DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–23–23FN; Docket No. CDC–2023–0044]

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 proposed information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled, Menthol-Flavored Tobacco Products Policy Evaluation, which aims to collect data on menthol-flavored tobacco product use, any tobacco use, quit rates, and product switching behaviors among adults 18 years of age and older.

DATES: CDC must receive written comments on or before August 8, 2023.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2023–0044 by either of the following methods:

- *Federal eRulemaking Portal: 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.*

Please note: Submit all comments through the Federal eRulemaking portal (*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.*

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

Menthol-Flavored Tobacco Products Policy Evaluation—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC) is submitting this new information collection request (ICR) for an evaluation of local policies restricting the sale of menthol and other flavored tobacco products on outcomes such as menthol-flavored tobacco product use, any tobacco use, quit rates, and product switching behaviors. The evaluation will also study the impact community education efforts associated with the flavored tobacco product sales restriction policies have on individuals' awareness of the policies and perceptions about the harms of tobacco use. This evaluation seeks to explore the effects of the policies on racial and ethnic groups (American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and Hispanic or Latino populations), and lesbian, gay, bisexual, transgender, queer, and/or questioning (LGBTQ+) communities specifically, as these populations are known to use menthol-flavored tobacco products at a higher prevalence than other populations and may therefore be most affected by policies addressing menthol-flavored tobacco use.

Understanding how the aforementioned policies impact menthol-flavored tobacco product use may help to inform public health activities and decisions regarding tobacco control. Although some research on local tobacco policies indicates they are effective at limiting the availability of policy-restricted products, there is a lack of information on the policies' potential impact on tobacco use behaviors (*e.g.,* product switching behavior, online purchasing). There have been no other evaluation data collection efforts conducted on this topic to date, nor does the information to be collected exist in any existing centralized data source. Each data collection tool submitted through this package has a distinct purpose with no overlap across other tools or data collection efforts.

OMB approval is requested for three years. The total annualized burden is 3,047 hours. There are no costs to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hr)	Total burden (in hr)
General population	Survey Screener Questionnaire	9,875	1	2/60	329

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hr)	Total burden (in hr)
Individuals in racial and ethnic groups.	Survey Screener Questionnaire	1,500	1	2/60	50
LGBTQ+ individuals	Survey Screener Questionnaire	1,125	1	2/60	38
General population	Community Web-Panel Survey	4,050	1	30/60	2,025
Individuals in racial and ethnic groups.	Community Web-Panel Survey	600	1	30/60	300
LGBTQ+ individuals	Community Web-Panel Survey	450	1	30/60	225
General population	Focus Group Screener Questionnaire.	34	1	3/60	2
Individuals in racial and ethnic groups.	Focus Group Screener Questionnaire.	33	1	3/60	2
LGBTQ+ individuals	Focus Group Screener Questionnaire.	33	1	3/60	2
General population	Community Focus Group	25	1	1	25
Individuals in racial and ethnic groups.	Community Focus Group	25	1	1	25
LGBTQ+ individuals	Community Focus Group	25	1	1	25
Total	.....	.....	.....	.....	3,047

Jeffrey M. Zirger,

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

[FR Doc. 2023–12358 Filed 6–8–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Medical Health Assessment Form and Public Health Investigation Forms, Tuberculosis and Non-Tuberculosis Illness (Office of Management and Budget 0970–0509); Correction

AGENCY: Office of Refugee Resettlement, Administration for Children and Families, United States Department of Health and Human Services.

ACTION: Request for public comments; correction.

SUMMARY: The Administration for Children and Families (ACF) published a document in the **Federal Register** of June 1, 2023, concerning request for comments on a 3-year extension of the *Mental* Health Assessment Form (formerly the Health Assessment Form) and Public Health Investigation Forms, Active Tuberculosis (TB) and Non-TB Illness (Office of Management and Budget (OMB) #0970–0509, expiration December 31, 2023). The published notice contained an incorrect title and a typo in the *Description* section.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of June 1, 2023, in FR Doc. 2023–11627, the following corrections apply:

1. On page 35879, in the third column, the correct title is: Proposed Information Collection Activity; Mental Health Assessment Form and Public Health Investigation Forms, Tuberculosis and Non-Tuberculosis Illness (Office of Management and Budget 0970–0509).

2. On page 35880 in the third column, there is a typo in the second sentence. The sentence should read: In addition, ORR has written an instructional letter for the Mental Health Assessment Form to explain the purpose of the form and provide general guidance on completion to healthcare providers.

DATES: Comments due on the information collection proposed in 88 FR 35879 on or before July 31, 2023.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing *infocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–12334 Filed 6–8–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1848]

Clinical Drug Interaction Studies With Combined Oral Contraceptives; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Clinical Drug Interaction Studies With Combined Oral Contraceptives.'' This guidance is intended to help sponsors of investigational new drug applications and new drug applications evaluate the need for drug-drug interaction (DDI) studies with combined oral contraceptives (COCs), design such studies, and determine how to communicate DDI study results and risk mitigation strategies to address potential risks associated with increased or decreased exposure of COCs in labeling. The guidance finalizes the draft guidance ''Clinical Drug Interaction Studies With Combined Oral Contraceptives'' issued on November 23, 2020.

DATES: The announcement of the guidance is published in the **Federal Register** on June 9, 2023.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows: