

broadly due to differences in case definitions, inconsistencies in classifying cause of death on death certificates, study populations, and case ascertainment. To address the need for improved estimates of SDY incidence and its epidemiology based on uniform cases definitions, CDC, in collaboration with NIH's National Heart, Lung, and Blood Institute (NHLBI) and National Institute of Neurological Disorders and Stroke (NINDS), implemented the SDY Case Registry in 2015. To meet the ongoing need to produce accurate and uniform information, CDC, and NIH continued the SDY Case Registry in 2018 with 13 recipients through a CDC-based cooperative agreement program

(DP18-1806). In 2023, a new cooperative agreement program was started with 12 recipients (DP23-0006) and was launched by CDC with continued support from NIH. The current Revision seeks to revise burden hour estimates, modify responses for data elements collected, and to extend OMB approval for a period of three years.

CDC recipients agree to compile a defined set of SDY information about a defined subset of child deaths through the jurisdiction's/state's existing CDR program. CDC estimates that the 12 participating state/jurisdictions will collect data on approximately 606 SDY cases per year. Each of the 12 CDC-

funded state/jurisdiction awardees will, on average, review and enter data on 51 of 606 cases each year. Burden is estimated for reporting required case information. It is estimated that approximately half (303) of the estimated 606 SDY cases will undergo advanced clinical review by a team of three medical experts.

OMB approval is requested for three years. The total estimated annual burden is 438 hours which is a decrease of 73 hours from the previously approved information collection request due to a decrease in the number of participating states/local jurisdictions from 13 to 12. There are no costs to respondents other than their time.

#### ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
State Health Personnel .....	SDY Module I .....	12	51	10/60
Medical Expert .....	Advanced Review .....	36	26	15/60
State Health Personnel .....	SDY Module N .....	12	51	10/60

**Jeffrey M. Zirger,**  
Lead, Information Collection Review Office,  
Office of Public Health Ethics and  
Regulations, Office of Science, Centers for  
Disease Control and Prevention.

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### Centers for Disease Control and Prevention

[60Day-25-0210; Docket No. CDC-2025-0455]

#### Proposed Data Collection Submitted for Public Comment and Recommendations

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice with comment period.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a continuing information collection project titled List of Ingredients Added to Tobacco in the Manufacture of Cigarette Products. This

data collection is developed so that cigarette manufacturers, packagers, and importers can submit annually to HHS (through CDC) a list of ingredients added to tobacco in the manufacturing of cigarettes.

**DATES:** CDC must receive written comments on or before November 10, 2025.

**ADDRESSES:** You may submit comments, identified by Docket No. CDC-2025-0455 by either of the following methods:

- *Federal eRulemaking Portal:* [www.regulations.gov](http://www.regulations.gov). Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21-8, Atlanta, Georgia 30329.

**Instructions:** All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to [www.regulations.gov](http://www.regulations.gov).

**Please note:** Submit all comments through the Federal eRulemaking portal ([www.regulations.gov](http://www.regulations.gov)) or by U.S. mail to the address listed above.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21-8, Atlanta, Georgia 30329;

Telephone: 404-639-7570; Email: [omb@cdc.gov](mailto:omb@cdc.gov).

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses; and

5. Assess information collection costs.

### Proposed Project

List of Ingredients Added to Tobacco in the Manufacture of Cigarette Products (OMB Control No. 0920-0210, Exp. 1/31/2026)—Extension—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

### Background and Brief Description

Cigarette smoking is the leading preventable cause of premature death and disability in our nation. Each year

more than 480,000 deaths occur as the result of cigarette smoking-related diseases. Since 1986, as required by the Comprehensive Smoking Education Act (CSEA) of 1984, which amended the Federal Cigarette Labeling and Advertising Act (FCLAA), 15 U.S.C. 1335a, CDC has collected information about the ingredients used in cigarette products. HHS has delegated responsibility for implementing the required information collection to CDC. Respondents are commercial cigarette manufacturers, packagers, or importers (or their representatives), who are required by FCLAA to submit ingredient reports to HHS on an annual basis.

Respondents are not required to submit specific forms; however, they are required to submit a list of all ingredients used in their products. CDC requires the ingredient report to be submitted by chemical name and Chemical Abstract Service (CAS)

Registration Number, consistent with accepted reporting practices for other companies currently required to report ingredients added to other consumer products. The information collected is subject to strict confidentiality provisions.

Ingredient reports are due annually on March 31. Upon receipt and verification of the annual ingredient report, CDC issues a Certificate of Compliance to the respondent. As deemed appropriate by the Secretary of HHS, HHS is authorized to use the information to report to Congress the health effects of ingredients, research activities related to the health effects of ingredients, and other information that the Secretary determines to be of public interest.

The total estimated annualized burden hours are 358. OMB approval is requested for three years. There are no costs to respondents other than their time.

### ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Business Entities .....	N/A .....	55	1	6.5	358
Total .....	.....	.....	.....	.....	358

**Jeffrey M. Zirger,**  
Lead, Information Collection Review Office,  
Office of Public Health Ethics and  
Regulations, Office of Science, Centers for  
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### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### Centers for Disease Control and Prevention

[60Day-25-0338; Docket No. CDC-2025-0420]

#### Proposed Data Collection Submitted for Public Comment and Recommendations

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice with comment period.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on

a continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a continuing information collection project titled Annual Submission of the Ingredients Added to, and the Quantity of Nicotine Contained in, Smokeless Tobacco Manufactured, Imported, or Packaged in the U.S. This activity is designed to allow CDC to collect a list of ingredients added to tobacco in the manufacture of smokeless tobacco products and a specification of the quantity of nicotine contained in each product.

**DATES:** CDC must receive written comments on or before November 10, 2025.

**ADDRESSES:** You may submit comments, identified by Docket No. CDC-2025-0420 by any of the following methods:

- *Federal eRulemaking Portal:* [www.regulations.gov](http://www.regulations.gov). Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21-8, Atlanta, Georgia 30329.

**Instructions:** All submissions received must include the agency name and Docket Number. CDC will post, without

change, all relevant comments to [www.regulations.gov](http://www.regulations.gov).

**Please note:** Submit all comments through the Federal eRulemaking portal ([www.regulations.gov](http://www.regulations.gov)) or by U.S. mail to the address listed above.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21-8, Atlanta, Georgia 30329; Telephone: 404-639-7570; Email: [omb@cdc.gov](mailto:omb@cdc.gov).

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information