prospective payment system (OPPS), we created a set of New Technology ambulatory payment classifications (APCs) to pay for certain new technology services under the OPPS. These APCs are intended to pay for new technology services that were not covered by the transitional pass-through payments provisions authorized by the Balanced Budget Refinement Act (BBRA) of 1999.

Since implementation of the OPPS on August 1, 2000, transitional pass-through payments have been made to hospitals for certain drugs, biologicals, and medical devices. These are temporary additional payments required by section 1833(t)(6) of the Social Security Act which was added by section 201(b) of the BBRA. The law required the Secretary to make these additional payments to hospitals for at least 2 but no more than 3 years.

In the April 7, 2000 final rule with comment period, we specified an application process and the information that must be supplied for us to consider a request for payment under the New Technology APCs (65 FR 18478). We posted the application process on our website at *www.cms.hhs.gov.* Services were only considered eligible for assignment to a New Technology APC if we listed them in one of a number of lists published in Medicare Program Memoranda, which are posted to our website (*https://www.cms.gov/medicare/regulations-guidance/transmittals/cms-program-memoranda*). We established a quarterly application process by which interested parties could submit applications to us for particular services. We assign new services to the New Technology APCs that we determine cannot be placed appropriately in clinical APCs. Under our current policy, we retain services in a New Technology APC until we gain sufficient information about actual hospital costs incurred to furnish a new technology service. *Form Number:* CMS–10054 (OMB control number: 0938–0860); *Frequency:* Once; *Affected Public:* Private sector, Business or other for-profit; *Number of Respondents:* 25; *Number of Responses:* 25; *Total Annual Hours:* 400. (For policy questions regarding this collection contact Josh Mcfeeters at 410–786–9732.)

William N. Parham III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024–15581 Filed 7–15–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Announcing the Intent To Award a Single-Source Supplement for the National Paralysis Resource Center (PRC)

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) announces the intent to award a single-source supplement to the current cooperative agreement held by the Christopher and Dana Reeve Foundation. The National Paralysis Resource Center (NPRC) is operated by the Christopher and Dana Reeve Foundation and offers important programmatic opportunities for persons with disabilities and older adults. The NPRC provides comprehensive information for people living with spinal cord injury, paralysis, and mobility-related disabilities and their families. Resources include information and referral by phone and email in multiple languages; a peer and family support mentoring program; a military and veterans' program; multicultural outreach services; multiple quality of life grants; and a national website. The administrative supplement for FY 2024 will be in the amount of $1,300,000, bringing the total award for FY 2024 to $10,000,000.

DATES: The supplement award will be issued to extend the project period to August 1, 2024, through June 30, 2025.

FOR FURTHER INFORMATION CONTACT: For further information or comments regarding this program supplement, contact Elizabeth Leef, U.S. Department of Health and Human Services, Administration for Community Living, Administration on Disabilities, Office of Disability Services Innovations; telephone (202) 475–2482; email *elizabeth.leef@acl.hhs.gov.*

SUPPLEMENTARY INFORMATION: The purpose of the supplemental funding is to support the expansion the National Paralysis Resource Center to improve the health and quality of life of individuals living with paralysis and their families by raising awareness of and facilitating access to a broad range of services relevant to individuals with paralysis. With the additional funding, the NPRC will work to expand the National Resource and Information Center; increase the health and quality of life of Americans with disabilities living with paralysis; increase support and resources to people with paralysis, their families and caregivers; expand collaboration with federal agencies and other national organizations that have a vested interested in the paralysis community; and strengthen performance measures.

Program Name: National Paralysis Resource Center.

Recipient: Christopher and Dana Reeve Foundation.

Period of Performance: The supplement award will be issued for the current project period, July 1, 2024, through June 30, 2025.

Award Amount: $1,300,000.

Award Type: Cooperative Agreement.

Basis for Award: The Christopher and Dana Reeve Foundation is currently funded to carry out the National Paralysis Resource Center (NPRC) for the period of July 1, 2024, through June 30, 2025. As a result of the 2024 budget, Congress appropriated additional funds for the expansion of the NPRC. It would be unnecessarily time consuming and disruptive to the NPRC project and the beneficiaries being served for the ACL to establish a new grantee at this time when critical services are presently being provided in an efficient manner.

Statutory Authority: This program is authorized under Section 317 of the Public Health Service Act (42 U.S.C. 247(b–4)); Consolidated and Further Continuing Appropriations Act, 2016, Public Law 114–113 (Dec. 18, 2015).

Dated: July 10, 2024.

Alison Barkoff,

Principal Deputy Administrator for the Administration for Community Living, performing the delegable duties of the Administrator and the Assistant Secretary for Aging.

[FR Doc. 2024–15611 Filed 7–15–24; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–2888]

Agency Information Collection Activities; Proposed Collection; Comment Request; Substantial Equivalence Reports for Tobacco Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing 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 substantial equivalence reports for tobacco products.

