Tobacco Products, Exemptions from Substantial Equivalence Requirements

Final Rule

0910-0684
RIN 0910-AG39
SUPPORTING STATEMENT

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 new chapter granting FDA important new 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 Tobacco Control Act Citations

21 CFR 1107.1(b). Section 21 CFR 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 request 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 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 Federal Food, Drug, and Cosmetic Act;
(6) A detailed explanation of why a report under section 905(j)(1) of the Federal Food, Drug, and Cosmetic 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 21 CFR 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 Federal Food, Drug, and Cosmetic 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. Sections 25.40(a) and (c) specifies the content requirements for EAs for nonexcluded actions.

Section 905(j)(1)(A)(ii) of the Tobacco Control Act. Section 905(j)(1)(A)(ii) of the Tobacco Control Act states that if an exemption has been requested and granted, a report must be submitted which 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 this Act, and all of the modifications are covered by exemptions granted by the Secretary pursuant to Section 905(j)(3).

Abstract

The Tobacco Control Act requires that, before a new tobacco product may be introduced or delivered for introduction into interstate commerce, one of the following must occur: 1) a premarket application under section 910(b) of the FD&C Act (21 U.S.C. 387j(b)) must be submitted to FDA, and FDA must issue an order finding that the new product may be introduced or delivered for introduction into interstate commerce under section 910(c) of the FD&C Act; or 2) a report under section 905(j) of the FD&C Act (21 U.S.C. 387e(j)) demonstrating the new tobacco product's substantial equivalence to an appropriate predicate product (as defined in the FD&C Act) must be submitted and FDA must issue an order finding the new product to be substantially equivalent to the predicate product and in compliance with the requirements of the Tobacco Control Act (section 910(a)(2) of the FD&C Act).

This rule implements section 905(j)(3) of the FD&C Act, as amended, which states that FDA may exempt tobacco products that are modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive, from the requirement of demonstrating substantial equivalence if the agency determines that (1) such modification would be a minor modification of a tobacco product that can be sold under the FD&C Act, (2) a report demonstrating substantial equivalence is not necessary to ensure that permitting the product to be marketed would be appropriate for the protection of public health, and (3) an exemption is otherwise appropriate. Section 905(j)(3)(B) of the FD&C Act requires FDA to issue regulations implementing this provision by July 1, 2011. This collection of information corresponds to the issuance of these regulations.

"Additive" is defined at section 900(1) of the FD&C Act, as "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substances intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding), except that such term does not include tobacco or a pesticide chemical residue in or on raw tobacco or a pesticide chemical" (21 U.S.C. 387(1)).

The rule would establish a pathway for manufacturers to request exemptions from the substantial equivalence requirements of the Tobacco Control Act. It would not establish categories of minor modifications, or identify specific modifications, that meet the statutory criteria for exemptions. As FDA acquires more information about the additives in tobacco products from which to establish such categorical exemptions, it may issue additional regulations or guidance.

The rule would require that an exemption request be submitted with supporting documentation and contain the manufacturer's address and contact information; a detailed explanation of the purpose for the modification; a detailed description of the modification, including whether the modification involves adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive; a detailed explanation of why the modification is considered a minor modification of a tobacco product that can be sold under the FD&C Act; a detailed explanation of why a report intended to demonstrate substantial equivalence is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for the protection of public health; a certification by a responsible official of the company, such as the chief executive officer, summarizing the supporting evidence and providing the rationale for the official's determination that the modification will not increase the product's toxicity, addictiveness, or appeal to or use by minors; and other information justifying an exemption.

The rule would require the submission of this information, along with supporting documentation, to enable FDA to determine whether an exemption from having to demonstrate substantial equivalence to an appropriate predicate product would be

appropriate for the protection of the public health, as required by the statute (section 905(j)(3) of the FD&C Act). The rule would also require a certification in the form of 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 will not increase the product's toxicity, addictiveness, or appeal to or use by minors. Because of the importance of this information to an exemption determination, FDA is requiring that a responsible official of the company, such as the chief executive officer, certify that the modification will not have these effects.

The regulation explains that FDA would review the information submitted in support of the request and determine whether to grant or deny the request for an exemption based on whether the criteria in the statute are satisfied. The rule also provides that, if FDA determines that the information submitted by the manufacturer is insufficient to enable it to determine whether an exemption is appropriate, FDA may request additional information from the manufacturer. The rule would also provide that if the manufacturer fails to respond within the timeframe requested, FDA will consider the exemption request withdrawn. An exemption determination will be publicly available consistent with the requirements of 21 CFR part 20; trade secret and confidential commercial information are exempted from disclosure requirements consistent with 21 CFR section 20.61.

The rule includes a procedural mechanism for rescinding an exemption where necessary to protect the public health. Before rescinding an exemption, FDA proposes to provide the manufacturer notice of the proposed rescission and an opportunity for an informal hearing under 21 CFR part 16, unless the continuance of the exemption presents a serious risk to public health. If the continuance of the exemption presents a serious risk to public health, FDA would rescind the exemption prior to giving notice and an opportunity for a hearing, and provide notice and opportunity for an informal hearing under 21 CFR part 16 as quickly as possible following the rescission.

