covered under OMB control number 0910–0731.

FDA is revising this collection to include a new form (Form FDA 3965b) and a validator tool for Form FDA 3965b that will help applicants submit information for their SE Reports in the correct format. Form FDA 3965b assists industry and FDA in identifying the products that are the subject of a submission, particularly where an applicant groups multiple new tobacco products into a single submission. This includes grouping products that are from the same manufacturer or domestic importer and in the same product category and subcategory into a single submission. FDA discussed bundled submissions in the SE rule (86 FR 55224) and noted that FDA intends to consider information on each new tobacco product and its corresponding predicate tobacco product as a separate, individual SE Report as required under § 1107.18(c)(7), § 1107.18(g), and § 1107.19. By having the identifying information for products contained in an SE Report be more clearly organized within the required forms, FDA will be able to process and review the applications contained in a grouped submission more efficiently.

The form assists applicants in providing the unique identifying information for each product in single and grouped submissions of SE Reports. A respondent would utilize Form FDA 3965b once for each submission. We assume the submitter could include from 1 to 2,000 products in each Form FDA 3965b. Entering data for up to 2,000 rows can take approximately 4 hours on average per Form FDA 3965b for manual data entry. We reflect the average time of 60 minutes per response based on the assumption that we expect to receive an average of 25 bundled products per submission. Assuming 60 minutes per Form FDA 3965b for 1,570 applications, we estimate a total burden of 1,570 hours for this activity.

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

The Validator allows industry users to validate product attributes in their product grouping spreadsheet with the defined and accepted product data standards and to make corrections as needed. If there are no errors found in a spreadsheet, the Validator will produce a certificate of completion that can be saved locally and included with the applicants FDA submission voluntarily. If errors are found during validation, the Validator will provide the applicants with the error at the end of each impacted row of the spreadsheet, allowing applicants to make necessary changes.

The software and any output files reside locally on an applicant's computer, allowing them to work on the product grouping spreadsheet offline. The Validator does not transmit any data across the web to FDA. FDA does not have the ability to access, review, or supplement the information on local computers through this application. We estimate that use of the Validator will take an average of 5 minutes per response.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity; 21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Recordkeeping SE Report under 1107.18–1107.58	471	1	471	5	2,355

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

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

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

Dated: July 11, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–15569 Filed 7–15–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–2889]

Agency Information Collection Activities; Proposed Collection; Comment Request; Premarket Tobacco Product Applications and Recordkeeping Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on premarket tobacco product applications and recordkeeping requirements.

DATES: Either electronic or written comments on the collection of information must be submitted by September 16, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 16, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be

considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–N–2889 for ''Premarket Tobacco Product Applications and Recordkeeping Requirements.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

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

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Premarket Tobacco Product Applications and Recordkeeping Requirements—Part 1114 (21 CFR Part 1114)

OMB Control Number 0910–0879—Revision

This information collection supports FDA regulations. Tobacco products are governed by chapter IX of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (sections 900 through 920) (21 U.S.C. 387 through 21 U.S.C. 387t). Section 910(a) established requirements for premarket review of new tobacco products.

The Consolidated Appropriations Act of 2022 (the Appropriations Act), that was 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) are now 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.

The Premarket Tobacco Product Applications and Recordkeeping Requirements regulation (§ 1114.45) outlines 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 also requires 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.

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 FDA regulations 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. Submitters can visit the following web page, which describes the process for submitting a PMTA (*https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/premarket-tobacco-product-applications*).

FDA has three forms required for use under §§ 1114.7(b) and 1114.9(a) when submitting PMTA information to the Agency: Form FDA 4057; Form FDA 4057a; and Form FDA 4057b. Form FDA 4057 is for use when submitting PMTA single and bundled submissions. For the purposes of this notice, no significant changes have been made to Form FDA 4057. Form FDA 4057a is for use when firms are submitting amendments and other general correspondence. Form FDA 4057a and the corresponding instructions have been updated to assist industry users in completing the form efficiently and correctly. The flow and organization of the form have been updated to follow a consistent style and sequence with Form FDA 4057. Form FDA 4057a instructions have been updated to reflect plain language principles as well as accurately mapped to correspond to the updates made to Form FDA 4057a. 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). Form FDA 4057b has been updated to add the following columns: Brand; Subbrand; Manufacturer. This update aligns with the requirements of part 1114. Additionally, Characterizing Flavor has been included as a required field.

The Center for Tobacco Products (CTP) is planning a significant upgrade to the submission process for PMTA applications. This upgrade, known as the CTP Portal Next Generation (CTP Portal NG), is a pivotal step forward in streamlining the application process for the tobacco industry. Presently, the tobacco industry uses multiple tools in the preparation and submission of PMTA applications to CTP, including PDF-editing software, FDA's eSubmitter Desktop Tool, and FDA's CTP Portal web application.

A submitter must first download and complete PDF versions of FDA Form 4057 and/or 4057a for PMTA applications and amendments, respectively, using any PDF-editing software. After 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 FDA Form 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 with the ability to create, prepare, and deliver their submissions in one place. CTP Portal NG will provide web forms of the FDA Forms 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. 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. A copy of revised FDA Form 4057, 4057a, 4057b and the validator tool will be available in the docket of this notice for review.

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

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 several 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 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.

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

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1] [2] [3]

21 CFR part; Activity; Form FDA #	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total Hours
1114.5; Submission of Standard Bundled PMTAs [2]	215	1	215	1,713	368,295
PMTA Submission; Form FDA 4057	215	1	215	0.58 (35 minutes)	125
PMTA Amendment and General Correspondence Submission; Form FDA 4057a	80	4	320	0.16 (10 minutes)	51
PMTA Unique Identification for New Tobacco Products; Form FDA 4057b	215	1	215	0.58 (35 minutes)	125
Tobacco Product Grouping Spreadsheet Validator	215	1	215	0.08 (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	0.25 (15 minutes)	1
Total	347		1,276		382,828

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] 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.
[3] 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. FDA has based these estimates on experience with this information collection, information 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 part 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 application.

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 §§ 1114.7(b) and 1114.9(a) when submitting PMTA information to the Agency. Form FDA 4057 for use when submitting PMTA single and bundled submissions. 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; as such, we expect 80 applicants to 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 four 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. Assuming 35 minutes per Form FDA 4057b for 215 applications, we estimate a total burden of 125 hours for this activity.

The FDA Tobacco Product Grouping Spreadsheet Validator (Validator) is a free software that validates the content of FDA product grouping spreadsheets such as ''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. We estimate the use of the validator tool will take an average of 5 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 and 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 one to three 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). 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 Agency experience, we are estimating that 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 will 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. FDA estimates the total burden hours for preparing amendments is 9,024 hours.

We anticipate 40 respondents will request meetings with CTP's Office of Science to discuss investigational plans. We base this figure on the average number of meeting requests received over the past 3 years and assume this will include meetings regarding NTN products. To request this meeting, applicants should compile and submit information to FDA for meeting approval. We assume 720 hours is necessary to compile and request a meeting with OS. This burden is covered under OMB control number 0910–0731, Meetings with Industry and Investigators on the Research and Development of Tobacco Products.

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, we believe it would take 0.25 hours (15 minutes) per waiver for a total of 1 hour.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR part; activity	Number of recordkeepers	Number 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

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

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. 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. We estimate that it would take 2 hours per record to establish the required records for a total of 4 hours for pre-existing products records and SE exemptions.

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 adjustment to adding a new form, the validator tool, and reevaluating our current estimates.

Dated: July 11, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–15570 Filed 7–15–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Ryan White HIV/AIDS Program Client-Level Data Reporting System

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than August 15, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Joella Roland, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Ryan White HIV/AIDS Program Client-Level Data Reporting System, OMB No. 0906–0039—Revision.

Abstract: The Ryan White HIV/AIDS Program (RWHAP), authorized under Title XXVI of the Public Health Service Act, is administered by the HIV/AIDS Bureau within HRSA. HRSA awards funding to recipients in areas of the greatest need to respond effectively to the HIV epidemic, with an emphasis on providing life-saving and life-extending medical care, treatment, and support services for people with HIV in the United States.

The RWHAP reporting requirements include the annual submission of client-level data in the RWHAP Services Report (RSR). The RSR is designed to collect information from grant recipients and their subawarded service providers, funded under Parts A, B, C, and D of the RWHAP statute.

HRSA is requesting a revision of the current RSR with two proposed updates:

Health Coverage

- HRSA proposes adding Medicare Advantage as a response option to the client's healthcare coverage data element.

Drug Addiction Treatment Act of 2000 Waiver Requirement

Current Questions

- Within your organization/agency, identify the number of physicians, nurse practitioners, or physician assistants who obtained a Drug Addiction Treatment Act of 2000 waiver to treat opioid use disorder with medication assisted treatment, (*e.g.,* buprenorphine, naltrexone) specifically approved by the U.S. Food and Drug Administration.
- How many of the above physicians, nurse practitioners, or physician assistants prescribed medication assisted treatment (*e.g.,* buprenorphine, naltrexone) for opioid use disorders in the reporting period?

Proposed Change to Question in 2024 RSR Form

- How many physicians, nurse practitioners, or physician assistants in your organization prescribed medications for opioid use disorder (*e.g.,* buprenorphine, naltrexone) for opioid use disorders during the reporting period?

A 60-day notice published in the **Federal Register** on April 24, 2024, vol. 89, No. 79; pp. 30384–85. There were no public comments.

Need and Proposed Use of the Information: The RWHAP statute specifies HRSA's responsibilities in administering grant funds, allocating funding, assessing HIV care outcomes (*e.g.,* viral suppression), and serving priority populations. The RSR collects data on the characteristics of RWHAP-funded recipients, their contracted service providers, and the patients or clients served. The RSR system consists of two primary components (the Recipient Report and the Provider Report) and a data file containing de-identified client-level data elements. Data are submitted annually. The RWHAP statute specifies the importance of recipient accountability. The RSR is used to ensure recipient compliance with the law, including evaluating the effectiveness of programs, monitoring recipient and provider performance, and preparing annual reports to Congress. Information collected through the RSR is critical for HRSA, state and local grant recipients, and individual providers to assess the status of existing HIV-related service delivery systems, monitor trends in service utilization, evaluate the impact of data reporting, and identify areas of greatest need.

Likely Respondents: RWHAP grant recipients, as well as their subawarded service providers, funded under RWHAP Parts A, B, C, and D.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.