

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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**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

in 44 U.S.C. 3502(3) and 5 CFR 1320.3 and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506 (c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, we are publishing a notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of our functions, including whether the information will have practical utility; (2) the accuracy of our estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

*Title:* Voluntary Self Inspection of Medicated Animal Feed Manufacturing Facilities.

*Description:* FDA considers a number of factors in determining inspectional

priorities and resource allocation for inspections of medicated feed manufacturing establishments. The agency is proposing a new approach to assist in prioritizing inspections to determine an individual facility's compliance with the act, and CGMP regulations published in part 225 relative to the manufacture and distribution of medicated animal feeds. 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.

Under this CPG, firms that conduct Voluntary Self Inspection would: (1) Submit written notification to local FDA field office(s) of intent to conduct self inspections for compliance with CGMP; (2) submit written reports of self inspection within sixty (60) days to local FDA Field Offices; (3) report self inspection results through the use of FDA forms 3621 or 3622; and (4) submit written reports of self reinspection within ninety (90) days for facilities that have on going deficiencies which continue to occur.

We expect approximately 1,000 feed mills will conduct Voluntary Self

Inspections. Eight hundred of these are expected to be licensed facilities and two hundred to be non-licensed facilities. Completing and sending the notifications to us is estimated to take about 15 minutes or 250 hours for the 1,000 firms. We estimate the time to review any previous self inspections, conduct an inspection and complete the report is 9 hours for licensed facilities and 4 hours for non-licensed facilities. For the 1,000 firms, self inspection burden would be 8,000 hours (9 x 800 = 7,200 hours for licensed facilities; 4 x 200 = 800 hours for non-licensed facilities). Facilities with ongoing deficiencies would self-reinspect and report to us. We estimate that 5 percent or 50 of the facilities will fall into this category with approximately 40 licensed facilities (9 hours x 40 firms = 360 hours) and 10 non-licensed facilities (4 hours x 10 = 40) for a total of 400 hours. Lastly, we estimate that it will take each facility approximately 1 hour (1 hour x 800 facilities = 800 hours for licensed and 1 hour x 200 firms = 200 hours for non-licensed facilities) for a total of 1,000 hours to collect the inspection forms, various reports and submit to FDA. For the 1,000 firms, total annual burden is estimated as 9,650 hours.

*Description of Respondents:* Manufacturers of medicated animal feeds.

We estimate the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Information	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Written notification of intent to conduct self inspections to local FDA field office	1,000	1	1,000	.025	250
FDA Form no. 3621, Self inspection report for FDA licensed facilities	8,000	1	800	9	7,200
FDA Form no 3622; Self inspection report for non-FDA licensed facilities	200	1	200	4	800
Written report of self-reinspection within ninety (90) days for FDA licensed facilities that have ongoing deficiencies that continue to occur.	40	1	40	9	360
Written report of self-reinspection within ninety (90) days for non-FDA licensed facilities that have ongoing deficiencies that continue to occur.	10	1	10	4	40
Written report to local FDA field Office within sixty (60) days of self inspection-FDA licensed facilities	800	1	800	1	800

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>—Continued

Information	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Written report to local FDA field Office within sixty (60) days of self inspection for non-FDA licensed facilities	200	1	200	1	200
Total					9,650

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimates in table 1 of this document resulted from discussions with industry and our experience in conducting medicated feed facility inspections.

**IV. Comments**

This draft CPG is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this draft CPG. Submit written or electronic comments by (see **DATES**) to ensure adequate consideration in preparation of the final document. Written comments concerning the information collection requirements must be received by the Division of Dockets Management by (see **DATES**).

Two paper copies of any comments are to be submitted, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

**V. Electronic Access**

Electronic comments may be submitted on the Internet at <http://www.fda.gov/dockets/ecomments>. Once on this site, select [Docket No. 2007D-0027] “Voluntary Self Inspection of Medicated Feed Manufacturing Facilities; Draft Compliance Policy Guide” and follow the directions. Copies of the CPG may also be downloaded to a personal computer with access to the Internet. The Office of Regulatory Affairs home pages include this draft CPG and may be

accessed at <http://www.fda.gov/ora> under “Compliance References.”

Dated: January 29, 2007.  
**Margaret O’K. Glavin**,  
*Associate Commissioner for Regulatory Affairs.*  
 [FR Doc. E7-2232 Filed 2-9-07; 8:45 am]  
**BILLING CODE 4160-01-S**

**DEPARTMENT OF HOMELAND SECURITY**

**Federal Emergency Management Agency**

**Agency Information Collection Activities: Proposed Collection; Comment Request**

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice and request for comments.

**SUMMARY:** The Federal Emergency Management Agency (FEMA), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on a proposed reinstatement, with change, of a previously approved collection for which approval has expired. In accordance with the Paperwork Reduction Act of 1995, this notice seeks comments concerning enrollment for students and score assessments for FEMA’s Independent Study Program.

**SUPPLEMENTARY INFORMATION:** FEMA’s Emergency Management Institute (EMI) provides a wide variety of training to emergency management personnel throughout the country. The EMI Independent Study (IS) Program is part of the FEMA training program authorized under the Robert T. Stafford Disaster Relief and Emergency Act,

Public Law 93-288 as amended. These courses are offered online by the Emergency Management Institute (EMI). The IS Program provides valuable training to Federal, State, local and Tribal emergency management personnel and the general citizenry of the United States without having to attend a resident course at EMI, or at a State-sponsored course. The National Incident Management System (NIMS) is our nation’s incident management system. Homeland Security Presidential Directive 5, “Management of Domestic Incidents” requires the adoption of NIMS by all Federal departments and agencies. This directive also requires that Federal preparedness assistance funding for States, Territories, local jurisdictions and Tribal entities be dependent on NIMS compliance.

**Collection of Information**

*Title:* EMI Independent Study Course Enrollment and Test Answer Sheet.

*Type of Information Collection:* Reinstatement, with change, of a previously approved collection for which approval has expired.

*OMB Number:* 1660-0046.

*Form Numbers:* FEMA Form 95-23.

*Abstract:* The IS program office collect data from FEMA Form 95-23 to create and update student records and provide students with credit for training completion. The system also allows FEMA to track completions and failures of course exams. The data on the electronic form will be encrypted and sent to the server to be parsed into the Independent Study database. The paper version of the form will be scanned and parsed into the database or key entered into the database.

*Affected Public:* Individuals or Households, Federal Government, and State, Local or Tribal Government.

*Estimated Total Annual Burden Hours:*