DEPARTMENT OF HEALTH AND HUMAN SERVICES

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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 [*insert date 75 days after publication in the* **Federal Register**] to ensure their adequate consideration in preparation of the final document. Submit written comments on the information collection requirements by [*insert date 60 days after publication in the* **Federal Register**]. 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*.

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[1]

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	.25	250

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

Information	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
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
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

[1] 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: JAN 2 9 2007
January 29, 2007.

Margaret O'K. Glavin,
Associate Commissioner for Regulatory Affairs.

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