Exemptions From Substantial Equivalence Requirements for Tobacco Products

0910-0684
SUPPORTING STATEMENT
EXTENSION

Terms of Clearance: None

A. Justification

1. Circumstances Making the Collection of Information Necessary

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 111-31) 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.

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 o
fficial 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 manufactures 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 December 19, 2013 (78 FR 76838). Six comment submissions were received, some of which included multiple comments.

   (Comment) Regarding the clarity of information collected, several comments indicated some confusion between the information being collected and the information needed to support an exemption request.

   (Response) Section 1107.1(a) sets out the general requirements for requesting an exemption, but a manufacturer will need to determine how to meet the requirements for any of its new products that use the pathway. FDA intends to consider issuing a regulation or guidance to further clarify terms as experience is gained with the pathway.

   (Comment) A few comments questioned the quality of the information being requested.

   (Response)We disagree that the information required in an exemption request is not sufficient. We believe the information requested is what FDA needs to make a determination on an exemption request. Furthermore, several commenters also agreed with the sufficiency of the information needed to support an exemption request.

   (Comment) Many comments addressed the accuracy of FDA's estimate of the burden for requesting a modification to an exemption request and questioned whether this burden

was underestimated. Additionally, there was reference to the submittal of duplicative information.

(Response) FDA disagrees with these comments. We believe the burden estimates are appropriate and reflect the information needed by FDA when reviewing an exemption request. FDA also disagrees that there is duplicative information requested. The regulations implement the requirements of the FD&C Act for the exemption pathway to market. The commenters may be referring to the other notification and reporting requirements related to additives, such as those in section 904(c) of the FD&C Act, but those requirements are not in the scope of this information collection.

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[1]

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
21 CFR 1107.1(b) Preparation of tobacco product exemption from substantial equivalence request	500	1	500	12	6,000
21 CFR 1107.1(c) Preparation of additional information for tobacco product exemption from substantial equivalence request	150	1	150	3	450
21 CFR 25.40 Preparation of an environmental assessment	500	1	500	12	6,000
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 product, and modifications covered by exemptions granted by Secretary pursuant to section 905(j)(3).	750	1	750	3	2,250
Total					**14,700**

Explanation of Reporting Hourly Burden Estimate

FDA estimates that 500 requests for exemption will be submitted annually, and that it will take approximately 12 hours to prepare an exemption request. FDA estimates that up to 30 percent (150) of the initial requests for information may require 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. FDA also estimates that 750 manufacturers will take approximately 12 hours to prepare and submit an environmental

assessment under 21 CFR part 25 in accordance with the requirements of § 25.40, as referenced in § 1107.1(b)(9). FDA estimates that 750 respondents will take 3 hours to prepare a report under section 905(j)(1)(A)(ii), which 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 will contain the manufacturer's basis that the tobacco product is modified within the meaning of 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. FDA's estimates are based on experience with and information on other FDA-regulated products and indications from industry.

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	6,000	$86.20	$517,200
21 CFR 1107.1(c) Tobacco manufacturers preparation of additional information for tobacco product exemption from substantial equivalence request	450	$86.20	$38,790
21 CFR 1107.1(c) Preparation of additional information for tobacco product exemption from substantial equivalence request	6,000	$86.20	$517,200
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).	2,250	$86.20	$193,950

Activity	Total Burden Hours	Hourly Wage Rate	Total Cost
Total			**$1,267,140**

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 this information collection.

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.