



United States Food and Drug Administration

Premarket Tobacco Product Applications and Recordkeeping Requirements

OMB Control No. 0910-0879--Revision

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 requirements for the content and format of Premarket Tobacco Applications (PMTA) Reports which are utilized for the premarket review of new tobacco products. Section 910 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 387(j)), established requirements for premarket review of new tobacco products and the implementing regulations per the PMTA final rule (86 FR 55300, October 5, 2021) that are found in 21 CFR 1114.

The regulation associated with this information collection interprets and establishes requirements related to the basic content and format of premarket tobacco product applications (PMTAs), the procedure by which FDA would review PMTAs, and the maintenance of records regarding the legal marketing of certain tobacco products without PMTAs. The regulation also addresses issues such as the procedures of retention of records related to the PMTA, confidentiality of application information, electronic submission of the PMTA and amendments, and postmarket reporting requirements.

The Consolidated Appropriations Act of 2022 (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) will be 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. The Appropriations Act also makes all rules and guidances applicable to tobacco products apply to NTN products on that same effective date. Additionally, the Appropriations Act includes a transition period for premarket review requirements, directing companies to submit premarket tobacco product applications (PMTAs) for NTN products by May 14, 2022, to receive an additional 60-day period of marketing without being considered in violation of premarket review requirements.

A PMTA can be submitted by any manufacturer for any new tobacco product seeking an FDA marketing order, under section 910(b) of the FD&C Act. A PMTA must provide scientific data that demonstrates a product is appropriate for the protection of the public health. In order to reach such a decision and to authorize marketing, FDA considers (among other things), the

risk and benefits to the population as a whole, including people who would use the proposed new product as well as nonusers, whether people who currently use any tobacco product would be more or less likely to stop using such products if the proposed new tobacco product were available, whether people who currently do not use any tobacco products would be more or less likely to begin using tobacco products if the new product were available, and the methods, facilities, and controls used to manufacture process, and pack the new tobacco product. Generally, an applicant may amend its PMTA (1114.9), withdraw its PMTA after submission (1114.11), change ownership of their PMTA (1114.13), submit a supplemental application (1114.15), and resubmit a PMTA (1114.17). Electronic submission of a PMTA is required, unless the applicant requests and is granted a waiver.

Submitters can visit the following webpage which describes the process for submitting a PMTA (<https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/premarket-tobacco-product-applications>).

We are revising the three FDA forms required for use under sections 1114.7(b) and 1114.9(a) when submitting PMTA information to the Agency. Forms FDA 4057 and 4057b are required when submitting PMTA single and bundled submissions. Form FDA 4057a is for use when firms are submitting amendments and other general correspondence. Form FDA 4057b assists industry and FDA in identifying the products that are the subject of a submission. The requirements for each form are provided within form instructions.

We are also revising this collection to incorporate the burden for PMTA submissions received under OMB Control Number 0910-0768 (which covers the burden for electronic nicotine delivery system (ENDS) products PMTA submissions).

We therefore request revision of OMB approval of provisions found in 21 CFR 1114 and related forms, as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

This information collection is used to implement the basic content and format of premarket tobacco product applications (PMTAs), including the information that PMTAs must include. FDA bases this information collection on the experience the Agency has in reviewing thousands of PMTAs 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 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.

The content in Form FDA 4057, 4057a and 4057b have not significantly changed. We streamlined language used on Form FDA 4057, 4057a and web-forms used in CTP Portal NG. Two columns Portion Mass Numeric Value and Units (Portion Mass) were added in 4057b for Smokeless Tobacco Product per PMTA rule. The structural and data field changes listed above

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

3. Use of Improved Information Technology and Burden Reduction

The regulation requires that respondents submit PMTAs 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 PMTAs. 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 PMTA 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 4057 and 4057a for PMTA 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 4057 and/or 4057a, 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 4057 and 4057a for PMTA 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 4057b after applicants complete Form FDA 4057b 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 and user-friendly experience.

FDA estimates that based on its experience with submittal of this type of information, approximately 93% 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 “FDA 4057b – PMTA Unique Identification for New 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.

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 FD&C Act authorizes the submission of this information from all manufacturers of tobacco products that submit PMTAs. The term ‘small tobacco product manufacturer’ means a tobacco product manufacturer that employs fewer than 350 employees. For purposes of determining the number of employees of a manufacturer under the preceding sentence, the employees of a manufacturer are deemed to include the employees of each entity that controls, is controlled by, or is under common control with such manufacturer.

