalence Requirements would be 23,871 hours.

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

12b. Annualized Cost Burden Estimate

FDA notes that preparation of a request for exemption from 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.

The estimated cost for this collection of information is \$1,267,140, which is the initial information request of \$517,200 (500 respondents x 12 hours x \$86.20) plus additional supporting information requests of \$38,790 (150 respondents x 3 hours x \$86.20) plus environmental assessment preparation and submission of \$517,200 (500 respondents x 12 hours x \$86.20) plus creation and submission of the section 905(j)(1)(A)(ii) reports of \$193,950 (750 respondents x 3 hours x \$86.20).

Activity	Total Burden Hours	Hourly Wage Rate	Total Cost
21 CFR 1107.1(b) Tobacco manufacturers preparation of tobacco product exemption from substantial equivalence request	19,488	\$86.20	\$ 1,679,866
21 CFR 1107.1(c) Tobacco manufacturers preparation of additional information for tobacco product exemption from substantial equivalence request	732	\$86.20	\$63,098
Section 905(j)(1)(A)(ii) of the FD&C Act 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).	3,651	\$86.20	\$314,716

Activity	Total Burden Hours	Hourly Wage Rate	Total Cost
Total			0

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

Based on FDA's experience in processing similar information, the average total annual cost to the Federal Government is expected to be \$580,000. This cost was obtained by evaluating the number of full-time equivalent (FTE) government employees who will review, compile, edit, and render a decision on exemption requests for substantial equivalence. FDA estimates that five FTE's will be needed to complete exemption to substantial equivalence requests.

Full-time Equivalents	5
Annual Cost per FTE	\$116,000
Annual Cost	\$580,000

15. Explanation for Program Changes or Adjustments

There are no changes to the currently approved burden.

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.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification statement.