**U.S Food and Drug Administration**
**Center for Tobacco Products**
**Premarket Tobacco Product Applications and Recordkeeping Requirements**

0910-0879
RIN 0910-AH44
SUPPORTING STATEMENT Part A

## A. Justification

1. Circumstances Making the Collection of Information Necessary

The Tobacco Control Act was enacted on June 22, 2009, amending the Federal Food, Drug, and Cosmetic Act (FD&C Act) and providing FDA with the authority to regulate tobacco products (Pub. L. 111-31; 123 Stat. 1776). Section 910(a) established requirements for premarket review of new tobacco products.

Effective April 14, 2022, Section 201(rr) of the Federal Food, Drug, and Cosmetic Act now applies to "any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption".

FDA is finalizing requirements for the content, format, submission, and review of PMTAs, as well as other requirements related to PMTAs, including recordkeeping requirements, and post market reporting. FDA will also require recordkeeping regarding the legal marketing of Pre-Existing Tobacco Products (i.e., those products that were commercially marketed as of February 15, 2007) and products that are exempt from the requirements of demonstrating substantial equivalence.

Section 910(a)(2) of the FD&C Act requires that a new tobacco product be the subject of a PMTA marketing granted order unless FDA has issued an order finding it to be substantially equivalent to a predicate product or exempt from the requirements of demonstrating substantial equivalence. A manufacturer may choose to submit a PMTA under section 910(b) of the FD&C Act to satisfy the requirements of premarket review. Section 910(b)(1) describes the required contents of a PMTA, which in addition to specific items, allows FDA to require applicants to submit other information relevant to the subject matter of the application.

As described in 21 CFR § 1114.5[1] 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 21 CFR part 1114 until FDA has issued a marketing granted order for the product. 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 Federal Food, Drug, and Cosmetic Act apply. The application must contain the following sections: general information,

[1] All references to regulatory sections of the Code of Federal Regulations are to Chapter 21 unless otherwise noted.

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.

Under § 1114.9 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, § 1114.9 will allow the submission of amendments to a pending application.

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. An applicant may transfer ownership of its PMTA at any time, including when FDA has yet to act on it.

Section 1114.15 discusses supplemental PMTAs which are an alternative format of submitting a PMTA. Specifically, supplemental PMTAs are a standardized cross-referencing format that FDA would implement under its authority of section 701(a) of the FD&C Act to efficiently enforce section 910 for submissions that are based on a PMTA that FDA has previously reviewed. Applicants that have received a marketing granted order would be 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 will restrict the use of supplemental PMTAs to only changes that require the submission of limited information or revisions to ensure that FDA is able to efficiently review the application. An applicant would also be able to submit a supplemental PMTA for modifications made to comply with a product standard issued under section 907 of the FD&C Act where FDA specifies that the submission of supplemental PMTAs would be appropriate.

Section 1114.17 describes resubmissions, which are an alternative format for submitting an application that meets the requirements of § 1114.7 or § 1114.15 to seek a marketing granted order for a tobacco product by responding to the deficiencies outlined in a no marketing granted order. 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. 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.

Section 1114.41 would require applicants that receive a marketing granted order to submit postmarket reports. FDA requires postmarket reports to determine or facilitate a determination of whether there may be grounds to withdraw or temporarily suspend a marketing granted order. 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 would be required under § 1114.41 to submit two types of reports after receiving a marketing granted order: periodic reports and adverse experience reports. Applicants would need to submit periodic reports 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 would also be 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 under § 1114.41(a)(2). The serious and unexpected adverse experience reports must be submitted to CTP's Office of Science through the HHS Safety Reporting Portal within 15 calendar days after receiving or becoming aware of a serious or unexpected adverse experience. FDA's Safety reporting portal is approved under 0910-0645.

Section 1114.45 would require applicants receiving a marketing granted order 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 agency upon request. Under § 1114.45(a)(1), an applicant must retain all documents submitted to FDA as part of an application and postmarket reports. An applicant must also retain any additional documentation supporting the application and postmarket reports that was not submitted to FDA.

Section § 1100.200 states that subpart C of part 1100 would establish requirements for the maintenance of records by tobacco product manufacturers who introduce a Pre-Existing Tobacco Product, or deliver it for introduction, into interstate commerce.

