Premarket Tobacco Product Applications and Recordkeeping Requirements

0910-NEW
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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.

FDA is proposing requirements for the content, format, submission, and review of PMTAs, as well as other requirements related to PMTAs, including recordkeeping requirements, and postmarket reporting. FDA is also proposing recordkeeping requirements regarding the legal marketing of grandfathered tobacco products 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 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.

Under proposed § 1114.5 an applicant may submit a PMTA to demonstrate that a new tobacco product meets the requirements to receive a marketing 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 order for the product. Proposed § 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, descriptive information, product samples, a statement of compliance with 21 CFR part 25, a summary, product formulation, manufacturing, health risk investigations, and a certification statement.

Proposed § 1114.9 provides that 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 proposed 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, is proposing § 1114.9 to allow the submission of amendments to a pending application. Proposed § 1114.13 describes the steps that an applicant would be required to take when it changes ownership of a PMTA. This proposed 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.

Proposed §1114.17 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 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 order. FDA is proposing to 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.

Proposed § 1114.19 describes resubmissions, which are an alternative format for submitting an application that meets the requirements of § 1114.7 or § 1114.17 to seek a marketing order for a tobacco product by responding to the deficiencies outlined in a no marketing order. An applicant may submit a resubmission for the same tobacco product that received a no marketing order or for a different new tobacco product that results from changes necessary to address the deficiencies outlined in a no marketing order. This application format allows an applicant to address the deficiencies described in a no marketing 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.

Proposed § 1114.41 would require applicants that receive a marketing order to submit postmarket reports. FDA requires as necessary to determine or facilitate a determination of whether there may be grounds to withdraw or temporarily suspend a marketing order.

Proposed § 1114.41 describes the reports that FDA would require through this regulation; however, FDA may require additional reporting in an individual applicant's marketing order. Applicants would be required under proposed § 1114.41 to submit two types of reports after receiving a marketing 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 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 proposed § 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.

Proposed § 1114.45 would require applicants receiving a marketing 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 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 proposed § 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.

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

Proposed § 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.

Proposed § 1114.49 would require an applicant to submit a PMTA and all supporting and related documents to FDA in electronic format. Under proposed § 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 proposed rule would 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 proposed 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 proposed 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 encourages electronic submission. 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. 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 authorization 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 authorization 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 authorization 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).

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.

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

Existing PMTA burden OMB #0910-0768

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
PMTA Submission (ENDS)	200	3.75	750	1,713	1,284,750[1]

Table 1.--Estimated Annual Reporting Burden

[1] This total will not be added to the total burden for this rule as its currently approved under a separate OMB control number.

Table 2.—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	.50	12
Premarket Tobacco Product Application Amendment And General Correspondence Submission (FDA Form 4057a)	24	14	336	.083	28
1114.41 Reporting Requirements (periodic reports)	3	1	3	50	150
1114.9 Amendments	24	4	96	188	18,048
1114.13 Change in Ownership	1	1	1	1	1
1114.17 Supplemental applications	2	1	2	428	856
1114.19 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					22,514

[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. Table 1 describes the current estimates for OMB control number 0910-0768 which 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). 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 2 describes the estimated annual reporting burden per the requirements in this proposed 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 orders through the PMTA pathway. For originally regulated products we expect to receive one full PMTA submission for a total of 1,713 hours.

FDA developed FDA Form 4057 for use when submitting PMTA single and bundled submissions. FDA estimates that 24 respondents will submit PMTA bundles using this form at .50 (30 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 FDA Form 4057a for use when firms are submitting amendments and other general correspondence. Our estimate is .0.83 (5 minutes) per response to fill out this form. We estimate there will be at least 1 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 estimates under proposed § 1114.41 that 3 respondents will submit a periodic report. This number is based on the average number of periodic report submissions expected between 2020-2022. The PRIA estimates that periodic reports will take between 20-80 hours per submission. For this estimate, we use the average of 50 hours per response for a total of 150 hours.

Under proposed § 1114.9 firms would prepare amendments to PMTA bundles in response to deficiency letters. These amendments contain additional information that we need to

complete substantive review. In the PRIA we state in our limited history reviewing PMTAs, we on average issue 4 deficiency letters. Based on this, we would anticipate 4 responses back per bundle. Therefore, we estimate that 24 respondents will submit 96 amendments (24 x 4). Assuming 1,500 hours as the time to prepare and submit a full PMTA, amendments may on average take 10-15% of that time (150-225). We averaged this time out (12.5% of a full submission preparation time) and arrived at 188 hours per response. FDA estimates the total burden hours for preparing amendments is 18,048 hours.

Proposed § 1114.13 would allow an applicant to transfer ownership of a PMTA to a new applicant. FDA believes this will be infrequent, so we have assigned 1 token hour acknowledging the requirement.

Proposed § 1114.17 is an alternative format of submitting a PMTA that meets the requirements of proposed § 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 submit supplemental PMTAs for 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% 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 proposed § 1114.19 an applicant may submit a resubmission for the same tobacco product that received a no marketing order or for a different new tobacco product that results from changes necessary to address the deficiencies outlined in a no marketing order. Based on the PRIA, we are estimating that out of all bundles received in 2020, 2021, and 2022, that an average of 3 bundles are authorized. If we receive 24 bundles yearly, and based on historical data, 58% fail at acceptance (down to 8 bundles remaining), 17% fail at filing (down to 7 bundles remaining), and 25% receive marketing orders (5 left). We estimate that 50% will try to resubmit in a year. Thus, this number of respondents is 3 (rounded up). FDA estimates that a resubmission will take 33% 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 proposed § 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 FDA Form 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. Proposed § 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 1 respondent to acknowledge the option to submit a waiver. Consistent with our other application estimates for waivers, we believe it would take .25 (15 minutes) per waiver for a total of .25.

Table 3.--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 Grandfathered products records	1	1	1	2	2
1107.3 Exemptions from Substantial Equivalence records	1	1	1	2	2
Total					52

Table 3 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 proposed rule, if finalized, would require that firms establish and maintain records related to SE Exemption Requests and Grandfathered products. We expect the burden hours of this proposed 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 proposed rule to be negligible for any Grandfathered products that have already submitted Standalone Grandfathered Submissions, because firms would have established the required records when submitting the Standalone Grandfathered 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 22,514 reporting hours and 52 recordkeeping hours for a total of 22,566.

12b. Annualized Cost Burden Estimate

We estimate the costs from the proposed 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 2018 mean wage estimates from the Bureau of Labor Statistics' National Industry-Specific Occupational

Employment and Wage Estimates (https://www.bls.gov/oes/current/oes_nat.htm#00-0000) for the tobacco manufacturing industry.

Occupation	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Composite Wage for Preparing PMTAs and Related Reports	22,566	$86.20	$1,945,189
Total			$1,945,189

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

This is a new data collection.

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.