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.

American Recovery and Reinvestment Act of 2009

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

2. Purpose and Use of the Information Collection

The information collected under these provisions of the FD&C Act 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 engaged in business in the private sector.

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.

3. Use of Improved Information Technology and Burden Reduction

The rule would require 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 website on how manufactures may provide the electronic submission to FDA (e.g., information on electronic media and methods of transmission). The rule would also require that the exemption request be legible (FDA must be able to read the document) and in English. These requirements would ensure that FDA could 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% 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 Tobacco Control Act is the only legislation which 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 500 respondents to the initial collection of information and 150 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 Tobacco Control 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 Tobacco Control Act provides that FDA may exempt from the requirements relating to the demonstration that a tobacco product is substantially equivalent, tobacco products that meet specific criteria. The rule would describe the process and statutory criteria for requesting an exemption and explain how FDA would review requests for exemptions. When approved, this rule will satisfy the requirement in the Tobacco Control 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

   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 January 6, 2011 (76 FR 737). FDA received 38 comments from 13 commenters that did not directly relate to aspects of the information collection, and received several comments which did relate to the information.

   After considering the comments received from the proposed rule, and to clarify the information to be submitted in an exemption request, FDA amended section 1107.1(b) to state that an exemption request must identify the tobacco product(s) that is the subject of the exemption request, and, as required by 21 CFR part 25, include an environmental assessment with the exemption request.

   Several comments noted that the hours per response were the same for both an exemption request and the submission of a section 905(j) substantial equivalence report, which indicated that the exemption pathway to market for manufacturers of tobacco products would not be less burdensome than the substantial equivalence report. Some comments stated that the estimated hours suggested that completing an exemption from substantial equivalence request would be a very burdensome process, and other comments suggested that the estimated burden hours were too low given the information required to fulfill the requirements of section 21 CFR 1107.1.

FDA's response is that the estimated hours per response in the notice of proposed rulemaking were based on Agency experience with approved information collections for similar types of submissions to the FDA, although those also vary greatly, depending on their statutory requirements. In estimating the time to complete an exemption request, FDA attempted to rely on those existing collections and FDA expertise, but there was no exact parallel for this process. The estimated hours for completion of the exemption request also reflected considerations that initial exemption request would most likely take longer to prepare, with subsequent submissions taking less time to prepare once knowledge and experience with the pathway develops. FDA believed that 360 hours to complete each exemption request would be at the high end of the estimated hours per response, and did not want to underestimate the hours per response at the outset of the process before industry experience with requesting exemptions develops. The comments received provided FDA with a much better sense of the range of modifications that are made to tobacco products. After reviewing the information and comments received, FDA believes that they overestimated, rather than underestimated, the hours that would be needed to prepare an exemption request. The estimated burden for this collection, therefore, has been revised with this rule.

Several comments to the proposed rule stated that the number of exemption requests may be much higher than the initial number of requests (50) stated in the proposed rule. Some commenters suggested that the number of requests could be in the hundreds or thousands, depending on the scope of modifications that might use the pathway. After reviewing the comments received, and considering the potential use of this process as indicated by the comments, FDA has increased the number of expected requests from 50 to 500 annually.

One commenter suggested that the collection being collected was not compliant with the Paperwork Reduction Act because there was no practical utility for the information collected and there was no plan for the efficient and effective use of the information to be collected. FDA disagrees with these comments because this regulation follows the statutory requirements imposed under the Tobacco Control Act, including the findings that FDA must make when determining whether it may make an exemption determination. The information required by this rule is needed by FDA so that the Agency can determine if the modification to a tobacco product is minor. Without this information, FDA will not be able to determine whether an exemption is appropriate.

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 rule would be 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:

Estimated Annual Reporting Burden

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
905(j)(1)(A)(ii) If exemption granted, Report submitted to demonstrate tobacco product is modified under 905(j)(3), modifications are to a product that is	750	1	750	3	2,250

commercially marketed and compliant product, and modifications covered by exemptions granted by Secretary pursuant to 905(j)(3).					
Total					**14,700**

Reporting Cost 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 also estimates that up to 30% (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 estimates that 750 respondents will take 3 hours to prepare the report required by 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 the exemption provision in 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. 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 section 21 CFR 25.40, as referenced in section 1107.1(b)(9). FDA's estimates are based on experience and information on other FDA-regulated products and indications from industry.

12a. 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
905(j)(1)(A)(ii) If exemption granted, Report submitted to demonstrate tobacco product is modified under 905(j)(3), modifications are to a product that is commercially marketed and compliant product, and modifications covered by exemptions granted by Secretary pursuant to 905(j)(3).	2,250	$86.20	$193,950
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 to substantial equivalence. FDA estimates that 5 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

    This is a new collection of information.

16. Plans for Tabulation and Publication and Project Time Schedule

FDA does not intend to publish the results of this information collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA is not requesting an exemption for display of the OMB expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification statement.