Section § 1107.3 describes that each applicant who submits an abbreviated report under section 905(j)(1)(A)(ii) of the FD&C Act and receives a letter acknowledging the receipt of an abbreviated report from FDA must maintain all records to support a determination that their exemption request meets the requirements of section 905(j)(3)(A)(i) of the FD&C Act that the modification to a product additive described in the exemption request was a minor modification made to a tobacco product that can be sold under the FD&C Act, and that an exemption is otherwise appropriate.

Section 1114.49 would require 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.

2. Purpose and Use of the Information Collection

This rule will interpret and establish 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 rule 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.

This rule applies to tobacco product manufacturers. Manufacturer is defined here 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 are for profit businesses from the private sector.

3. Use of Improved Information Technology and Burden Reduction

FDA requires electronic submission of PMTAs. FDA estimates that approximately 99% of respondents will submit electronically. FDA is also allowing for the alternative submittal of applications for premarket review in paper form for those individuals requesting a waiver from submitting in an electronic format.

4. Efforts to Identify Duplication and Use of Similar Information

This information collection is not duplicative. The FD&C Act, as amended by the Tobacco Control Act, is the only legislation which requires premarket review of new tobacco products. The FDA is the only Federal agency responsible for the collection of such premarket review information, and the primary federal regulatory authority with respect to the manufacture, marketing, and distribution of tobacco products. FDA received PRA approval for the Deeming Rule in 2016 (0910-0768). The rule provided CTP the authority to collect full PMTAs for ENDS products.

The PMTA rule sets forth the content and format requirements for new tobacco product application submissions. It further codifies the general procedures and creates postmarket reporting requirements for applicants that receive marketing granted orders. The rule also requires tobacco product manufacturers to submit their applications electronically via new submission forms and to keep records establishing that their tobacco products are legally marketed.

Although both collections contain PMTA application submissions, the burden under the Deeming rule does not cover any tobacco products beyond ENDS and only a full application submission. Whereas the PMTA rule covers PMTAs from any new tobacco product entity and submissions of bundled applications. Therefore, no duplication of data exists.

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.

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. It is important to note that ENDS PMTA submissions were not added to the total burden for this rule as its currently approved under a separate OMB control number (0910-0768).

6. Consequences of Collecting the Information Less Frequently

Where a new tobacco product is not substantially equivalent to a tobacco product commercially marketed in the United States as of February 15, 2007 or exempt from the requirement to obtain a substantial equivalence determination, applicants must submit a premarket tobacco product application under section 910(b) of the FD&C Act and receive a marketing granted order under section 910(c)(1)(A)(i) prior to marketing the product. Collecting the information less frequently would not meet the FD&C Act premarket requirements. There are no legal obstacles to reduce the burden.

Respondents to this collection of information include those manufacturers seeking a marketing granted order for a new tobacco product under section 910 who must submit a premarket tobacco product application under section 910(b). If this information were not collected, FDA would be unable to make the findings required by section 910(c) of the FD&C Act in order to provide a marketing granted order under section 910(c)(1)(A)(i) prior to the manufacturer being able to market the product.

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 provided an opportunity for public comment on the information collection requirements of the proposed rule that published in the *Federal Register* of September 25, 2019 (84 FR 50566) and March 10, 2020 (85 FR 13840). In response to this rule FDA received two PRA-related comments:

(Comment) One comment made specific comments requesting changes to elements in Form 4057.

(Response) FDA has considered these comments and agrees that many updates are necessary. The list below details the updates we have made to the form in response to the comments.

- FDA has harmonized, as appropriate, terms used within the PMTA and other FDA forms.
- FDA has revised the form by adding fields for address and contact information for manufacturer information to provide for the situation where the manufacturer is different from the Applicant.
- FDA agrees that the draft form did not collect organization information for certain parties. Additionally, FDA has revised the form by providing fields to enter organization information for certain parties, e.g., the authorized representative. FDA has revised the form by providing additional fields to describe the alternate point of contact.
- FDA has revised section III which now contains additional fields to identify cross-referenced submissions (ITP, SE, and MRTPA) and formal meetings held with FDA that pertain to the PMTA. For example, the applicant can now input in the revised form document keywords, document filenames, and submission dates for cross-referenced content. For formal meetings with FDA, the applicant can now input in the revised form the new tobacco product name. These fields would also help ensure FDA identify the cross-referenced content or related submission.
- Section III of the revised form also contains new fields (e.g., "document keyword" and "document filename") that allow the submitter to adequately describe the content they are cross-referencing. Section III now allows the applicant to indicate if the cross-referenced content is relevant to a specific product or to all bundled products in the application. Across all product categories, the subcategory of "co-package" has been removed. However, co-packaged items can be grouped within the same submission and the unique identification of this co-packaged product would include the specific items needed to identify each product within the co-package.
- In section IV, FDA has added a "Submission Table of Contents" with fields for "filename," "title," "table of contents category," and "keyword" in order that FDA can easily identify the application contents listed in section IV.

