

their blood. However, the microcystin concentrations in Lake 2 were below the LOD and in Lake 1 were actually 2ug/L to 5ug/L, much lower than we anticipated based on data from the previous week. Thus, the recreational exposures were not likely high enough for us to quantify microcystins in blood and the serum samples were all below the LOD for microcystins.

For the new data collection, we will recruit 100 study participants who are at risk for swallowing water or inhaling spray (*i.e.*, water skiers, jet skiers, people sailing small boats) and who

would normally be doing these activities, even in the presence of a bloom. We may recruit people who train for organized swimming events (*e.g.*, triathlons) in lakes. In addition, we will recruit 50 study participants from lakes with no blooms as a comparison group to assess the health effects associated with recreational activities on "clean" lakes. Study participants will be asked to sign a consent form, complete a symptom survey before and after doing their recreational water activities, provide one 10-ml whole blood sample after their recreational activities, and

complete a telephone symptom survey 8–10 days after doing study activities.

The purpose of the new data collection is to continue assessing the public health impact of exposure to the cyanobacterial toxins, microcystins, during recreational activities. We will examine the extent of human exposure to microcystins present in recreational waters and associated aerosols and whether serum levels of microcystins can be used as a biomarker of exposure.

There is no cost to the respondents other than their time.

#### ESTIMATE OF ANNUALIZED BURDEN HOURS

Forms	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Screening Questionnaire .....	188	1	10/60	31
Pre-exposure Questionnaire .....	150	1	10/60	25
Post-exposure Questionnaire .....	150	1	10/60	25
10-day post exposure Questionnaire .....	150	1	10/60	25
Total .....				106

Dated: February 6, 2007.

**Joan F. Karr,**

*Acting Reports Clearance Officer, 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

[60Day-07-0630]

#### 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 404-639-5960 and send comments to Joan Karr, CDC Acting Reports Clearance Officer, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an e-mail to [omb@cdc.gov](mailto: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

Work Organization Predictors of Depression in Women—Extension—The National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

#### Background and Brief Description

Depression is a costly and debilitating occupational health problem. Research has indicated that the costs to an organization of treatment for depression can rival those for heart disease, and both major depressive disorder and forms of minor depression have been found to be associated with more disability days than other types of health diagnoses. This may be of particular relevance for working women. Various national and international studies indicate that women in developed countries experience depression at up to twice the rate of men. Studies that have examined this gender difference have focused on

social, personality, and genetic explanations while few have explored factors in the workplace that may contribute to the gender differential. Examples of workplace factors that may contribute to depression among women include: Additive workplace and home responsibilities, lack of control and authority, and low paying and low status jobs. Additionally, women are much more likely to face various types of discrimination in the workplace than men, ranging from harassment to inequalities in hiring and promotional opportunities, and these types of stressors have been strongly linked with psychological distress and other negative health outcomes. On the positive side, organizations that are judged by their employees to value diversity and employee development engender lower levels of employee stress, and those that enforce policies against discrimination have more committed employees. Such organizational practices and policies may be beneficial for employee mental health, particularly the mental health of women.

*This research focuses on the following questions:* (1) Which work organization factors are most predictive of depression in women, and (2) are there measurable work organization factors that confer protection against depression in women employees?

The research uses repeated measures, prospective design with data collection at three points (baseline and 1-year and 2-year follow-ups). A 45-minute survey

is being administered by telephone to 400 women and men at 16 different organizations. The survey contains questions about traditional job stressors (e.g., changes in workload, social support, and work roles), stressors not traditionally examined, but which may be linked with depressive symptoms among women (e.g., roles and responsibilities outside of the

workplace, discrimination, and career issues) depression symptoms, and company policies, programs and practices. One Human Resource (HR) representative at each company has also been surveyed about company policies, programs and practices. Analyses will determine which work organization factors are linked with depressive symptoms and what effect the

organizational practices/policies of interest have on depression. Findings from this prospective study will also help target future intervention efforts to reduce occupationally related depression in women workers. An extension request is being sought for an additional three years, in order to finish data collection. There will be no cost to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	No. of respondents	No. of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Employees .....	400	3	45/60	900
HR Representatives .....	16	1	20/60	5
				905

Dated: February 5, 2007.  
**Joan F. Karr,**  
*Acting Reports Clearance Officer, Centers for Disease Control and Prevention.*  
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**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2007D-0027]

**Voluntary Self Inspection of Medicated Feed Manufacturing Facilities; Draft Compliance Policy Guide; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft compliance policy guide (CPG) entitled "Voluntary Self Inspection of Medicated Feed Manufacturing Facilities." This draft CPG is intended to provide guidance to the FDA field offices in prioritizing inspections of medicated feed manufacturing facilities for compliance with Current Good Manufacturing Practices for Medicated Feeds regulations (CGMP).

**DATES:** Submit written or electronic comments on this draft CPG by April 30, 2007 to ensure their adequate consideration in preparation of the final document. Submit written comments on the information collection requirements by April 13, 2007. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of this CPG to the Director,

Division of Compliance Policy (HFC-230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-827-0482. Submit written comments on this draft CPG to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Comments should be identified with the full title of the CPG and the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the document.

Submit written comments on the guidance to the Division of Dockets Management (address above). Comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** *For Technical Questions Concerning This CPG:* Paul Bachman, Center for Veterinary Medicine (HFV-230), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9225, e-mail: [Paul.Bachman@fda.hhs.gov](mailto:Paul.Bachman@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In this CPG, we are announcing a new proposed approach to assist in prioritizing inspections to determine an individual facility's compliance with the Federal Food, Drug, and Cosmetics Act (the act) and CGMP regulations published in part 225 (21 CFR part 225) relative to the manufacture and

distribution of medicated animal feed. The CPG describes a voluntary self inspection program whereby firms would conduct their own inspection on an annual basis and provide the results of the inspection to us. The proposed CPG states that in determining its inspectional priorities for CGMP inspections for medicated feed manufacturing establishments, FDA intends to consider, among other factors, whether the firm conducts this voluntary self inspection. We are calling this approach "Voluntary Self Inspection," but the idea has also been referred to as "first-party inspection."

In addition to seeking comments on this concept, we are considering piloting this new approach for at least 1 year once comments have been received and evaluated. A pilot would be announced in a separate **Federal Register** document.

**II. Significance of Guidance**

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance, when finalized, will represent the agency's current thinking on the topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative method may be used as long as it satisfies the requirements of applicable statutes and regulations.

**III. Paperwork Reduction Act of 1995**

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined