United States Food and Drug Administration

Substantial Equivalence Reports for Tobacco Products

OMB Control No. 0910-0673--Revision

SUPPORTING STATEMENT

Terms of Clearance**:** None.

**Part A. Justification:**

1. Circumstances Making the Collection of Information Necessary

This information collection supports the Food and Drug Administration requirements for the content and format of substantial equivalence (SE) Reports which are utilized to establish the SE of a tobacco product. Sections 905(j)(1)(A)(i) and 910(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 387e(j) and 387j(a)), established requirements for SE and premarket review of new tobacco products and the implementing regulations per the SE final rule (86 FR 55224, October 5, 2021) that are found in 21 CFR 1107.18 and 1107.19.

The regulation associated with this information collection interprets and establishes requirements related to the basic content and format of Substantial Equivalence Reports (SEs), the procedure by which FDA reviews SEs, and the maintenance of records regarding the legal marketing of certain tobacco products without SEs. The regulation also addresses the procedures of retention of records related to the SE, confidentiality of application information, electronic submission of the SE and amendments, and postmarket reporting requirements.

The Consolidated Appropriations Act of 2022 (Pub. L. 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 (21 U.S.C. 321(rr)) to include products that contain nicotine from any source. As a result, beginning on April 14, 2022, 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, including the requirement of premarket review for new tobacco products. The Appropriations Act also makes all regulations and guidances applicable to tobacco products apply to NTN products on that same effective date.

An SE Report can be submitted by any manufacturer for any new tobacco product seeking an FDA substantially equivalent order, under section 905(j) of the FD&C Act. A substantially equivalent tobacco product is one that has been found by FDA to have either the same characteristics as the predicate tobacco product or that has different characteristics than the predicate tobacco product, but the SE Report demonstrates that the new product does not raise different questions of public health. A predicate tobacco product is one that was commercially marketed (other than for test marketing) in the United States as of February 15, 2007, or is a product previously found to be substantially equivalent by FDA. Generally, an applicant may amend its SE Report (§ 1107.20), withdraw its SE Report after submission (§ 1107.22), and change the ownership of its SE Report (§ 1107.24). Electronic submission of SE Reports is required, unless the applicant requests and is granted a waiver.

Submitters can visit the following webpage which describes the process for submitting a SE Report (<https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/substantial-equivalence>). FDA has also published a guidance for industry entitled “Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions”
(<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/demonstrating-substantial-equivalence-new-tobacco-product-responses-frequently-asked-questions>). This guidance provides responses to frequently asked questions received from manufacturers and other interested stakeholders on demonstrating the substantial equivalence (SE) of a new tobacco product.

FDA will have three forms (Form FDA 3965; Form FDA 3965a; and new Form FDA 3965b) required for use (once this revision is approved) under section 21 CFR 1107.18(a)) when submitting an SE Report to the Agency. Forms FDA 3965 and 3965b are required when submitting single and bundled SE submissions. Form FDA 3965a is for use when firms are submitting amendments and other general correspondence. Form FDA 3965b assists industry and FDA in identifying the products that are the subject of a submission.

We therefore request revision of OMB approval of provisions found in 21 CFR 1107.18 and 1107.19, and related forms, as discussed in this supporting statement.

1. Purpose and Use of the Information Collection

This information collection is used to implement requirements related to the content and format of SE Reports, including the information that SE Reports must contain. FDA bases this information collection on the experience the Agency has in reviewing thousands of SE Reports since the issuance of the regulation.

This collection of information is requested of respondents from private sector and for-profit businesses. Respondents are tobacco product manufacturers (also “applicants”) 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.

Respondents to this collection of information include those applicants who wish to demonstrate that a new tobacco product is substantially equivalent to a predicate tobacco product. If this information is not collected, FDA will be unable to make the findings required by section 910(a)(2)(A)(i) of the FD&C Act for a new tobacco product to enter the market via the SE pathway. Instead, applicants generally need to submit premarket applications under section 910(b) of the FD&C Act.

Form FDA 3965 is the Tobacco SE Report Submission. Form FDA 3965 is for use when submitting a tobacco SE Report to the Agency. Form FDA 3965 and its corresponding instructions have been updated to assist industry users in completing the form efficiently and correctly. The flow and organization of the form have been updated to follow a consistent style and appearance with other FDA forms related to tobacco product submissions. The content in Form FDA 3965 has not significantly changed. We have removed fields that led to duplicate data collection and reorganized the form to follow a more logical and sequential flow for the applicant. For example, we have consolidated all applicant, representative, and point of contact data collection into one section. Previously, these data fields were spread throughout the form which caused extra time burden to the industry applicant and duplicated entries of data. The structural and data field changes reduced the length and complexity of the form and moved most of the detailed instructions and completion tips to the appendices to be used a resource without confusing or burdening the industry applicant.

Form FDA 3965a is the Tobacco SE Report Amendment and General Correspondence Submission form that was formerly Form FDA 3964. FDA has revised the form number of Form FDA 3964 to Form FDA 3965a to align to Form FDA 3965, the Tobacco SE Report Submission. Form FDA 3965a is for use when firms are submitting amendments and other general correspondence for an SE Report to the Agency. Form FDA 3965a and its corresponding instructions have been updated to assist industry users in completing the form efficiently and correctly. The flow and organization of the form have been updated to follow a consistent style and appearance with Form FDA 3965. As part of the form organization update, Form FDA 3965a has been split into three main parts: Applicant Information, Amendment Information and General Correspondence. Industry users are able to select the submission type, selecting from Amendment or General Correspondence, in Part B of Section I – Applicant Information.

Form FDA 3965b is the new SE Unique Identification for New and Predicate Tobacco Products form that assists industry and FDA in identifying the products that are the subject of a submission.

Additionally, some of the language used on the existing forms and in the instructions were unclear. To adhere to the requirements of the Plain Writing Act of 2010, all forms have been updated to be clearer and more concise for the industry applicant to understand and to complete all required fields correctly.

1. Use of Improved Information Technology and Burden Reduction

The regulation requires that respondents submit SEs in an electronic format, unless a waiver from this requirement is requested by the applicant and granted by FDA. CTP is planning a significant upgrade to the submission process for SEs. This upgrade, known as the CTP Portal Next Generation (CTP Portal NG), is a pivotal step forward in streamlining the application process for the tobacco industry.

Presently, the tobacco industry uses multiple tools in the preparation and submission of SE applications to CTP, including PDF-editing software, the FDA’s eSubmitter Desktop tool, and the FDA’s CTP Portal web application. A submitter must first download and complete PDF versions of Form FDA 3965 and 3965a for SE applications and amendments, respectively, using any PDF-editing software. Once the PDF form is complete, the tobacco industry uses the eSubmitter Desktop tool (<https://www.fda.gov/industry/fda-esubmitter/using-esubmitter-prepare-tobacco-product-submissions>) to prepare the submission for delivery to CTP, which requires creating a new submission using eSubmitter’s electronic CTP Transmittal Form and providing contact information, the completed Form FDA 3965 and/or 3965a, and any supporting documentation. When complete, the eSubmitter tool then packages the submission form, data, and documents into a ZIP file, saved locally, and the tobacco industry must log into their CTP Portal account (<https://www.fda.gov/tobacco-products/manufacturing/submit-documents-ctp-portal>) and upload the packaged submission ZIP file. To use CTP Portal, an organization must first go through the process of setting up an Industry Account Manager (IAM) (<https://www.fda.gov/tobacco-products/manufacturing/request-industry-account-manager-iam-ctp-portal>), which will then allow the IAM to manage CTP Portal accounts for their organization and submit submissions.

