Tobacco Products

Exemptions from Substantial Equivalence Requirements

Proposed Rule

0910-NEW

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.

Among other things, 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). Section 905(j)(3) of the FD&C Act, as amended, 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.

"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 proposed rule, if finalized, 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 proposed 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 proposed 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 proposing to require that a responsible official of the company, such as the chief executive officer, certify that the modification will not have these effects.

The proposed 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 proposed 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 proposed 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.

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.

3. Use of Improved Information Technology and Burden Reduction

The proposed 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 proposed 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 905(j) relating the demonstration that a tobacco product is substantially equivalent. 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 50 respondents to the initial collection of information and 40 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. 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 proposed rule would describe the process and statutory criteria for requesting an exemption and explain how FDA would review requests for exemptions. Once finalized, 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 three comments that did not relate to any aspect of the 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 proposed 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	Annual Frequency per Response	Total Annual Respondents	Hours per Response	Total Hours
Preparation of Tobacco Product Exemption from Substantial Equivalence Request 21 CFR 1107.1(b)	50	1	50	360	18,000
Preparation of Additional Information for Tobacco Product Exemption from Substantial Equivalence Request 21 CFR 1107.1(c)	40	1	40	50	2,000
Total					20,000

Reporting Cost Burden Estimate

FDA estimates that 50 requests for exemption will be submitted annually, and that it will take approximately 360 hours to prepare an exemption request. In addition, FDA estimates that up to 80% (40) of the initial requests for information may require additional information in support of the initial exemption request, and it will take an average of 50 hours to prepare the additional information. FDA's estimates are based on experience 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 $1,724, 000, which is the initial information request of $1,551,600 (50 respondents x 360 hours x $86.20) plus supporting information request of $172,400 (40 respondents x 50 hours x $86.20).

Activity	Total Burden Hours	Hourly Wage Rate	Total Cost
Tobacco manufacturers preparation of Tobacco Product Exemption from Substantial Equivalence Request 21 CFR 1107.1(b)	18,000	$86.20	$1,551,600
Tobacco manufacturers preparation of Additional Information for Tobacco Product Exemption from Substantial Equivalence Request 21 CFR 1107.1(c)	2,000	$86.20	$172,400
Total			$1,724,000

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

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

The average total annual cost to the Federal Government is $696,000, which was obtained by evaluating the number of full time equivalent (FTE) government employees will review, compile, edit, and render a decision on exemption requests to substantial equivalence. The

Full time Equivalents	6
Annual Cost per FTE	$116,000
Annual Cost	$696,000

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.