We estimate that we would receive, on average, 1 bundle every 2 years, impacting at most 10 small entities over the burden estimate timeframe. Furthermore, firms would only submit originally regulated bundles if the expected lifetime profits from submission were greater than the expected lifetime cost of submission. Therefore, while this cost may be significant for some small entities, we do not anticipate that it would affect a substantial number of small entities.

6. Consequences of Collecting the Information Less Frequently

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

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

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

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 57907). FDA received one (1) comment responsive to the four information collection topics solicited and nine (9) comments that were 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 PMTA 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 Premarket Tobacco Application (“PM” or “PMTA”) 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 modifications to the FDA Form 4057a and to inform stakeholders that FDA Forms 4057 and 4057a would be made available as web-based forms through the new CTP Portal NG. The wireframes provided in the Notice were intended to serve as an approximate representation of the planned web-form fields and workflow specifically associated with the new 4057 and 4057a web-forms for public comment, and as such, do not detail all 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 PMTAs 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 Premarket Tobacco Product Applications 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.

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

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

Freedom of Information Act

Among the laws governing the disclosure of reports submitted under sections 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."

11. Justification for Sensitive Questions

The information collection does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

An applicant may submit a PMTA to demonstrate that a new tobacco product meets the requirements to receive a marketing granted order. A new tobacco product may not be introduced or delivered for introduction into interstate commerce under this part until FDA has issued a marketing granted order for the product (§ 1114.5). Further, § 1114.7 describes the required content and format of the PMTA. The PMTA must contain sufficient information for FDA to determine whether any of the grounds for denial specified in section 910(c)(2) of the FD&C Act apply. The application must contain the following sections: general information, descriptive information, product samples, labeling, a statement of compliance with 21 CFR part 25, a summary, product formulation, manufacturing, health risk investigations, effect on the population as a whole, and a certification statement.

After submission of a PMTA FDA may request, and an applicant may submit, an amendment to a pending PMTA. FDA generally expects that when an applicant submits a PMTA, the submission will include all information required by section 910(b)(1) of the FD&C Act and part 1114 to enable FDA to determine whether it should authorize the marketing of a new tobacco product. However, FDA recognizes that additional information may be needed to complete the review of a PMTA and, therefore FDA allows the submission of amendments to a pending application.

An applicant may transfer ownership of its PMTA at any time, including when FDA has yet to act on it. Section 1114.13 describes the steps that an applicant would be required to take when it changes ownership of a PMTA. This section is intended to facilitate transfers of ownership and help ensure that FDA has current information regarding the ownership of a PMTA.

Supplemental PMTAs are an alternative format of submitting a PMTA (§ 1114.15). Applicants that have received a marketing granted order are able to submit a supplemental PMTA to seek marketing authorization for a new tobacco product that results from a modification or modifications to the original tobacco product that received the marketing granted order. FDA restricts the use of supplemental PMTAs to only changes that require the submission of limited information or revisions to ensure that FDA can efficiently review the application.

If an applicant receives a marketing denial order, they may submit a resubmission to respond to the deficiencies outlined in the marketing denial order (§ 1114.17). A resubmission may be submitted for the same tobacco product that received a marketing denial order or for a different new tobacco product that results from changes necessary to address the deficiencies outlined in a marketing denial order. This application format allows an applicant to address the deficiencies described in a marketing denial order without having to undertake the effort of submitting a standard PMTA. The resubmission format is not available for PMTAs that FDA refused to accept, refused to file, cancelled, or administratively closed, or that the applicant withdrew because FDA has not previously completed reviews of such applications upon which it can rely, and such applications may need significant changes to be successfully resubmitted.

FDA requires applicants that receive a marketing granted order to submit postmarket reports. Postmarket reports determine or facilitate a determination of whether there may be grounds to withdraw or temporarily suspend a marketing granted order (§ 1114.41). Additionally, § 1114.41 describes the reports that FDA would require through this regulation; however, FDA may require additional reporting in an individual applicant's marketing granted order. Applicants are required to submit two types of postmarket reports after receiving a marketing granted order: periodic reports and adverse experience reports. Periodic reports are required to be submitted within 60 calendar days of the reporting date specified in the marketing granted order. FDA anticipates that the reports would be required on an annual basis, but FDA may require in a specific order that reports be made more or less frequently depending upon a number of factors.