The new CTP Portal NG application transforms this process by providing the tobacco industry the ability to create, prepare, and deliver their submissions in one place. CTP Portal NG will provide web forms of Form FDA 3965 and 3965a for SE applications and amendments, respectively, which will improve the submission preparation process for the tobacco industry as it will provide tools to expedite the entry of data and supporting documentation, dynamically guide users to relevant sections of the forms based on their input, and improve quality by providing helpful information on the questions being requested and verifying all required data has been provided. CTP Portal NG has a built-in process for applicants to upload Form FDA 3965b after applicants complete Form FDA 3965b.When complete, CTP Portal NG allows applicants to submit the completed web forms to CTP for review. This innovation eliminates the current three-step process using PDF-editing software, eSubmitter, and CTP Portal, and provides a more integrated and user-friendly experience.

FDA estimates that based on its experience with submittal of this type of information, approximately 83% of the respondents will submit the information in an electronic format. Although FDA believes most respondents will submit electronically, to be conservative we estimate that 20% of applicants may submit a waiver to submit by paper.

The FDA Tobacco Product Grouping Spreadsheet Validator (validator) is a free software that validates the content of FDA product grouping spreadsheets such as “Form FDA 3965b – SE Unique Identification for New and Predicate Tobacco Products”. The validator is available for voluntary use by the tobacco industry (sponsors, manufacturers, and importers) prior to submitting a product grouping spreadsheet to FDA. The validator allows industry users to validate product attributes in their product grouping spreadsheet with the defined and accepted product data standards, and make corrections as needed. If there are no errors found in a spreadsheet, the validator will produce a certificate of completion that can be saved locally and included with the applicants FDA submission voluntarily. If errors are found during validation, the validator will provide the applicants with the error to the end of each impacted row of the spreadsheet, allowing applicants to make necessary changes.

The software and any output files reside locally on an applicant’s computer, allowing them to work on the product grouping spreadsheet offline. The validator does not transmit any data across the web to FDA. FDA does not have the ability to access, review, or supplement the information on local computers through this application.

1. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

1. Impact on Small Businesses or Other Small Entities

The FD&C Act authorizes the submission of this information from all manufacturers of tobacco products that submit SE Reports (also “applicants”). Under the assumption that the percentage of tobacco product manufacturing establishments in the Tobacco Tax and Trade Bureau (TTB) data that are small is the same as the percentage of tobacco manufacturing firms that are small. The impact on these small entities is dependent on how many SE Reports the entity submits, and FDA’s reporting and recordkeeping burdens at section 12 of this document. In certain scenarios, the regulation also permits a certification instead of the submission of detailed information, which may further reduce the burden for smaller entities. FDA also 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 statutory intent.

1. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with statutory and regulatory requirements.

1. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

1. 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 published a 60-day notice for public comment in the Federal Register of July 16, 2024 (89 FR 57903). FDA received one (1) comment responsive to the four information collection topics solicited and one (1) comment that was not responsive to those topics.

(Comment**)** FDA should provide clarity around how Portal Next Generation will operate and hold a workshop to solicit feedback from regulated industry prior to its implementation. In addition, FDA should focus on other SE process reforms that can have an even greater impact on efficiency.

(Response)Thank you for your detailed comments in response to the Federal Register Notice regarding the proposed information collection for substantial equivalence (“SE”) reports and associated recordkeeping requirements. We appreciate your engagement and value your feedback on the planned upgrade to the submission process through the Center for Tobacco Products Portal Next Generation (“CTP Portal NG”).

The purpose of the Federal Register Notice was to introduce updates to the FDA Form 3965 and 3965a (previously 3964) paper forms and to inform stakeholders that FDA Forms 3965 and 3965a (previously 3964) will be made available as web-forms through the new CTP Portal NG. The wireframes included in the Notice were intended to serve as an approximate representation of the fields and workflow specifically associated with the new 3965 and 3965a web-forms for public comment, and as such, do not detail all of the planned functionality for CTP Portal NG nor do they represent the final versions of the forms.

The Center for Tobacco Products (CTP) acknowledges and agrees with the need for further clarity regarding the implementation and functionality of CTP Portal NG. To address these concerns, CTP will provide the regulated industry, and other stakeholders, an opportunity to engage directly with the new system, navigate the platform, and offer substantive feedback on the workflow and usability of the new Portal.

Additionally, we would like to clarify that SE applications submitted under the current system will be seamlessly integrated into the new platform. The intent of CTP Portal NG is to streamline and enhance the efficiency of the submission process by providing web-based forms that simplify data entry, minimize the need for multiple tools, and support the submission of required information in a structured manner.

CTP looks forward to engaging with our industry partners and will take all feedback into consideration to ensure that the final implementation of CTP Portal NG meets the needs of the regulated community while fulfilling CTP’s regulatory and statutory obligations.

FDA is also actively working on improving the application review process. As new processes are developed, FDA is committed to transparency with industry and other stakeholders. CTP Portal Next Generation (NG) is in line with our intent to improve application review. It helps the applicant provide information required by the Substantial Equivalent and Recordkeeping Requirements regulations in an identifiable format. Additionally, the guidance provided in CTP Portal NG will reduce applicant burden by highlighting missing information in fields that contain required content prior to submission and providing applicants with an opportunity to include missing content.

1. Explanation of Any Payment or Gift to Respondents

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

1. Assurance of Confidentiality Provided to Respondents

Data will be kept private to the extent provided by law.

*Freedom of Information Act*

Among the laws governing the disclosure of SE Reports submitted under section 910 and 905 of the FD&C Act are the Freedom of Information ACT (FOIA) (5 U.S.C. 552) and FDA’s implementing regulations 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.

Section 906(c) of the FD&C Act prohibits FDA from disclosing any information reported to FDA if that information is confidential commercial or trade secret information exempt from disclosure under FOIA Exemption 4 (5 U.S.C. 552(b)(4)). The provision contains exceptions allowing disclosure of the information to other officers of employees concerned with carrying out the tobacco products chapter of the FD&C Act and, when relevant, in any proceeding under the tobacco products chapter of the FD&C Act. Section 301(j) of the FD&C Act generally prohibits release of trade secret information obtained by FDA outside of the Department of Health and Human Services, except to courts when relevant in any judicial proceeding under the FD&C Act and to Congress in response to an authorized Congressional request.

*The Privacy Act of 1974*

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. The privacy impact assessment (PIA) associated with this information collection is currently awaiting approval by HHS, and it will be approved under the heading “CTP - eSubmissions Modernization”.

1. Justification for Sensitive Questions

This information collection does not involve sensitive questions.

1. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

FDA estimates the burden as the following:

Table 1.--Estimated Annual Reporting Burden1,2

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Activity; FDA Form; 21 CFR Section | No. of Respondents | No. of Responses per Respondent | Total Annual Responses | Average Burden per Response | Total Hours |
| SE Report--1107.18 | 1,139 | 1 | 1,139 | 300 | 341,700 |
| SE Report where applicant provides certification for identical characteristics--1107.18(g) and 1107.18(l)(2) | 431 | 1 | 431 | 10 | 4,310 |
| Form FDA 3965--Tobacco Substantial Equivalence Report Submission | 1,570 | 1 | 1,570 | .75(45 minutes) | 1,178 |
| Form FDA 3965a1—Tobacco Amendment and General Correspondence Report | 628 | 1 | 628 | .16(10 minutes) | 100 |
| Form FDA 3965b SE Unique Identification for New and Predicate Tobacco Products | 1,570 | 1 | 1,570 | 1 | 1,570 |
| SE Grouping Spreadsheet Validator | 1,570 | 1 | 1,570 | .08(5 minutes) | 126 |
| Waiver from Electronic submission--1107.62(b) | 5 | 1 | 5 | .25(15 minutes) | 1 |
| Totals | 6,913 |  | 348,985 |

1 Formerly Form FDA 3964, Tobacco Substantial Equivalence Report Amendment and General Correspondence Submission

2 Totals may not sum due to rounding.

Table 1 describes the estimated annual reporting burden. FDA has based these estimates on experience with this information collection, information we have available from interactions with industry, registration and listing data, information related to other regulated products, and FDA expectations regarding the tobacco industry’s use of the SE pathway to market their products. We have revised our previous estimates based on these experiences. Utilizing registration and listing data for deemed tobacco products, the estimated annual number of SE Reports is expected to be 1,570.

FDA estimates that we will receive 1,139 full initial SE Reports for a new tobacco product each year under § 1107.18 that take a manufacturer approximately 300 hours to prepare. In Table 1, we have consolidated our previous numbers in the burden chart of full and bundled SE Reports (683 and 456) to reach the 1,139 estimate. In addition, anyone submitting an SE Report is required to submit an environmental assessment prepared in accordance with § 25.40 under § 1107.18(k). The burden for environmental reports has been included in the burden per response for each type of SE Report. Based on FDA’s experience with environmental assessments for currently regulated tobacco products, we expect industry to spend 80 hours preparing an environmental assessment for a full SE Report under § 1107.18.

FDA estimates receiving 239 SE Reports where applicants provide a certification for some identical characteristics under §§ 1107.18(g) and 1107.18(l)(2). We also estimate receiving 192 bundled SE Reports where applicants provide a certification for some identical characteristics under §§ 1107.18(g) and 1107.18(l)(2) (other than the initial SE Report in the bundle). FDA anticipates the burden for an applicant to be generally the same if they submit bundled submissions or individual applications as such, both are captured under SE Report where applicant provides certification for identical characteristics. We believe that the number of SE Reports that include a certification will increase because applicants may certify that certain characteristics are identical in the new tobacco product and the predicate tobacco product. However, in the absence of specific information on how many more applicants might choose to certify, we are maintaining our previous estimates at this time. As certification statements and additional guidance are given by the agency within Form FDA 3965, FDA expects applicants to submit less technical information. As a result, we expect applicants total burden hours per applications to decrease. Therefore, we have decreased the burden per response for these SE Reports.

Manufacturers are required to submit SE Reports electronically (§ 1107.62). We estimate that it will initially take about 45 minutes per product to fill out the Form FDA 3965. However, for amendments we estimate that filling out the Form FDA 3965a will take 10 minutes as applicants can copy and paste from the first submission. Section 1107.62(b) also allows applicants to request a waiver from the electronic format requirement. Based on experience since implementing the SE Rule, FDA does not believe we will receive many waivers, so we have decreased the number of respondents to five respondents to acknowledge the option to submit a waiver, consistent with our other application estimates for waivers.

FDA is revising this collection to include a new form (Form FDA 3965b) and a validator tool for Form FDA 3965b that will help applicants submit information for their SE Reports in the correct format. Form FDA 3965b assists industry and FDA in identifying the products that are the subject of a submission, particularly where an applicant groups multiple new tobacco products into a single submission. This includes grouping products that are from the same manufacturer or domestic importer and in the same product category and subcategory into a single submission. FDA discussed bundled submissions in the SE rule (84 FR 55224) and noted that FDA intends to consider information on each new tobacco product and its corresponding predicate tobacco product as a separate, individual SE Report as required under § 1107.18(c)(7), § 1107.18(g), and § 1107.19. By having the identifying information for products contained in an SE Report be more clearly organized within the required forms, FDA will be able to process and review the applications contained in a grouped submission more efficiently.

Form FDA 3965b assists applicants in providing the unique identifying information for each product in single and grouped submissions of SE Reports. A respondent will utilize Form FDA 3965b once for each submission. We assume the submitter could include from 1 to 2,000 products in each Form FDA 3965b. Entering data for up to 2,000 rows can take approximately 4 hours on average per Form FDA 3965b for manual data entry. We reflect the average time of 60 minutes per response based on the assumption that we expect to receive an average of 25 bundled products per submission.

