## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2024–N–2888]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Substantial Equivalence Reports for Tobacco Products

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Submit written comments (including recommendations) on the collection of information by December 26, 2024.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0673. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

### Substantial Equivalence Reports for Tobacco Products

*OMB Control Number 0910–0673—Revision*

This information collection supports FDA requirements for the content and format of Substantial Equivalence (SE) Reports which are utilized to establish the substantial equivalence 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)(1)(A)(i) and 387j(a)) established requirements for substantial equivalence and premarket review of new tobacco products and the implementing regulations per the SE final rule (86 FR 55224) are found in §§ 1107.18 and 1107.19 (21 CFR 1107.18 and 1107.19).

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 a predicate product or 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 (21 CFR 1107.20), withdraw its SE Report after submission (21 CFR 1107.22), and change the ownership of its SE Report (21 CFR 1107.24). Electronic submission of SE Reports is required, unless the applicant requests and is granted a waiver.

FDA will have three forms required for use (once this revision is approved) under § 1107.18(a) when submitting an SE Report to the Agency: Form FDA 3965; Form FDA 3965a; and Form FDA 3965b.

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.

Form FDA 3965a is the Tobacco Substantial Equivalence 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 Substantial Equivalence 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. After a selection is made, industry users may skip to the appropriate section to complete. 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 where an applicant groups multiple SE Reports into a single submission (referred to as a bundled submission or a grouped submission).

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, 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 that began on April 14, 2022, 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.

The Center for Tobacco Products (CTP) is planning a significant upgrade to the submission process for SE applications. 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, FDA's eSubmitter Desktop tool, and 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 with 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 and validate it using a new validator tool. 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, user-friendly experience.

Existing CTP Portal user accounts will be migrated to CTP Portal NG. Users may be prompted for a password reset during their initial login to the new system. The process for creating new user accounts and overall user account management will largely remain consistent with the current system. CTP is committed to ensuring a smooth transition to CTP Portal NG and will provide necessary support and guidance throughout this change.

Submitters can visit the following web page which describes the process for submitting a SE Report: *https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/substantial-equivalence.*

In the **Federal Register** of July 16, 2024 (89 FR 57903), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment responsive to the four information collection topics solicited and one 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 SE reports and associated recordkeeping requirements. We appreciate your engagement and value your feedback on the planned upgrade to the submission process through the 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 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 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.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1] [3]

| Activity; FDA form; 21 CFR section | Number of respondents | Number 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 | 0.75 (45 minutes) | 1,178 |

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1] [3]—Continued

| Activity; FDA form; 21 CFR section | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| Form FDA 3965a [2]—Tobacco Amendment and General Correspondence Report. | 628 | 1 | 628 | 0.16 (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 | 0.08 (5 minutes) ..... | 126 |
| Waiver from Electronic submission—1107.62(b) ..... | 5 | 1 | 5 | 0.25 (15 minutes) ... | 1 |
| Totals ..... | ..... | ..... | 6,913 | ..... | 348,985 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Formerly Form FDA 3964, Tobacco Substantial Equivalence Report Amendment and General Correspondence Submission.
[3] Totals may not sum due to rounding.

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 substantial equivalence 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.

When several full SE Reports contain identical content, these SE Reports may be bundled into a single submission. Similarly, SE Reports in which the characteristics of the products are certified as identical and the contents of the SE Reports are also identical, these may also be bundled. 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 Reports. As mentioned previously, NTN products that were not previously subject to the FD&C Act (*e.g.,* products containing synthetic nicotine) are now subject to all tobacco product provisions in the FD&C Act beginning on April 14, 2022. Based on this new authority, we do not believe a change is needed in our burden estimates because FDA has received significantly fewer NTN SE Reports than anticipated.

Table 1 describes the annual reporting burden per the requirements in §§ 1107.18 and 1107.19. 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. 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 21 CFR 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.

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 (21 CFR 1107.62)). We estimate that it would initially take about 45 minutes per product to fill out the Form FDA 3965. However, for amendments, we estimate that filling out 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 Premarket Tobacco Product Application (PMTA) 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, we believe it would take 0.25 hours (15 minutes) per waiver for a total of 1 hour.

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 (86 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.

The form assists applicants in providing the unique identifying information for each product in single and grouped submissions of SE Reports. A respondent would 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. Assuming 60 minutes per Form FDA 3965b for 1,570 applications, we estimate a total burden of 1,570 hours for this activity.

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 to 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 at 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. We estimate that use of the Validator will take an average of 5 minutes per response.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

| Activity; 21 CFR section | Number of recordkeepers | Number 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 |

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

FDA estimates that 30 percent of SE Reports or 471 respondents will maintain required records related to their SE Reports at 5 hours per record for a total of 2,355 recordkeeping hours (table 2). The first SE Report in a chain must use a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007, as a predicate product for the SE Report. Therefore, we believe that manufacturers will have records on those ''original'' predicate tobacco products from their initial SE Reports.

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.

Dated: November 20, 2024.

**P. Ritu Nalubola,**

*Associate Commissioner for Policy.*

[FR Doc. 2024–27654 Filed 11–25–24; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

**[Document Identifier: OS–4040–0008]**

## Agency Information Collection Request; 60-Day Public Comment Request

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

**DATES:** Comments on the ICR must be received on or before January 27, 2025.

**ADDRESSES:** Submit your comments to *sagal.musa@hhs.gov* or by calling (202) 205–2634.

**FOR FURTHER INFORMATION CONTACT:** When submitting comments or requesting information, please include the document identifier 4040–0008–60D and project title for reference, to Sagal Musa, email: *sagal.musa@hhs.gov,* or call (202) 205–2634 the Reports Clearance Officer.

**SUPPLEMENTARY INFORMATION:** Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Title of the Collection:* Budget Information for Construction Programs (SF–424C).

*Type of Collection:* Extension.

*OMB No.:* 4040–0008.

### Abstract

Budget Information for Construction Programs (SF–424C) is used by applicants to apply for Federal financial assistance. The Budget Information for Construction Programs (SF–424C) form allows the applicants to provide budget details as part of their grant proposals. This form is evaluated by Federal agencies as part of the overall grant application. This IC expires on February 28, 2025. *Grants.gov* seeks a three-year clearance of these collections.