Applicants are also required to report all serious and unexpected adverse experiences associated with the tobacco product that have been reported to the applicant or of which the applicant is aware. The serious and unexpected adverse experience reports must be submitted to the Center for Tobacco Products' Office of Science through the HHS Safety Reporting Portal (<https://www.safetyreporting.hhs.gov/>) within 15 calendar days after receiving or becoming aware of a serious or unexpected adverse experience. FDA's Safety Reporting Portal is approved under OMB Control Number 0910-0291.

Applicants receiving a marketing granted order are required to maintain all records necessary to facilitate a determination of whether there are or may be grounds to withdraw or temporarily suspend the marketing granted order, including records related to both the application and postmarket reports, and ensure that such records remain readily available to the FDA upon request (§ 1114.45). Under § 1114.45(a)(1), an applicant must also retain any additional documentation supporting the application and postmarket reports that was not submitted to FDA.

Section 1114.49 requires an applicant to submit a PMTA and all supporting and related documents to FDA in electronic format. Under § 1114.49(c), an applicant that has a waiver would submit a paper submission to the address that FDA provides in the letter granting the waiver.

Table 1.--Estimated Annual Reporting Burden^{1,2}

21 CFR Part; Activity; Form FDA #	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
1114.5; Submission of Standard Bundled PMTAs ¹	215	1	215	1,713	368,295
PMTA Submission; Form FDA 4057	215	1	215	.58 (35 minutes)	125
PMTA Amendment and General Correspondence Submission; Form FDA 4057a	80	4	320	.16 (10 minutes)	51
PMTA Unique Identification for New Tobacco Products; Form FDA 4057b	215	1	215	.58 (35 minutes)	125
Tobacco Product Grouping Spreadsheet Validator	215	1	215	.08 (5 minutes)	17
1114.41; Reporting Requirements (periodic reports)	10	3	30	50	1,500
1114.9; Amendments	24	2	48	188	9,024
1114.13; Change in Ownership	10	1	10	1	10
1114.15; Supplemental applications	2	1	2	428	856
1114.17; Resubmissions	5	1	5	565	2,825
1114.49(b) and (c); Waiver from Electronic Submission	1	1	1	.25 (15 minutes)	1
Total			0		382,828

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

¹ FDA anticipates that applicants will submit bundled PMTAs, which are single submissions containing PMTAs for several similar or related products. We estimate that a bundle will contain on average between 6 and 11 distinct products.

² Totals may not sum due to rounding

Table 1 describes the estimated annual reporting burden. FDA has based these estimates on agency experience with current PMTA submissions. This assessment is grounded on experience with this information collection, information we have available from interactions with industry, and FDA expectations regarding established requirements for premarket review of new tobacco products. We have revised our previous estimates based on these experiences. In addition, FDA is revising this collection to incorporate the burden for PMTA submissions received under OMB Control Number 0910-0768 (which covers the burden for electronic nicotine delivery system (ENDS) products PMTA submissions). We believe the original PMTA burden in 0910-0768 is now covered by the current PMTA process under this control number. Although that burden only covered ENDS products these estimates include all categories of products.

FDA estimates that we will receive 215 PMTAs for a new tobacco product each year under § 1114. Our average represents a wide range of hours that will be required for these applications under different circumstances, with some requiring more hours (e.g., as many as 5,000 hours for early applications that involve complex products and for which the company has no experience conducting studies or preparing analysis of public health impacts, or for which reliance on master files is not possible) as well as many requiring fewer hours (e.g., as few as 50 hours for applications for products that are very similar to other new products). FDA estimates that it will take each respondent approximately 1,500 hours to prepare a PMTA seeking an order from FDA allowing the marketing of a new tobacco product. FDA also estimates that it would on average take an additional 213 hours to prepare an environmental assessment (EA) in accordance with the requirements of 21 CFR 25.40, for a total of 1,713 hours per PMTA.

FDA assumes that firms will submit all applications as PMTA bundles. We believe that bundling PMTAs results in efficiencies for applicants when compared to submitting standalone, full-text submissions for each product. We expect to receive bundled PMTAs where applicants can use the same evidence to support PMTAs for similar or related products. Bundling PMTAs into a single submission would eliminate the administrative burden of having to reproduce the same evidence in a standalone PMTA for each product.