As previously discussed in Item 3, the FDA Tobacco Product Grouping Spreadsheet Validator (validator) is a free software that validates the content of FDA product grouping spreadsheets such as “Form FDA 3965b – SE Unique Identification for New and Predicate Tobacco Products”. The validator is available for voluntary use by the tobacco industry (sponsors, manufacturers, and importers) prior to submitting a product grouping spreadsheet to FDA.

Table 2. -- Estimated Annual Recordkeeping Burden

| Activity; 21 CFR Section | No. of Recordkeepers | No. of Records per Recordkeeper | Total Annual Records | Average Burden per Recordkeeping | Total Hours |
| --- | --- | --- | --- | --- | --- |
| Recordkeeping SE Report under 1107.18-1107.58 | 471 | 1 | 471 | 5 | 2,355 |

The total burden for the collection of information is 348,985 reporting hours and 2,355 recordkeeping hours for a total of 351,340 hours.

12b. Annualized Cost Burden Estimate

FDA notes that preparation of a request for SE will involve life, physical, and social science occupations, architecture and engineering occupations, and legal occupations.

|  |  |  |  |
| --- | --- | --- | --- |
| Type of Respondent | Total Burden Hours | Hourly Wage Rate | Total Respondent Costs |
| Tobacco product manufacturers | 351,340 | $111.46 | $39,160,356.40 |

Estimates of the cost of the annual burden are based on an hourly wage rate of $55.73, doubled to $111.46 per hour to account for benefits and overhead. This rate is derived from the Department of Labor’s Bureau of Labor Statistics for Tobacco Manufacturers (The Bureau of Labor Statistics (BLS) May 2023 average (mean) hourly wage for life, physical, and social science occupations, architecture and engineering occupations, and legal occupations - NAICS 312200 - [<https://www.bls.gov/oes/2023/may/naics4_312200.htm#17-0000>](https://www.bls.gov/oes/2023/may/naics4_312200.htm#17-0000)). We estimate the annualized cost to respondents with this collection to be $39,160,356.40.

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

There are no capital, start-up, operating or maintenance costs associated with this information collection.

1. Annualized Cost to the Federal Government

Our estimated cost to the Federal government reflects the allocation of 63 full-time equivalent (FTE) employees to administering the requirements. Using as a basis salary and wage data for the Washington DC-Metropolitan area found at https://www.opm.gov for a GS-13/4 employee, we calculate a total cost of $8,174,817 ($129,759 x 63).

1. Explanation for Program Changes or Adjustments

*Program Change Burden*

The content in Form FDA 3965 and 3965a have not significantly changed and we do not attribute program change burden related to the form revisions. There is a program change increase in reporting burden hours related to use of the addition of Form FDA 3965b and the validator tool.

*Adjustment Burden*

The burden adjustment is related to an increase in respondents reporting information. There is an increase in the average response time associated with SE Report--1107.18 due to the consolidation of SE Report--1107.18 and Bundled SE--1107.18. Bundled SE--1107.18 previously had a lower estimated average response time. There is a decrease in the number of responses associated with waiver requests, as well as a decrease in the average response time associated with the SE Report where applicant provides certification for identical characteristics--1107.18(g) and 1107.18(l)(2).

*Total Burden*

Our estimated burden for the information collection reflects an overall increase of 69,010 hours and a corresponding increase of 2,905 responses/records. We attribute this to adding a new form, providing the validator tool, and reevaluating our current estimates.

1. Plans for Tabulation and Publication and Project Time Schedule

The information collected will not be published or tabulated.

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

FDA is not requesting an exemption from display of the OMB expiration date and is also not seeking OMB approval to exclude the expiration date for this information collection.

1. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.