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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention

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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 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

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	No. of Respondents	No. 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

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