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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-13-13BF]

Proposed Data Collections Submitted for

Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-7570 and send comments to Ron Otten, at CDC 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an email to omb@cdc.gov.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d)

ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 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

The mission of the National Institute for Occupational Safety and Health (NIOSH) is to promote safety and health at work for all people through research and prevention. The Occupational Safety and Health Act, Public Law 91-596 (section 20[a] [1]), authorizes NIOSH to conduct research to advance the health and safety of workers. NIOSH is proposing to conduct a study characterizing the nature of restrictive lung disease occurring in flavoring and microwave popcorn workers.

Preliminary evidence suggests that flavorings exposures may be associated with restrictive lung disease in exposed workers. In two previous NIOSH health hazard evaluations, we found excesses of restrictive spirometry among workers in a flavoring

manufacturing plant and a flavoring-exposed food production plant. There was virtually no obstructive lung disease in either of these health hazard evaluations. Over the course of eight cross-sectional studies at a microwave popcorn plant, we also found strong relationships between decreases in FEV1 and cumulative exposure estimates, without differentiating between obstructive and restrictive abnormalities.

NIOSH requests OMB approval to collect additional information on a subset of participants from previous NIOSH studies to determine if restrictive lung disease is occurring among flavoring and popcorn workers. Diagnostic methods for restrictive lung disease will be applied in field settings. This will include spirometry, lung volume testing such as total lung capacity (TLC) and diffusing capacity of the lung to carbon monoxide (DLCO), as well as high resolution computed tomography (HRCT), which can detect lung abnormalities consistent with interstitial lung disease. These medical tests are critical to establishing lung disease of a fibrotic or inflammatory nature in persons with spirometric restriction.

Recent literature has demonstrated that bronchiolitis obliterans and obstructive lung disease are related to flavoring exposures in an exposure-dependent way. However, secondary prevention of

further impairment among flavoring workers with spirometric restriction and excessive declines in lung function of a restrictive nature is not occurring. Flavoring workers with restrictive abnormalities are not identified as having possible occupational lung disease, are not removed from further flavorings exposure, are not counseled about respiratory protection and work practices, and are unlikely to be successful in claims for work-related lung disease and medical expenses. These cases of restrictive spirometric abnormality do not motivate employers to implement controls to prevent lung injury to co-workers or to enhance medical surveillance programs.

Results from this study will benefit many stakeholders, including physicians who can appropriately manage workers with restrictive lung disease with consideration of enhanced respiratory protection or reassignment; workers who can make decisions regarding continued exposures and apply for compensation if warranted; companies who can set data driven priorities for preventive interventions; and policy makers who can recommend measures to prevent flavoring-related lung diseases.

For this study, we will recruit participants from two study populations: approximately 100 workers from a flavorings plant for whom we have spirometry data and 130 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 during the summer of 2013 for the microwave popcorn workers and for the flavorings workers in the summer of 2014. Both study populations will be offered a questionnaire, spirometry, TLC test, DLCO, and HRCT of the chest. Those with abnormal spirometry will also be offered a bronchodilator test. Testing is expected to take between 3 to 3.25 hours per respondent. All testing will be conducted by trained NIOSH personnel, except for the HRCT chest scan, which will be done at a local hospital or radiology clinic. Participants will receive a letter which will explain their testing results. All study results will be stored at NIOSH.

The total estimated burden for the one-time collection of data is 822 hours. This is an overestimate of the actual burden to account for any possible waiting at the radiology clinic. Participation in this study is voluntary, and there are no costs to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondents	Testing	No. of Respondents	No. of Responses per Respondent	Average burden per response (in hours)	Total burden hours
Popcorn workers with normal spirometry	Questionnaire Spirometry DLCO TLC HRCT	30	1	3	90
Popcorn workers with abnormal spirometry	Questionnaire Spirometry DLCO TLC HRCT Bronchodilator test	130	1	3.25	423
Flavoring workers with normal spirometry	Questionnaire Spirometry DLCO TLC HRCT	64	1	3	192
Flavoring workers with abnormal spirometry	Questionnaire Spirometry DLCO TLC HRCT Bronchodilator test	36	1	3.25	117
Total					822

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