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–2011–D–0147 for ''Substantial Equivalence Reports.'' 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 revision 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.

Substantial Equivalence Reports for Tobacco Products—21 CFR 1107.18 and 1107.19

OMB Control Number 0910–0673—Revision

This information collection supports FDA requirements for the content and format of Substantial Equivalence (SE) Reports which are utilized to establish the substantial equivalence of a tobacco product. Sections 905(j)(1)(A)(i) and 910(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 387e(j)(1)(A)(i) and 387j(a)) established requirements for substantial equivalence and premarket review of new tobacco

products and the implementing regulations per the SE final rule (86 FR 55224) are found in §§ 1107.18 and 1107.19 (21 CFR 1107.18 and 1107.19).

An SE Report can be submitted by any manufacturer for any new tobacco product seeking an FDA substantially equivalent order, under section 905(j) of the FD&C Act. A substantially equivalent tobacco product is one that has been found by FDA to have either the same characteristics as a predicate product or has different characteristics than the predicate tobacco product, but the SE Report demonstrates that the new product does not raise different questions of public health. A predicate tobacco product is one that was commercially marketed (other than for test marketing) in the United States as of February 15, 2007, or is a product previously found to be substantially equivalent by FDA. Generally, an applicant may amend its SE Report (21 CFR 1107.20), withdraw its SE Report after submission (21 CFR 1107.22), and change the ownership of its SE Report (21 CFR 1107.24). Electronic submission of SE Reports is required, unless the applicant requests and is granted a waiver.

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

Form FDA 3965 is for use when submitting a tobacco SE Report to the Agency. Form FDA 3965 and its corresponding instructions have been updated to assist industry users in completing the form efficiently and correctly. The flow and organization of the form have been updated to follow a consistent style and appearance with other FDA forms related to tobacco product submissions.

Form FDA 3965a is the Tobacco Substantial Equivalence Report Amendment and General Correspondence Submission form that was formerly Form FDA 3964. FDA has revised the form number of Form FDA 3964 to Form FDA 3965a to align to Form FDA 3965, the Tobacco Substantial Equivalence Report Submission. Form FDA 3965a is for use when firms are submitting amendments and other general correspondence for an SE Report to the Agency. Form FDA 3965a and its corresponding instructions have been updated to assist industry users in completing the form efficiently and correctly. The flow and organization of the form have been updated to follow a consistent style and appearance with Form FDA 3965. As part of the form organization update, Form FDA 3965a has been split into three main parts: Applicant Information, Amendment Information, and General Correspondence. Industry users are able to select the submission type, selecting from Amendment or General Correspondence, in Part B of Section I—Applicant Information. After a selection is made, industry users may skip to the appropriate section to complete. Form FDA 3965b is the new SE Unique Identification for New and Predicate Tobacco Products form that assists industry and FDA in identifying the products that are the subject of a submission where an applicant groups multiple SE Reports into a single submission (referred to as a bundled submission or a grouped submission).

The Consolidated Appropriations Act of 2022 (Pub. L. 117–103) (the Appropriations Act), enacted on March 15, 2022, amended the definition of the term ''tobacco product'' in section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)) to include products that contain nicotine from any source. As a result, non-tobacco nicotine (NTN) products that were not previously subject to the FD&C Act (*e.g.,* products containing synthetic nicotine) are now subject to all of the tobacco product provisions in the FD&C Act that began on April 14, 2022, including the requirement of premarket review for new tobacco products. The Appropriations Act also makes all regulations and guidances applicable to tobacco products apply to NTN products on that same effective date.

The Center for Tobacco Products (CTP) is planning a significant upgrade to the submission process for SE applications. This upgrade, known as the CTP Portal Next Generation (CTP Portal NG), is a pivotal step forward in streamlining the application process for the tobacco industry. Presently, the tobacco industry uses multiple tools in the preparation and submission of SE applications to CTP, including PDF-editing software, FDA's eSubmitter Desktop tool, and FDA's CTP Portal web application. A submitter must first download and complete PDF versions of Form FDA 3965 and 3965a for SE applications and amendments, respectively, using any PDF-editing software. Once the PDF form is complete, the tobacco industry uses the eSubmitter Desktop tool (*https://www.fda.gov/industry/fda-esubmitter/using-esubmitter-prepare-tobacco-product-submissions*) to prepare the submission for delivery to CTP, which requires creating a new submission using eSubmitter's electronic CTP Transmittal Form and providing contact information, the completed Form FDA 3965 and/or 3965a, and any supporting documentation. When complete, the eSubmitter tool then packages the submission form, data, and documents into a ZIP file, saved locally, and the tobacco industry must log into their CTP Portal account (*https://www.fda.gov/tobacco-products/manufacturing/submit-documents-ctp-portal*) and upload the packaged submission ZIP file. To use CTP Portal, an organization must first go through the process of setting up an Industry Account Manager (IAM) (*https://www.fda.gov/tobacco-products/manufacturing/request-industry-account-manager-iam-ctp-portal*), which will then allow the IAM to manage CTP Portal accounts for their organization and submit submissions.

