

United States Food and Drug Administration

Exemptions From Substantial Equivalence Requirements for Tobacco Products

OMB Control No. 0910-0684 – EXTENSION

SUPPORTING STATEMENT

Terms of Clearance: None

Part A. Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, us or we) regulations. The Federal Food, Drug, and Cosmetic Act (the FD&C Act) authorizes FDA to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

Tobacco products are governed by chapter IX of the FD&C Act (sections 900 through 920) (21 U.S.C. 387 through 21 U.S.C. 387u). Section 201(rr) of the FD&C Act, as amended, defines a tobacco product as “any product made or derived from tobacco or containing nicotine from any source that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).”

The Consolidated Appropriations Act, 2022 (Public Law 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 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 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 manufacturer) 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 [21 CFR part 25](#) prepared in accordance with the requirements of § [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 21 CFR 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 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)(1)(A)(ii)) 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) of the FD&C Act, 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 of Health and Human Services (the Secretary) under section 905(j)(3).

We therefore request extension of OMB approval of provisions found in 21 CFR 1107.1(b) and (c), and section 905(j)(3) of the FD&C Act, as discussed in this supporting statement.

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

Section 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 website on how manufacturers 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: 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 Center for Tobacco Products (CTP) Portal Next Generation (NextGen) can be found here: www.fda.gov/tobacco-products/manufacturing/submit-documents-ctp-portal-next-generation .

The CTP Portal NextGen web application requires that an organization request an Industry Account Manager (IAM) role be set up for an individual of the organization to act as an administrator for all of the organization's CTP Portal NextGen accounts. Once the IAM account is created by CTP, the IAM can create, manage, and set roles for all of the organization's employees' CTP Portal NextGen user accounts. Users may then prepare submissions on behalf of their organization using the FDA's eSubmitter tool for supported submission types and can send these submissions to CTP directly from CTP Portal NextGen. Instructions on requesting a free IAM account for CTP Portal NextGen are available at www.fda.gov/tobacco-products/manufacturing/request-industry-account-manager-iam-ctp-portal-next-generation .

FDA does not anticipate any need for a manufacturer 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 CTP document control center (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

We are unaware of duplicative information collection.

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.

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

FDA published a 60-day notice for public comment in the *Federal Register* of June 27, 2025 (90 FR 27623). No comments were received.

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 8/10/2023 and was assigned PIA ID FDA2107988.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

FDA estimates the burden for this information collection as follows:

Table 1.—Estimated Annual Reporting Burden¹

21 CFR Section and/or Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (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	682	1	682	24	16,368
Total Hours (§ 1107.1(b))					16,368
§ 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	150	1	150	3	450
Total Hours (§ 1107.1(c))					450
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)					
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)	186	1	186	2	372
Total Hours (section 905(j)(1)(A)(ii) of the FD&C Act)					372
Total Hours Exemptions From Substantial Equivalence Requirements					17,190

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

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 682 exemption requests under § 1107.1(b) for 24 hours per response including EA for a total of 16,368 hours. We have reduced the number of respondents from 812 to 682 based on the average number of exemption requests received during the past 3 years.

FDA estimates, that 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 186 respondents will prepare an Abbreviated Report, as required by section 905(j)(1)(A)(ii) of the FD&C Act, with each report taking approximately 2 hours to prepare for a total of 372 hours. We have reduced the estimated number of respondents who are expected to prepare and submit an Abbreviated Report required by section 905(j)(1)(A)(ii) of the FD&C Act from 1,217 to 186 based on the average number of exemptions issued during the past 3 years..

Therefore, FDA estimates the total hours for the collection of information associated with exemptions from substantial equivalence requirements is 17,190 hours (16,368 + 450 + 372 = 17,190 total 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.

12b. Annualized Cost Burden Estimate

The estimated annual reporting cost to respondents for this collection of information is \$1,211,895. This estimate assumes that the tobacco manufacturing industry (all occupations) labor category will account for the preparation of a request for exemption from substantial equivalence at an average (mean) hourly wage of \$35.25 (Department of Labor's Bureau of Labor Statistics May 2024: data.bls.gov/oes/#/industry/312200). We double this to account for benefits and overhead, yielding an hourly wage rate of \$70.50.

FDA notes that the annualized cost burden estimate will involve the initial exemption from substantial equivalence request plus environmental assessment preparation and submission at a cost of \$1,153,994 (16,368 total burden hours x \$70.50) plus additional supporting information requests at a cost of \$31,725 (450 total burden hours x \$70.50) plus creation and submission of the section 905(j)(1)(A)(ii) Abbreviated Reports at a cost of \$26,226 (372 total burden hours x \$70.50).

Table 2.—Estimated Annual Cost Burden

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 and 21 CFR 25.40 Preparation of an environmental assessment	16,368	\$70.50	\$ 1,153,944

Activity	Total Burden Hours	Hourly Wage Rate	Total Cost
21 CFR 1107.1(c) Tobacco manufacturers preparation of additional information for tobacco product exemption from substantial equivalence request	450	\$70.50	\$31,725.00
Section 905(j)(1)(A)(ii) of the FD&C Act If exemption granted, Abbreviated 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).	372	\$70.50	\$26,226.00
Total			01,211,895

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no additional capital, start-up, or maintenance 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 equivalent employees (FTEs) who will review, compile, edit, and render a decision on exemption for substantial equivalence requests and review reports submitted under section 905(j)(1)(A)(ii) of the FD&C Act. Using as a basis 2025 salary and wage data for the Washington DC-Metropolitan area found at www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/25Tables/pdf/DCB.pdf for a GS-13/Step 4 employee, we calculate a total annual cost to the federal government of \$663,190 (\$132,638 x 5).

15. Explanation for Program Changes or Adjustments

FDA has adjusted its burden estimates based on updated respondent numbers. Specifically, we have reduced the annual number of respondents submitting exemption requests from 812 to 682 based on the average number of exemption requests received during the past 3 years. We have reduced the number of respondents who will submit Abbreviated Reports, as required by section 905(j)(1)(A)(ii) of the FD&C Act, from 1,217 to 186 annually based on the average number of exemptions issued during the past 3 years.

Our estimated burden for the information collection reflects an overall decrease of 5,182 hours and 1,161 total respondents. We attribute this adjustment to the number of submissions we received over the last 3 years. Therefore, FDA now estimates the respondent burden associated with Exemptions for Substantial Equivalence Requirement is 17,190 hours.

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.