(Comment) One comment made specific comments requesting changes to elements in Form FDA 4057a.

(Response) FDA has considered these comments and agrees that many updates are necessary. The list below details the updates we have made to the form in response to the comments.

- FDA has combined sections I and IV to only ask for current owner's information once. The current owner's information is now only required in section I of the revised form.
- FDA now allows the manufacturer's address and contact information to be provided (if a different entity from the applicant) contact information is to be provided.
- FDA has revised the form to allow the organization's name to be provided (where an organization is an alternate point of contact). Additionally, FDA added a field so that organizational affiliation of the authorized representative information can be provided.

- For a change in authorized representative FDA agrees that "Replace" is the appropriate step and has added this as an option in section I, subsection C of the form.
- The form has been edited to allow the submitter to indicate the purpose of the amendment (i.e., whether it was for a single new tobacco product or for a bundled/grouped submission).
- Section III of the form has been revised to allow the submitter to indicate the addition, updating or removal of cross-referenced content, related submissions, and meetings with FDA. Section III now allows the submitter to describe the cross-referenced content, related submissions, and meetings, and to indicate the purpose of the cross-referenced content, related submissions, and meetings. Additionally, section III allows the submitter to indicate whether the submitter intends to "add," "update" or "remove" referenced content, related submissions, and meetings.
- Section III of the revised form now contains a "submission summary" field which allows the applicant to be used to describe the subject of the amendment.
- Section II of the revised form now allows information for "bundled" or grouped PMTAs to be submitted. Section II now allows submitters to submit updated tobacco product information for all new tobacco products including co-packaged products. Additionally, section II of the revised form enables submitters to describe the subject of their correspondence and provide a submission summary describing the intended use of the submitted contents.

Where appropriate, FDA has harmonized the terminology in the form with other FDA forms and has harmonized the layout of the Amendment and General Correspondence submission form with the layout of the PMTA submission form. For example, section I of the revised PMTA form is used to describe the applicant, the authorized representative, the alternate point of contact and other applicant information. Correspondingly, section I of the revised Amendment and General Correspondence submission form is used to update applicant information. Similarly, section II of the revised PMTA form is used to set out tobacco product information. Correspondingly, section II of the revised Amendment and General Correspondence submission form is used to update tobacco product information. FDA received generally supportive comments regarding proposed Form FDA 4057b. Comments agreed the form was a positive step towards streamlining the current PMTA submission process, as well as promoting efficient processing and review of bundled PMTAs.

(Comment) One comment noted that Form FDA 4057b failed to include an "oral tobacco-derived nicotine (OTDN)" category or subcategory designation. The comment argued that OTDN products are both distinct, being tobacco-free and non-dissolvable, and one of the fastest growing tobacco product segments in the U.S. market. Including an OTDN product subcategory would provide clarity for applicants and streamline FDA review of these products. The comment also noted that Form FDA 4057b requires applicants to include characterizing flavor information but does not define this term in Form FDA 4057b or within the proposed rule.

