

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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BILLING CODE 4163-18-P

## 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](mailto: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]

**BILLING CODE 4163-18-P**

## 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](http://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]

**BILLING CODE 4184-01-M**

## 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](mailto: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](mailto:Keith.Webber@fda.gov), or Chris  
Joneckis, Center for Biologics  
Evaluation and Research (HFM-1),