

axis function, and increased risk of chronic disease.

This study will investigate the relationship between workplace stress and function of the HPA axis among a sample population of coal miners. Coal miners experience a number of work-related stresses, such as long hours of work, heavy workloads, shift work, and concerns about stability of employment. Miners will be asked to complete a 25-minute survey which asks about traditional job stressors including shift schedule and rotation, workload, and degree of control over work. The survey

also addresses stressors not typically examined in work stress surveys, including time spent in second jobs, commuting time to work, and responsibilities for care of children and the elderly.

Function of the HPA axis will be assessed by obtaining a series of cortisol samples from subjects right after they wake up in the morning. Recent studies have shown that the response of cortisol to awakening, measured in saliva, serves as a good marker of HPA axis function. Miners will be asked to obtain saliva samples at home, and send them to the

NIOSH Morgantown laboratory for analysis.

Analyses will examine the relationship between the cortisol response to awakening, an indicator of HPA axis function, and measures of workplace stress. Data collected in this study will help NIOSH determine if workplace stress results in HPA axis dysfunction, which has been linked to a number of chronic disease conditions. The estimated annualized burden is 167 hours.

Respondents	No. of respondents	No. responses per respondent	Average burden per respondent (in hrs.)
Coal Miners	400	1	25/60

Dated: August 10, 2004.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-04-0260]

Proposed Data Collections Submitted for Public Comment and Recommendations

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 the CDC Reports Clearance Officer at (404) 498-1210 or send an e-mail to *omb@cdc.gov*. Send written comments to CDC Desk Officer, Human Resources and Housing Branch, New Executive Office Building, Room 10235,

Washington, DC 20503 or by fax to (202) 395-6974. Written comments should be received within 30 days of this notice.

Proposed Project

Health Hazard Evaluations/Technical Assistance and Emerging Problems, OMB No. 0920-0260—Extension—National Institute for Occupational Safety and Health ("NIOSH"), Centers for Disease Control and Prevention ("CDC").

Background

In accordance with the mandates of the Occupational Safety and Health Act of 1970 and the Federal Mine Safety and Health Act of 1977, the National Institute for Occupational Safety and Health ("NIOSH") responds to requests for health hazard evaluations to identify chemical, biological, or physical hazards in workplaces throughout the United States.

To comprehensively evaluate hazards in response to a request for a health hazard evaluation, NIOSH frequently conducts an on-site evaluation. The main purpose of an on-site evaluation is to help employers and employees identify and eliminate occupational health hazards. The interview and questionnaires are specific to each

workplace and its suspected disease(s) and hazards. The questionnaires are composed of items that were developed from standard medical and epidemiologic techniques.

NIOSH distributes interim and final reports of health hazard evaluations (excluding personal identifiers) to requesters, employers, employee representatives, the Department of Labor, and as appropriate to the Occupational Safety and Health Administration or Mine Safety and Health Administration and other state and federal agencies.

NIOSH administers a followback program to assess the effectiveness of its health hazard evaluation program in reducing workplace hazards. This program entails the mailing of followback questionnaires to employer and employee representatives in the workplace and, in some instances, a followback on-site evaluation. Due to the large number of investigations conducted each year, as well as the diverse and unpredictable nature of these investigations and the need to respond quickly to requests for assistance, NIOSH requests consolidated clearance for data collection of its health hazard evaluations. The estimated annualized burden is 3,901 hours.

Respondents	No. of respondents	No. of responses/ respondent	Average burden/ response (in hrs)
A. Employees (interview)	4000	1	15/60
B. Employees (questionnaire)	4240	1	30/60
C. Followback for onsite evaluations:			
Year 1	1000	1	15/60
Year 1	1000	1	15/60
Year 2	1000	1	15/60

Respondents	No. of respondents	No. of responses/ respondent	Average burden/ response (in hrs)
D. Followback for evaluations without onsite evaluations:			
Year 1	75	1	10/60
Year 2	75	1	15/60

Dated: August 10, 2004.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 04-18677 Filed 8-13-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Notice of Public Consultation

AGENCY: Administration for Native Americans (ANA).

ACTION: Notice of Public Consultation.

SUMMARY: The Administration for Children and Families (ACF) will be holding a half-day Tribal Consultation Session on September 20, 2004 at the Rayburn House Office Building in Washington, DC.

DATES: September 20, 2004.

FOR FURTHER INFORMATION CONTACT: Kim Vigue, Administration for Native Americans, toll free at 1-877-922-9262 or www.masterkeyconsulting.com/acfconference.

SUBMISSION INFORMATION: Tribal leaders and representatives interested in submitting written testimony or topics to be discussed on the Consultation Session agenda should contact Kim Vigue toll free at 1-877-922-9262.

If you are proposing a topic to be addressed in the Consultation Session, please be sure to include a brief description of the topic area along with the name and contact information of a suggested presenter.

The public record will remain open for 60 days following the September 20, 2004 consultation. Written comment and testimony can be submitted until November 19, 2004.

SUPPLEMENTARY INFORMATION:

The Administration for Children and Families would like to invite Tribal leaders to participate in a formal consultation Session with ACF senior officials and program directors. The Consultation Session will take place Monday, September 20, 2004 from 8:30 a.m. to 12:30 p.m. in Rayburn House Office Building Room B-339.

The intent of this Consultation Session is to allow ACF officials to hear first hand from Tribal leaders and representatives of Tribal organizations and Native Americans non-profit organizations about the implementation of ACF programs in Native Americans communities. Of particular interest are the challenges that Tribes and Tribal organizations face in accessing ACF program funding and using program funding to support social and economic development activities in Native American communities. ACF offices such as the Administration for Native Americans, Office of Child Support Enforcement, Office of Community Services, Office of Family Assistance, Child Care Bureau, Children's Bureau, Head Start Bureau, and the Family and Youth Services Bureau will be represented.

Because of the limited time, ACF has collaborated with Master Key Consulting to plan and facilitate the session. Master Key Consulting will be responsible for coordinating the stakeholders who wish to participate in the Consultation Session and will work with a planning committee to develop a structured agenda, identifying key issues to be raised and spokespersons to present testimony on the issues.

Dated: August 6, 2004.

Quanah Crossland Stamps,

Commissioner, Administration for Native Americans.

[FR Doc. 04-18588 Filed 8-13-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0355]

Scientific Considerations Related to Developing Follow-On Protein Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop on scientific and technical considerations related to the

development of follow-on protein pharmaceutical products. The agency is planning to develop draft guidance on this topic during the coming year. The purpose of this workshop is to obtain input from interested persons on the topics outlined in this document related to developing and approving follow-on protein pharmaceutical products. The agency will consider presentations made at the workshop and comments submitted to the docket before and after the workshop when developing the draft guidance.

DATES: The public workshop will be held on Tuesday, September 14, 2004, from 8:30 a.m. to 5 p.m. and Wednesday, September 15, 2004 from 8 a.m. to 12 noon. Submit requests to make a presentation by September 7, 2004.

ADDRESSES: The public workshop will be held at the University of Maryland—Shady Grove Conference Center, 9630 Gudelsky Dr., Rockville, MD 20850.

Submit written comments on scientific topics related to follow-on protein products to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

To register to present: Marilyn Welschenbach, Center for Drug Evaluation and Research (HFD-121), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852, 301-443-5089, FAX: 301-443-5245, e-mail: Marilyn.Welschenbach@fda.gov.

With regard to the scientific topics outlined in this notice: Keith Webber, Center for Drug Evaluation and Research, Food and Drug Administration (HFD-121), 5600 Fishers Lane, Rockville, MD 20852, 301-443-5089, FAX: 301-443-5234, e-mail: Keith.Webber@fda.gov, or Chris Joneckis, Center for Biologics Evaluation and Research (HFM-1),