(Response) Providing unique identifying information, such as product category or subcategory, ensures FDA can identify the new tobacco product and distinguish it from other tobacco products, including additional new tobacco products in a bundled submission submitted using Form FDA 4057b, and assists FDA in performing its

acceptance and filing reviews. At this time, FDA does not yet have the experience necessary to create requirements for OTDN as a standalone product category or subcategory. Review of OTDN products will be handled on a case-by-case basis and any future decision to update or change the requirements of the rule and form to include OTDN products will follow appropriate notice and comment procedures. While the rule does not specifically include OTDN as a category or subcategory, where an applicant believes its new tobacco product, such as OTDN, does not fit within a product category set forth in the rule, it should identify the product category as "other". Applicants are encouraged to include any properties in addition to those required by the "other" category or subcategory to fully identify the tobacco product, if applicable.
In addition, the requirement for applicants to include product-specific information, such as characterizing flavor(s), corresponds to the general information requirements of § 1114.7.(c)(3)(iii) that will allow FDA to quickly check whether the product is within CTP's purview and identify the specific product that is the subject of the submission. For the characterizing flavor item, FDA is looking to see how the applicant identifies the tobacco product as having no characterizing flavor or having a particular characterizing flavor. If applicants do not consider the product to have a characterizing flavor, applicants must state "none". As discussed in the proposed rule, applicants that have questions regarding how to describe their product's characterizing flavor are encouraged to contact FDA prior to submission.

(Comment) Another comment noted that while the use of Form FDA 4057b would be a positive step, the current PMTA process is prohibitively expensive for most individual manufacturers of nicotine e-liquids.
(Response) As discussed in the proposed regulatory impact analysis, FDA has considered the costs and benefits associated with the rule, if finalized. While there are costs associated with the rule, the analysis also noted that the rule, would create cost savings for firms and for FDA by reducing the number of follow-on submissions for PMTAs (i.e., additional PMTAs submitted for the same product(s) after FDA refuses to accept or file, or issues a marketing denial order in response to, an initial PMTA). The analysis also noted small manufacturers who submit ENDS PMTA bundles would benefit from the proposed rule, if finalized. Submitted bundles, such as those submitted via Form FDA 4057b, would receive marketing granted orders through the PMTA pathway earlier with rulemaking than without rulemaking, increasing lifetime profits for the ENDS products included in the submitted ENDS bundles.

9. Explanation of Any Payment or Gift to Respondents

This information collection does not provide for any payment or gift to respondents.

10. Assurance of Confidentiality Provided to Respondents

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. CTP also identified privacy compliance requirements and coordinated with FDA's Privacy Officer to ensure responsible offices in CTP satisfy all in accordance with law and policy. CTP received HHS approval on the privacy impact assessment and was assigned PIA Unique Identifier P-7465194-382822.

11. Justification for Sensitive Questions

This information collection does not contain questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

Table 1.—Estimated Annual Reporting Burden (per this rule)

| "21 CFR Part" and Activity | 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] | 1 | 1 | 1 | 1,713 | 1,713 |
| Premarket Tobacco Product Application (PMTA) Submission (FDA Form 4057) | 24 | 1 | 24 | .75 | 18 |
| Premarket Tobacco Product Application Amendment And General Correspondence Submission (FDA Form 4057a) | 24 | 14 | 336 | .016 | 54 |
| Premarket Tobacco Product Application Grouping Submission (FDA Form 4057b) | 24 | 1 | 24 | 0.75 | 18 |

| | | | | | |
|---|---|---|---|---|---|
| 1114.41 Reporting Requirements (periodic reports) | 3 | 1 | 3 | 50 | 150 |
| 1114.9 Amendments | 24 | 2 | 48 | 188 | 9,024 |
| 1114.13 Change in Ownership | 1 | 1 | 1 | 1 | 1 |
| 1114.15 Supplemental applications | 2 | 1 | 2 | 428 | 856 |
| 1114.17 Resubmissions | 3 | 1 | 3 | 565 | 1,695 |
| 1114.41(a)(2) Adverse Experience Reports | 3 | 6 | 18 | .60 | 11 |
| 1114.49(b) and (c) Waiver from Electronic Submission | 1 | 1 | 1 | .25 | .25 |
| Total | | | | | 13,540 |

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

FDA has based these estimates on the full analysis of economic impacts and experience with current PMTA submissions. The estimates for OMB control number 0910-0768 covers the burden for ENDS products PMTA submissions. These estimates were originally published in the Deeming Rule and recently in the Federal Register of Apr 22, 2019 (84 FR 16673). In that rule we described that this 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 in accordance with the requirements of § 25.40, for a total of 1,713 hours per PMTA application.

