U.S. Food and Drug Administration
Center for Tobacco Products
Exemptions From Substantial Equivalence Requirements for Tobacco Products
OMB Control Number 0910-0684
Supporting Statement - Part A

Terms of Clearance: None

A. Justification

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, us or we) laws and regulations. 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 Tobacco Control Act also gave FDA the authority to issue regulations deeming other products that meet the statutory definition of a tobacco product to be subject to chapter IX of the FD&C Act (section 901(b) of the FD&C Act (21 U.S.C. 387a(b))).

The Consolidated Appropriations Act of 2022 (PL 117-103) (the Appropriations Act), enacted on March 15, 2022, amended the definition of the term "tobacco product" in section 201(rr) of the FD&C Act to include products that contain nicotine from any source. As a result, non-tobacco nicotine (NTN) products that were not previously subject to the FD&C Act (e.g., products containing synthetic nicotine) are now subject to all of the tobacco product provisions in the FD&C Act beginning on April 14, 2022, including the requirement of premarket review for new tobacco products.

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

The FD&C Act, as amended by the Tobacco Control Act, requires that before a new tobacco product may be introduced or delivered for introduction into interstate commerce, the new tobacco product must undergo premarket review by FDA. FDA must issue an order authorizing the commercial distribution of the new tobacco product or find the product exempt from the requirements of substantial equivalence under section 910(a)(2)(A) of the FD&C Act (21 U.S.C. 387j(a)(2)(A)), before the product may be introduced into commercial distribution.

FDA has established a pathway for manufacturers to request exemptions from the substantial equivalence requirements of the FD&C Act in 21 CFR 1107.1 of the Agency's regulations. As described in § 1107.1(a), 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) the 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 tobacco product to be marketed would be appropriate for the protection of public health; and (3) an exemption is otherwise appropriate.

Section 1107.1(b) states that a request for exemption under section 905(j)(3) of the FD&C Act (21 U.S.C. 387e(j)(3)) may be made only by the manufacturer of a legally marketed tobacco product for a minor modification to that tobacco product and that the manufacturer must submit the request and all information supporting it to FDA. The request must be made in an electronic format that FDA can process, review, and archive (or a written request must be made by the manufacturer explaining in detail why the manufacturer 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 (EA) under part 25 (21 CFR part 25; 42 U.S.C. 4332(2)) prepared in accordance with the requirements of 21 CFR 25.40.

The National Environmental Policy Act of 1969 (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 for every major Federal action that will significantly affect the quality of the human environment.

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

The information required by § 1107.1(b) is submitted to FDA so FDA can determine whether an exemption from substantial equivalence to the product is appropriate for the protection of the public health. 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.

This collection of information also contains a requirement, referred to as an "Abbreviated Report," that a manufacturer 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 (21 U.S.C. 387e(j)) 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 the modifications are covered by exemptions granted by the Secretary under 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 and for manufacturers to comply with section 905(j)(1)(A)(ii) of the FD&C Act if an exemption has been requested and granted.

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; FDA would also be unable to effectively regulate section 905(j)(1)(A)(ii) of the FD&C Act.

This collection of information will be requested of respondents from private sector, for-profit businesses. Respondents are tobacco product manufacturers defined as any person, including any repacker or relabeler, who: (1) manufactures, fabricates, assembles, processes, or labels a tobacco product; or (2) imports a finished tobacco product for sale or distribution in the United States.

3. Use of Improved Information Technology and Burden Reduction

21 CFR 1107.1(b) requires that the exemption request and supporting information, including the Abbreviated Report, be submitted in an electronic format that FDA can process, review, and archive. The exemption request and supporting information must be legible and in English. These requirements ensure that FDA can review the exemption request expeditiously and appropriately.

FDA provides information on its Web site on how manufactures may provide electronic submissions and regulatory correspondence, such as the exemption request and supporting information, as well as the abbreviated report, to FDA (e.g., information on electronic media and methods of transmission), Steps on how to prepare and the recommended structure of an Exemption Request and Abbreviated Report can be found at: https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/exemption-substantial-equivalence. Information on how to submit Exemption Requests and Abbreviated Reports to the CTP Portal can be found here: https://www.fda.gov/tobacco-products/manufacturing/submit-documents-ctp-portal.

FDA does not anticipate any need to submit an exemption request or supporting information in a non-electronic format. However, a company that is not able to submit the documentation in an electronic format may submit a written request to the Center for Tobacco Products document control center (https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/contact-ctp). 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) of the act 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 and that manufacturers comply with section 905(j)(1)(A)(ii) of the FD&C Act if an exemption has been requested and granted. 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. 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

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the FEDERAL REGISTER of February 25, 2022 (87 FR 10797). One PRA related comment was received.

(Comment) The comment stated that the Agency should consider making the exemption request pathway (section 905(j)(3) of the FD&C Act) more flexible for new products, devices and technology innovations.

(Response) FDA appreciates the comment and notes that although we may consider the comment, these types of actions may necessitate guidance (as noted in the comment). Currently, we believe that the exemption pathway is providing applicants an efficient pathway to make additive changes to their products and receive a marketing order. If the agency decides to consider revising the suggested actions, these types of actions would need to be done pursuant to separate notice and comment procedures.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

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.

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 consulted with FDA's Privacy office, which conducted a Privacy Impact Assessment (PIA). The PIA was approved on 6/24/22, and was assigned PIA ID 2060831.

11. Justification for Sensitive Questions

This information collection does not involve 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

21 CFR Section and/or Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
21 CFR 1107.1(b); Optional 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
21 CFR 1107.1(c); Preparation of additional information for tobacco product exemption from substantial equivalence request	150	1	150	3	450
Abbreviated 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)	1217	1	1217	2	2,434
Total					22,372

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. 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 exemption 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 150 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 450 hours.

FDA estimates that 1,217 respondents will prepare 1,217 responses and each response will take approximately 2 hours to prepare an abbreviated report, as required by section 905(j)(1)(A)(ii), for a total of 2,434 hours. The estimates reflect a decrease of 1,217 hours to account for a reduction in average response time for preparing an abbreviated

report. FDA provides a recommended format for applicants in the exemption order letter that significantly reduces the burden hours for preparing the abbreviated report.

Therefore, FDA now estimates the total hours for the collection of information associated with exemptions from substantial equivalence requirements is 22,372 hours.

Although there may be year-to-year variability in the absolute number of exemption requests submitted, FDA considers any trends in our analysis, and the overall number of extension requests from manufacturers of tobacco products has remained consistent. Additionally, although manufacturers of NTN products are now subject to all of the tobacco product provisions in the FD&C Act, including the need to submit premarket submissions to the FDA and obtain authorization from the Agency to market their product, FDA expects to receive premarket tobacco product applications (PMTAs) for most currently marketed NTN products. FDA does not expect to receive many exemption requests for currently marketed NTN products. Thus, no additional adjustments to the number of respondents in our burden estimate are needed for NTN products as the current estimate accounts for some year-to-year variability in the absolute number of exemption requests submitted.

12b. Annualized Cost Burden Estimate

The estimated annual reporting cost to respondents for this collection of information is $1,393,775.60. This estimate assumes that tobacco industry (all occupations) will account for the preparation of a request for exemption from substantial equivalence at an average wage of $31.15 (Department of Labor's Bureau of Labor Statistics for Tobacco Manufacturers (May 2021: https://www.bls.gov/oes/current/naics4_312200.htm). We double this to account for benefits and overhead, yielding an hourly wage rate of $62.30.

FDA notes that the annualized cost burden estimate will involve the initial information request plus environmental assessment preparation and submission of $1,214,102.40 (19,488 total burden hours x $62.30) plus additional supporting information requests of $28,035 (450 total burden hours x $62.30) plus creation and submission of the section 905(j)(1)(A)(ii) reports of $151,638.20 (2,434 total burden hours x $62.30).

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	$62.30	$ 1,214,102.40
21 CFR 1107.1(c) Tobacco manufacturers preparation of additional information for tobacco product exemption from substantial equivalence request	450	$62.30	$28,035.00
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).	2,434	$62.30	$151,638.20
Total			**01,393,775.60**

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

Our estimated cost to the Federal government reflects the allocation of 5 full-time equivalents (FTEs) employees who will review, compile, edit, and render a decision on exemption requests for substantial equivalence and review reports submitted under section 905(j)(1)(A)(ii). Using as a basis salary and wage data for the Washington DC-Metropolitan area found at www.opm.gov for a GS-13/4 employee, we calculate a total cost of $587,525 ($117,505 x 5).

15. Explanation for Program Changes or Adjustments

Our estimated burden for the information collection reflects an overall decrease of 1,499 hours and 94 respondents. The estimates reflect a decrease of 1,217 hours to account for a reduction in average response time for preparing an abbreviated report. FDA provides a recommended format for applicants in the exemption order letter that significantly reduces the burden hours for preparing the abbreviated report.

The estimates also reflect a decrease of 94 responses for submissions requiring additional information in support of the initial exemption request, which resulted in a decrease of 282 hours. We attribute this adjustment to the number of submissions we received over the last few years. Therefore, FDA now estimates the burden for exemptions from substantial equivalence requirements is 22,372 hours.

The agency submits this revision request to reflect the inclusion of manufacturers of NTN products now subject to all of the tobacco product provisions in the FD&C Act. However, FDA does not expect to receive many exemption requests for currently marketed NTN products. Thus, no additional adjustments to the number of respondents in our burden estimate are needed for NTN products as the current estimate accounts for some year-to-year variability in the absolute number of exemption requests submitted.

16. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated.

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

FDA is not requesting an exemption for 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

There are no exceptions to the certification statement.