

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

Dated: November 20, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–27654 Filed 11–25–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–4040–0008]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before January 27, 2025.

ADDRESSES: Submit your comments to *sagal.musa@hhs.gov* or by calling (202) 205–2634.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 4040–0008–60D and project title for reference, to Sagal Musa, email: *sagal.musa@hhs.gov*, or call (202) 205–2634 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments

regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency’s functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Budget Information for Construction Programs (SF–424C).

Type of Collection: Extension.
OMB No.: 4040–0008.

Abstract

Budget Information for Construction Programs (SF–424C) is used by applicants to apply for Federal financial assistance. The Budget Information for Construction Programs (SF–424C) form allows the applicants to provide budget details as part of their grant proposals. This form is evaluated by Federal agencies as part of the overall grant application. This IC expires on February 28, 2025. *Grants.gov* seeks a three-year clearance of these collections.

ANNUALIZED BURDEN HOUR TABLE

Forms (if necessary)	Respondents (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
Budget Information for Construction Programs (SF-424C).	Grant-seeking organizations	239	1	1	239
Total	1	239

Sherrette A. Funn,
Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.
 [FR Doc. 2024-27598 Filed 11-25-24; 8:45 am]
BILLING CODE 4151-AE-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-4040-0007]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.
ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before January 27, 2025.
ADDRESSES: Submit your comments to *sagal.musa@hhs.gov* or by calling (202) 205-2634.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 4040-0007-60D and project title for reference, to Sagal Musa, email: *sagal.musa@hhs.gov*, or call (202) 205-2634 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity

of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Assurances for Non-Construction Programs (SF424B).
Type of Collection: Extension.
OMB No.: 4040-0007.

Abstract

Assurances for Non-Construction Programs (SF-424B) is used by applicants to apply for Federal financial assistance. The Assurances for Non-Construction Programs (SF-424B) form requests that the applicants certify specified required assurances as part of their grant proposals. This form is evaluated by Federal agencies as part of the overall grant application. This IC expires on February 28, 2025. *Grants.gov* seeks a three-year clearance of these collections.

ANNUALIZED BURDEN HOUR TABLE

Forms (if necessary)	Respondents (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
Assurances for Non-Construction Programs (SF-424B).	Grant-seeking organizations	9,772	1	0.5	4,886
Total	1	4,886

Sherrette A. Funn,
Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.
 [FR Doc. 2024-27595 Filed 11-25-24; 8:45 am]
BILLING CODE 4151-AE-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Notice of Publication of Common Agreement for Nationwide Health Information Interoperability (Common Agreement) Version 2.1

AGENCY: Assistant Secretary for Technology Policy/Office of the National Coordinator for Health

Information Technology, Department of Health and Human Services.
ACTION: Notice.

SUMMARY: This notice fulfills an obligation under the Public Health Service Act (PHSA). The act requires the National Coordinator for Health Information Technology to publish on the Office of the National Coordinator for Health Information Technology's public internet website, and in the **Federal Register**, the trusted exchange framework and common agreement developed under the PHSA. This notice is for publishing an updated version of the Common Agreement (Version 2.1).

ADDRESSES: Common Agreement Version 2.1 is also available on the Office of the National Coordinator for

Health Information Technology's public internet website at *www.HealthIT.gov/TEFCA*.

FOR FURTHER INFORMATION CONTACT: Mark Knee, Office of the National Coordinator for Health Information Technology, 202-664-2058.

SUPPLEMENTARY INFORMATION: This notice fulfills the obligation under section 3001(c)(9)(C) of the Public Health Service Act (PHSA) to publish the trusted exchange framework and common agreement, developed under section 3001(c)(9)(B) of the PHSA (42 U.S.C. 300j-11(c)(9)(B)), in the **Federal Register**. This publication consists of the following document: