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Director, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–13–13KZ]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call (404) 639–7570 or send an email to *omb@cdc.gov*. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Salt Sources Study—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Stroke and heart disease are directly related to high blood pressure, a condition that affects about 67 million Americans (31 percent of U.S. adults). Sodium intake directly and progressively increases blood pressure and subsequently increases the risk of heart disease and stroke. It has been estimated that an average reduction of as little as 400 mg of sodium daily, or about 11% of average U.S. sodium intake, would prevent more than 28,000 deaths and save 7 billion health care dollars annually. The U.S. Department of Health and Human Services (HHS) has designated reduction in sodium intake as one of CDC's Winnable Battles, as a component of the Million Hearts™ initiative, and as a Healthy People 2020 objective.

There is a critical need for current, accurate information about the sources of sodium intake among diverse groups of adults living in the United States. CDC plans to conduct a new Salt Sources Study to obtain information about the amount of sodium consumed from various sources (including sodium from processed and restaurant foods, sodium inherent in foods, and salt added at the table and during cooking) and to examine variability across population subgroups. Data collection will include an observational component as well as a sub-study designed to refine the accuracy of estimates of total sodium intake and discretionary sodium intake.

Information will be collected in three distinct geographic regions: (1) Minneapolis/St. Paul, Minnesota, (2) Birmingham, Alabama, and (3) Palo Alto, California. Over a two-year period, a study center in each location will recruit 150 participants (total N=450) with the aim of selecting an equal number of adults ages 18–74 years by approximately 10-year age groups in each sex-race group, including whites, blacks, Hispanics, and Asians. A sub-study will be conducted among a subgroup of 150 of these participants (50 per site). One study center will serve as a study coordinating center and will transmit de-identified information to CDC through a secure Web site. CDC is authorized to conduct this information collection under section 301 of the Public Health Service Act (42 U.S.C. 241).

For the observational study component, CDC estimates that each study site will enroll 75 participants per year. After completing a screening process, each participant will complete a personal questionnaire, a tap water questionnaire, four 24-hour dietary recalls, and four qualitative food records. In addition, height and weight information on each participant will be collected, and each participant will collect duplicate portions of their cooking/table salt. Fifteen participants at each site will also provide water samples that will be analyzed to produce estimates of the amount of sodium in private sources of tap water.

The Salt Sources Study will include a sub-study to help determine the accuracy of estimates of total sodium intake and discretionary salt intake. CDC will ask about 25 participants at each site to use a Study Salt for 11 days instead of their own household salt, provide additional information based on four 24-hour urine collections, four follow-up urine collection questionnaires, and three follow-up questionnaires on Study Salt use. The Study Salt contains a very small amount of lithium, a metal found in trace amounts in all plants and animals.

Results from the Salt Sources Study will be used to inform public health strategies to reduce sodium intake, determine if substantial variability in sources of sodium intake exists by socio-demographic subgroups, and better inform estimates of salt added at the table used in Healthy People 2020 objectives related to sodium reduction.

OMB approval is requested for two years. Participation in the Salt Sources Study is voluntary and there are no costs to participants other than their time. The total estimated annualized burden hours are 1,372.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hr)
Adults aged 18–74 years	Telephone Recruitment and Screening	225	1	10/60
	Participant Questionnaire	225	1	10/60
	Discretionary Salt Use Questions from NHANES 2009.	225	1	5/60
	Height and Weight	225	1	10/60
	Study Orientation and Scheduling	225	1	20/60
	Tap Water Questionnaire	225	1	5/60
	24-Hour Dietary Recall	225	4	30/60
	Food Record	225	4	15/60
	Duplicate Salt Sample Collection	225	4	10/60
	Water Collection Form and Instructions	15	1	5/60
	24-hour Urine Collection	75	4	50/60
	Follow-up Urine Collection Questionnaire	75	4	10/60

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hr)
	Study Salt Supplement Questionnaire	75	3	5/60

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Proposed Project

Spectrum of Flavoring Chemical-Related Lung Disease—New—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

This project involves a questionnaire, along with clinical testing, to investigate and characterize the nature of lung disease occurring in popcorn and flavoring workers. Since publication of the 60-day **Federal Register** Notice, the annual burden estimate has been revised. We added the inclusion of job and medication forms to be completed by the participant prior to the testing session. We also included the time needed to review the informed consent. The overall burden hours is now estimated to be 115 hours.

The purpose of this study is to investigate the spectrum of lung disease occurring in flavoring and microwave popcorn workers. A secondary aim is to study the natural history of lung disease. For this study, we plan on interviewing and conducting clinical testing on participants from a previously investigated flavoring plant and microwave popcorn plant.

For this study, we will recruit participants from two study populations: Approximately 112 workers from a flavorings plant for whom we have spirometry data and 132 workers that had abnormal spirometry on any test from a previous NIOSH health hazard evaluation at a microwave popcorn plant. Thirty additional workers from the microwave popcorn plant who had normal spirometry on their last test also will be chosen at random.

NIOSH anticipates that information collection will begin in the 2013 fiscal year for the microwave popcorn workers and for the flavorings workers in fiscal year 2014. Prior to the testing, participants will be mailed a copy of the informed consent to review and asked to complete a job history form and current medication form. This will take no more than 25 minutes (total) to review and complete. On the day of testing, a NIOSH staff member will review the consent form with the participant, which will take about 5 minutes. Participants will then be given a NIOSH-administered questionnaire which will take approximately 20 minutes to complete. All study results will be stored at NIOSH.

Participation in all components of the study is completely voluntary. There are no costs to the respondents other than their time. The total estimated annual burden hours are 115.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Popcorn workers	Informed consent	81	1	15/60
	Medication form	81	1	5/60
	Job history form	81	1	10/60
	Questionnaire	81	1	20/60
Flavoring workers	Informed consent	56	1	15/60
	Medication form	56	1	5/60
	Job history form	56	1	10/60
	Questionnaire	56	1	20/60