The new CTP Portal NG application transforms this process by providing the tobacco industry with the ability to create, prepare, and deliver their submissions in one place. CTP Portal NG will provide web forms of Form FDA 3965 and 3965a for SE applications and amendments, respectively, which will improve the submission preparation process for the tobacco industry as it will provide tools to expedite the entry of data and supporting documentation, dynamically guide users to relevant sections of the forms based on their input, and improve quality by providing helpful information on the questions being requested and verifying all required data has been provided. CTP Portal NG has a built-in process for applicants to upload Form FDA 3965b after applicants complete Form FDA 3965b and validate it using a new validator tool. When complete, CTP Portal NG allows applicants to submit the completed web forms to CTP for review. This innovation eliminates the current three-step process using PDF-editing software, eSubmitter, and CTP Portal and provides a more integrated, user-friendly experience. A copy of Form FDA 3965, 3965a, 3965b 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.

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

and-distribute-tobacco-product/substantial-equivalence.

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

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

Activity; FDA form; 21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
SE Report—1107.18	1,139	1	1,139	300	341,700
SE Report where applicant provides certification for identical characteristics—1107.18(g) and 1107.18(l)(2).	431	1	431	10	4,310
Form FDA 3965—Tobacco Substantial Equivalence Report Submission.	1,570	1	1,570	0.75 (45 minutes)	1,178
Form FDA 3965a[2]—Tobacco Amendment and General Correspondence Report.	628	1	628	0.16 (10 minutes)	100
Form FDA 3965b—SE Unique Identification for New and Predicate Tobacco Products.	1,570	1	1,570	1	1,570
SE Grouping Spreadsheet Validator	1,570	1	1,570	0.08 (5 minutes)	126
Waiver from Electronic submission—1107.62(b)	5	1	5	0.25 (15 minutes)	1
Totals	2,203		6,913		348,985

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

FDA has based these estimates on experience with this information collection, information we have available from interactions with industry, registration and listing data, information related to other regulated products, and FDA expectations regarding the tobacco industry's use of the substantial equivalence pathway to market their products. We have revised our previous estimates based on these experiences. Utilizing registration and listing data for deemed tobacco products, the estimated annual number of SE Reports is expected to be 1,570.

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

Table 1 describes the annual reporting burden per the requirements in §§ 1107.18 and 1107.19. FDA estimates that we will receive 1,139 full initial SE Reports for a new tobacco product each year under § 1107.18 that take a manufacturer approximately 300 hours to prepare. We have consolidated our previous numbers in the burden chart of full and bundled SE Reports (683 and 456) to reach the 1,139 estimate. In addition, anyone submitting an SE Report is required to submit an environmental assessment prepared in accordance with 21 CFR 25.40 under § 1107.18(k). The burden for environmental reports has been included in the burden per response for each type of SE Report.

FDA estimates receiving 239 SE Reports where applicants provide a certification for some identical characteristics under §§ 1107.18(g) and 1107.18(l)(2). We also estimate receiving 192 bundled SE Reports where applicants provide a certification for some identical characteristics under §§ 1107.18(g) and 1107.18(l)(2) (other than the initial SE Report in the bundle). FDA anticipates the burden for an applicant to be generally the same if they submit bundled submissions or individual applications as such, both are captured under SE Report where applicant provides certification for identical characteristics. We believe that the number of SE Reports that include a certification will increase because applicants may certify that certain characteristics are identical in the new tobacco product and the predicate tobacco product. However, in the absence of specific information on how many more applicants might choose to certify, we are maintaining our previous estimates at this time. As certification statements and additional guidance are given by the Agency within Form FDA 3965, FDA expects applicants to submit less technical information. As a result, we expect applicants total burden hours per applications to decrease. Therefore, we have decreased the burden per response for these SE Reports.

Manufacturers are required to submit SE Reports electronically (§ 1107.62 (21 CFR 1107.62)). We estimate that it would initially take about 45 minutes per product to fill out the Form FDA 3965. However, for amendments, we estimate that filling out Form FDA 3965a will take 10 minutes as applicants can copy and paste from the first submission. Section 1107.62(b) also allows applicants to request a waiver from the electronic format requirement. Based on experience since implementing the Premarket Tobacco Product Application (PMTA) rule, FDA does not believe we will receive many waivers, so we have decreased the number of respondents to five respondents to acknowledge the option to submit a waiver. Consistent with our other application estimates for waivers, we believe it would take 0.25 hours (15 minutes) per waiver for a total of 1 hour.

We anticipate five respondents will request meetings with CTP's Office of Science (OS) 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 90 hours are necessary to compile and request a meeting with OS. This burden is already

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