FDA has three forms required for use under sections 1114.7(b) and 1114.9(a) when submitting PMTA information to the Agency. Form FDA 4057 is for use when submitting a PMTA. FDA estimates that 215 respondents will submit PMTA bundles using this form at 0.58 (35 minutes) per response. Included in this estimate are the 15 expected bundles submitted for NTN products. The number 215 is accounting for the bundles of ENDS products and the 1 bundle we expect to receive yearly for originally regulated products for a total of 125 hours.

Form FDA 4057a is for use when firms are submitting amendments and other general correspondence. We expect 80 applicants for submit 4057a for either amendments or general correspondence submissions. Our estimate is 0.16 (10 minutes) per response to fill out this form. Included in this estimate are the 15 expected submissions submitted from NTN products. We estimate there will be at least 4 amendments per application for a total of 51 hours. With most applications being submitted toward the end of our 3-year range, we expect fewer amendments during this period. With updated forms and additional guidance given by the agency, FDA expects applicants to submit more complete applications reducing the need for the issuance of Deficiency letters and Environmental Information request letters. As a result, we expect applicants to submit fewer amendments with Form FDA 4057a. However, FDA expects amendments from earlier applications to be submitted during this period. As a result, we have decreased the number of responses per respondent (from 14 to 4 responses) associated with Form FDA 4057.

Form FDA 4057b assists industry and FDA in identifying the products that are the subject of a submission where an applicant groups multiple PMTAs into a single submission (referred to as a bundled submission or a grouped submission). FDA has previously stated that one approach to submitting PMTAs could be to group applications for products that are both from the same manufacturer or domestic importer and in the same product category and subcategory into a single submission. FDA intends to consider information on each tobacco product as a separate,

individual PMTA as required under § 1114.7(c)(3)(iii). By having the identifying information for products contained in a submission 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. As a result, we decreased the average burden per response associated with the Form FDA 4057b by 10 minutes (from 45 to 35 minutes per response).

The form assists applicants in providing the unique identifying information for each product in a grouped submission of PMTAs. A respondent would utilize Form FDA 4057b once for each submission. We assume the submitter could include from 1 to 2,000 products in each Form FDA 4057b. Entering data for up to 2,000 rows can take approximately 4 hours on average per Form FDA 4057b for manual data entry. We reflect the average time of 35 minutes per response based on the assumption that we expect to receive an average of nine bundled products per submission. Included in this estimate are the 15 expected submissions submitted from NTN products.

As previously mentioned 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 “FDA 4057b – PMTA Unique Identification for New 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. We estimate the use of the validator tool will take an average of five minutes per response.

Applicants are required under § 1114.41 to submit two types of reports after receiving a marketing granted order: Periodic reports and adverse experience reports. Applicants must submit periodic reports within 60 calendar days of the reporting date specified in the marketing granted order (or potentially sooner if they choose to use the application as the basis for a supplemental PMTA under § 1114.15). FDA anticipates that the reports will be required on an annual basis, but FDA may require, by a specific order, that reports be made more or less frequently depending upon a number of factors (e.g., the novelty of the type of product). As such, FDA estimates under § 1114.41 that 10 respondents will submit a periodic report with 3 responses per respondent. This number is based on the average number of periodic report submissions received between 2020-2022. The Agency estimates that periodic reports will take on average of 50 hours per response for a total of 1,500 hours. FDA expects this number to increase as we continue to authorize more products in the PMTA pathway. As FDA continues to grant marketing authorization for more submissions FDA expects the number of respondents and total responses to grow. As a result, we have increased the number of responses per respondent (from 1 to 3 responses per respondent) associated with periodic reports.

Section 1114.13 allows an applicant to transfer ownership of a PMTA to a new owner. FDA believes this will be infrequent, so we have assigned 1 hour acknowledging the requirement.

Section 1114.15 is an alternative format of submitting a PMTA, supplemental PMTA, meeting the requirements of § 1114.7 that would reduce the burden associated with the submission and review of an application. Our estimated number of 2 respondents is based on the number estimated for postmarket reports, which is 4 bundles (approximately 34 products). Not all applicants will resubmit modifications to previously authorized products, so we estimate 2 bundles (which is approximately 17 products). FDA estimates further that a supplemental PMTA will take 25

percent of the time it takes (estimated at 428 hours per response) to complete an original submission (including EA hours).

Under § 1114.17 an applicant may submit a resubmission for the same tobacco product that received a marketing denial order or for a different new tobacco product that results from changes necessary to address the deficiencies outlined in a marketing denial order. Based on agency experience, we are estimating that out of all bundles received in 2020 through 2023, that an average of three bundles are authorized. If we receive 24 bundles yearly, and based on historical data, 58 percent fail at acceptance (8 bundles remaining), 17 percent fail at filing (7 bundles remaining), and 25 percent receive marketing orders (5 bundles remaining). We estimate that 50 percent will resubmit in a year. Thus, the number of respondents is three. FDA estimates that a resubmission will take 33 percent of the time it takes to complete an original submission (including EA hours) estimated at 565 hours per response for a total of 1,695 hours. As FDA continues to deny marketing authorization for more submissions FDA expects the number of respondents and total responses to grow.

Firms must also submit adverse experience reports (§ 1114.41(a)(2)) for tobacco products with marketing orders. We assume the same number of firms submitting periodic reports will submit adverse experience reports. Firms may submit voluntary and mandatory adverse experience reports using Form FDA 3800 under OMB Control Number 0910-0291.

Under § 1114.9 firms may prepare amendments to PMTA bundles in response to deficiency letters. These amendments contain additional information that we need to complete substantive review. We anticipate 2 responses back per bundle and therefore, we estimate that 24 respondents will submit 48 amendments (24×2). Assuming 1,500 hours as the time to prepare and submit a full PMTA and amendments may on average take 10 percent to 15 percent of that time (150-225 hours). We averaged this time out (12.5 percent of a full submission preparation time) and arrived at 188 hours per response.

An applicant is required to submit a PMTA and all supporting and related documents to FDA in electronic format that FDA can process, review, and archive unless an applicant requests, and FDA grants, a waiver from this requirement (§ 1114.49). FDA does not believe we will receive many waivers, so we have assigned one respondent to acknowledge the option to submit a waiver, consistent with our other application estimates for waivers.

Table 2.--Estimated Annual Recordkeeping Burden

21 CFR Part; Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
1114.45; PMTA records	215	1	215	2	430
1100.204; Pre-existing products records	1	1	1	2	2
1107.3; Exemptions from Substantial Equivalence (SE) records	1	1	1	2	2
Total			217		434

Table 2 describes the annual recordkeeping burden. FDA estimates that 215 recordkeepers will maintain records at 2 hours per record. Included in this estimate are the 15 expected recordkeepers of NTN products. Firms are also required to establish and maintain records related to SE exemption requests and pre-existing products (§ 1100.200 states that subpart C of part 1100). We expect the burden hours to be negligible for SE exemption requests. Firms would have already established the required records when submitting the SE exemption request. Similarly, we expect the hours to be negligible for any pre-existing tobacco products that have already submitted stand-alone pre-existing tobacco product submissions, because firms would have established the required records when submitting the stand-alone pre-existing tobacco product submissions.

The total burden for the collection of information is 382,828 reporting hours and 434 recordkeeping hours for a total of 383,262 hours.

12b. Annualized Cost Burden Estimate

The estimated annual reporting cost to respondents for this collection of information is \$24,896,700. This estimate assumes that tobacco industry (all occupations) will account for the submissions regarding PMTAs at an average wage of \$32.48 (Department of Labor’s Bureau of Labor Statistics for Tobacco Manufacturers (May 2023: https://www.bls.gov/oes/current/naics4_312200.htm)). We double this to account for benefits and overhead, yielding an hourly wage rate of \$64.96.

Activity; Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Preparing PMTAs and Related Reports; Tobacco Industry	383,262	\$64.96	\$24,896,700

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

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

14. Annualized Cost to the Federal Government

Our estimated cost to the Federal government reflects the allocation of 130 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 \$16,868,670 (\$129,759 x 130).

15. Explanation for Program Changes or Adjustments

Program Change Burden

The content in Form FDA 4057, 4057a and 4057b 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 validator tool.

Adjustments Burden

The burden adjustment is related to an increase in respondents reporting information and an increase in periodic reporting responses. The increase is off-set by burden decreases in the number of responses associated with reporting under the Form FDA 4057 and waiver requests, as well as a decrease in the average response time associated with the Form FDA 4057b.

Total Burden

Our estimated burden for the information collection reflects an overall increase of 369,555 hours and a corresponding increase of 1,302 responses/records. We attribute this to providing the validator tool and reevaluating our current estimates.

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.