Table 1 describes the estimated annual reporting burden per the requirements in this rule. For this analysis, FDA assumes that firms will submit all applications as PMTA bundles. We also considered updated data on market consolidation that has occurred since Deeming Rule published. For originally regulated products that would receive marketing granted orders through the PMTA pathway. For originally regulated products we expect to receive one full PMTA submission for a total of 1,713 hours. 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.

Additional efficiencies this creates for FDA can include, lessening the burden for FDA to process the submission and upload the files into our systems for review. Also, this is a review resource efficiency where we can review products more efficiently where the data can be reviewed once for multiple products to which it applies rather than reviewing individually for each separate PMTA (if we don't know it's identical data for many products across that are individually submitted).

Other than as specifically described for supplemental PMTAs and resubmisisons, having previously submitted a PMTA for an ENDS product could improve the efficiency of preparing a subsequent PMTA; however, whether and how much of a benefit it could provide would depend on both the quality of the prior submission and how similar the product is to the one in the new PMTA.

FDA conducted a thorough analysis of the current paperwork burden associated with the PMTA program and other similar forms and applied the most accurate burden to the forms; however, upon further review and certain updates made to the form based on comments received and product categorization changes, FDA has revised the burden associated with entering the data into the form (which includes searching existing data sources and gathering and maintaining the data needed) to be 45 minutes per individual product (rather than 30 minutes per product) on Form FDA 4057. For Form FDA 4057a, FDA has revised the burden for this form to 10 minutes (from 5 minutes). This form serves several purposes from changing a point of contact (minimal burden) to providing additional substantive information for the purpose of the review of the PMTA application (more burdensome).

FDA developed Form FDA 4057 for use when submitting PMTA single and bundled submissions. FDA estimates that 24 respondents will submit PMTA bundles using this form at 0.75 (45 minutes) per response. The number 24 is accounting for the bundles of ENDS products and the 1 bundle we expect to receive yearly for originally regulated products. (200 +1 = 201/8.5 products on average in a bundle) for a total of 12 hours.
FDA developed Form FDA 4057a for use when firms are submitting amendments and other general correspondence. Our estimate is 0.16 (10 minutes) per response to fill out this form. We estimate there will be at least one amendment per application for a total of 28 hours. With most applications being submitted toward the end of our 3-year range, we expect fewer amendments during this period. However, FDA expects correspondence from earlier applications to be submitted during this period.

FDA developed an additional form (Form FDA 4057b) that will assist 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 discussed bundled submissions in the proposed rule (84 FR 50566 at 50578) and noted that FDA intends to consider

information on each tobacco product as a separate, individual PMTA. The form will assist applicants in providing the unique identifying information for each product in a grouped submission of PMTAs that are required § 1114.7(c)(3)(iii). By having the identifying information for products contained in a submission be more clearly organized, FDA will be able to more efficiently process and review the applications contained in a grouped submission.

Based on the Form FDA 4057 for use when submitting PMTA single and bundled submissions, a respondent would utilize Form FDA 4057b once for each submission containing more than one PMTA. We assume the submitter could include from 2 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. However, FDA's original estimate that Form 4057b would estimate 4 hours per response was a high-end estimate and not an average. We now reflect the average time of 45 minutes per response based on the assumption that we expect to receive an average of nine bundled products per submission. Assuming 45 minutes per Form FDA 4057b for 24 applications, we estimate a total burden of 18 hours for this activity.

FDA estimates under § 1114.41 that three respondents will submit a periodic report. This number is based on the average number of periodic report submissions expected between 2020-2022. The RIA estimates that periodic reports will take between 20 and 80 hours per submission. For this estimate, we use the average of 50 per response for a total of 150 hours. Under § 1114.9 firms will prepare amendments to PMTA bundles in response to deficiency letters. These amendments contain additional information that we need to complete substantive review. In the RIA we state in our limited history reviewing PMTAs, we on average issue two deficiency letters. Based on this, we would anticipate two responses back per bundle. 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). We averaged this time out (12.5 percent of a full submission preparation time) and arrived at 188 hours per response. FDA estimates the total burden hours for preparing amendments is 9,024 hours.

Section § 1114.13 would allow 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 that meets 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 3 bundles (which is approximately 26 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 to do an original submission (including EA hours) for 428 hours per response. We estimate a total of 856 burden hours for this activity.

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 the

preliminary RIA, we are estimating that out of all bundles received in 2020, 2021, and 2022, that an average of three bundles are authorized. If we receive 24 bundles yearly, and based on historical data, 58 percent fail at acceptance (down to 8 bundles remaining), 17 percent fail at filing (down to 7 bundles remaining), and 25 percent receive marketing orders (5 left). We estimate that 50 percent will try to resubmit in a year. Thus, this number of respondents is three (rounded up). FDA estimates that a resubmission will take 33 percent of the time it takes to complete an original submission (including EA hours) at 565 hours per response for a total of 1,695 hours.

Under § 1114.41(a)(2), firms would also submit adverse experience reports for tobacco products with marketing orders. We assume the same number of firms submitting periodic reports will submit adverse experience reports. Currently, firms may voluntarily submit adverse experience reports using Form FDA 3800 under OMB control number 0910-0645. We have based our estimates on this information collection which estimates that it takes 1 hour (for mandatory reporting) to complete this form for tobacco products for a total of 18 hours.
Section § 1114.49 would require an applicant 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. 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, we believe it would take .25 hours (15 minutes) per waiver for a total of .25 hours.

Table 2.--Estimated Annual Recordkeeping Burden

| "21 CFR Part" and "Activity" | No. of Recordkeepers | No. of Records per Recordkeeper | Total Annual Records | Average Burden per Recordkeeping | Total Hours |
|---|---|---|---|---|---|
| 1114.45 PMTA Records | 24 | 1 | 24 | 2 | 48 |
| 1100.204 Pre-Existing products records | 1 | 1 | 1 | 2 | 2 |
| 1107.3 Exemptions from Substantial Equivalence records | 1 | 1 | 1 | 2 | 2 |
| Total | | | | | 52 |

Table 2 describes the annual recordkeeping burden per the requirements in this rule. FDA estimates that 26 recordkeepers will maintain records at 2 hours per record. Additionally, the rule, would require that firms establish and maintain records related to SE Exemption Requests and Pre-Existing products. We expect the burden hours of this rule 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 of this rule to be negligible for any Pre-Existing Tobacco Products that have already submitted Standalone Pre-Existing Tobacco Product Submissions, because firms would have established the required records when submitting the Standalone Pre-Existing Tobacco Product Submissions. We believe this time is usual and customary for these firms. We estimate that it would take 2 hours per record to establish the required records for a total of 4 hours. Therefore, the total recordkeeping burden hours is estimated to be 52 hours.

The total burden for these new collections of information in this rulemaking is 13,540 reporting hours and 52 recordkeeping hours for a total of 13,592 hours.

12b. Annualized Cost Burden Estimate

We estimate the costs from the rule using the cost of labor. Following guidelines from the Department of Health and Human Services (https://aspe.hhs.gov/system/files/pdf/242926/HHS_RIAGuidance.pdf), we estimate the cost of labor as the fully loaded wage, or the wage including benefits and overhead equal to 100 percent of the mean wage. For industry wages, we use wage per hour adjusted for benefits and overhead estimated at $86.20 per hour.

| Occupation | Total Burden Hours | Hourly Wage Rate | Total Respondent Costs |
|---|---|---|---|
| Composite Wage for Preparing PMTAs and Related Reports | 13,592 | $86.20 | $1,171,630 |
| Total | | | $1,171,630 |

13. 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.

14. Annualized Cost to the Federal Government

FDA anticipates that the Federal government will incur the following costs:

Staff Costs
Total annual cost to the Federal government = $7,150,000
Full-time Equivalents (FTEs) = 55
Annual Cost per FTE=$130,000

15. Explanation for Program Changes or Adjustments

The Food and Drug Administration is submitting this nonmaterial/non-substantive change request to revise FDA Form 4057b to allow for products containing non-tobacco derived nicotine to submit PMTA applications. Effective April 14, 2022, Section 201(rr) of the Federal Food, Drug, and Cosmetic Act now applies to "any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption". Additionally, we have incorporated other edits in the form to improve the data quality obtained. Currently, we do not have an estimate on the impact to our burden estimates. Once FDA has more data, we will submit another ICR to OMB to adjust our numbers (if necessary).

16. Plans for Tabulation and Publication and Project Time Schedule

FDA does not intend to publish the results of this information collection.

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

FDA is not seeking approval not to display the expiration date of OMB approval.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.