



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0601]

Agency Information Collection Activities; Proposed Collection; Comment Request; Current Good Manufacturing Practice Regulations for Medicated Feeds

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the recordkeeping requirements for manufacturers of medicated animal feeds.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF

PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2010-N-0601 for "Current Good Manufacturing Practice Regulations for Medicated Feeds." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469,

September 18, 2015, or access the information at:

<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), 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(c) 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, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing 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 FDA's functions, including whether the information will have practical utility;

(2) the accuracy of FDA's 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.

Current Good Manufacturing Practice Regulations for Medicated Feeds --21 CFR Part 225

OMB Control Number 0910-0152--Extension

Under section 501 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 351), FDA has the statutory authority to issue current good manufacturing practice (cGMP) regulations for drugs, including medicated feeds. Medicated feeds are administered to animals for the prevention, cure, mitigation, or treatment of disease, or growth promotion and feed efficiency. Statutory requirements for cGMPs have been codified under part 225 (21 CFR part 225). Medicated feeds that are not manufactured in accordance with these regulations are considered adulterated under section 501(a)(2)(B) of the FD&C Act. Under part 225, a manufacturer is required to establish, maintain, and retain records for a medicated feed, including records to document procedures required during the manufacturing process to assure that proper quality control is maintained. Such records would, for example, contain information concerning receipt and inventory of drug components, batch production, laboratory assay results (i.e., batch and stability testing), labels, and product distribution.

This information is needed so that FDA can monitor drug usage and possible misformulation of medicated feeds to investigate violative drug residues in products from treated animals and to investigate product defects when a drug is recalled. In addition, FDA will use the cGMP criteria in part 225 to determine whether or not the systems and procedures used by

manufacturers of medicated feeds are adequate to assure that their feeds meet the requirements of the FD&C Act as to safety, and also that they meet their claimed identity, strength, quality, and purity, as required by section 501(a)(2)(B) of the FD&C Act.

A license is required when the manufacturer of a medicated feed involves the use of a drug or drugs that FDA has determined requires more control because of the need for a withdrawal period before slaughter or because of carcinogenic concerns. Conversely, a license is not required, and the recordkeeping requirements are less demanding for those medicated feeds for which FDA has determined that the drugs used in their manufacture need less control. Respondents to this collection of information are commercial feed mills and mixer/feeders.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Recordkeeping Burden (Registered Licensed Commercial Feed Mills)¹

| 21 CFR Section | No. of Recordkeepers | No. of Records per Recordkeeper | Total Annual Records | Average Burden per Recordkeeping | Total Hours |
|--|----------------------|---------------------------------|----------------------|----------------------------------|--------------|
| 225.42(b)(5) through (8) requires records of receipt, storage, and inventory control of medicated feeds. | 825 | 260 | 214,500 | 1 | 214,500 |
| 225.58(c) and (d) requires records of the results of periodic assays for medicated feeds that are in accord with label specifications and also those medicated feeds not within documented permissible assay limits. | 825 | 45 | 37,125 | 0.50 (30 minutes) | 18,562.50 |
| 225.80(b)(2) requires that verified medicated feed label(s) be kept for 1 year. | 825 | 1,600 | 1,320,000 | 0.12 (7 minutes) | 158,400 |
| 225.102(b)(1) through (5), requires records of master record files and production records for medicated feeds. | 825 | 7,800 | 6,435,000 | 0.08 (5 minutes) | 514,800 |
| 225.110(b)(1) and (2) requires maintenance of distribution records for medicated feeds. | 825 | 7,800 | 6,435,000 | 0.02 (1 minute) | 128,700 |
| 225.115(b)(1) and (2) requires maintenance of complaint files by the medicated feed manufacturer. | 825 | 5 | 4,125 | 0.12 (7 minutes) | 495 |
| Total | | | | | 1,035,457.50 |

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

Table 2.--Estimated Annual Recordkeeping Burden (Registered Licensed Mixer/Feeders)¹

| 21 CFR Section | No. of Recordkeepers | No. of Records per Recordkeeper | Total Annual Records | Average Burden per Recordkeeping | Total Hours |
|--|----------------------|---------------------------------|----------------------|----------------------------------|-------------|
| 225.42(b)(5) through (8) requires records of receipt, storage, and inventory control of medicated feeds. | 100 | 260 | 26,000 | 0.15 (9 minutes) | 3,900 |
| 225.58(c) and (d) requires records of the results of periodic assays for medicated feeds that are in accord with label specifications and also those medicated feeds not within documented permissible assay limits. | 100 | 36 | 3,600 | 0.50 (30 minutes) | 1,800 |
| 225.80(b)(2) requires that verified medicated feed label(s) be kept for 1 year. | 100 | 48 | 4,800 | 0.12 (7 minutes) | 576 |
| 225.102(b)(1) through (5) requires records of master record files and production records for medicated feeds. | 100 | 260 | 26,000 | 0.40 (24 minutes) | 10,400 |
| Total | | | | | 16,676 |

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

Table 3.--Estimated Annual Recordkeeping Burden (Nonregistered Unlicensed Commercial Feed Mills)¹

| 21 CFR Section | No. of Recordkeepers | No. of Records per Recordkeeper | Total Annual Records | Average Burden per Recordkeeping | Total Hours |
|---|----------------------|---------------------------------|----------------------|----------------------------------|-------------|
| 225.142 requires procedures for identification, storage, and inventory control (receipt and use) of Type A medicated articles and Type B medicated feeds. | 4,186 | 4 | 16,744 | 1 | 16,744 |
| 225.158 requires records of investigation and corrective action when the results of laboratory assays of drug components indicate that the medicated feed is not in accord with the permissible assay limits. | 4,186 | 1 | 4,186 | 4 | 16,744 |

| | | | | | |
|---|-------|-----|-----------|-------------------|---------|
| 225.180 requires identification, storage, and inventory control of labeling in a manner that prevents label mix-ups and assures that correct labels are used for medicated feeds. | 4,186 | 96 | 401,856 | 0.12 (7 minutes) | 48,223 |
| 225.202 requires records of formulation, production, and distribution of medicated feeds. | 4,186 | 260 | 1,088,360 | 0.65 (39 minutes) | 707,434 |
| Total | | | | | 789,145 |

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

Table 4.--Estimated Annual Recordkeeping Burden (Nonregistered Unlicensed Mixer/Feeders)¹

| 21 CFR Section | No. of Recordkeepers | No. of Records per Recordkeeper | Total Annual Records | Average Burden per Recordkeeper | Total Hours |
|---|----------------------|---------------------------------|----------------------|---------------------------------|-------------|
| 225.142 requires procedures for identification, storage, and inventory control (receipt and use) of Type A medicated articles and Type B medicated feeds. | 3,400 | 4 | 13,600 | 1 | 13,600 |
| 225.158 requires records of investigation and corrective action when the results of laboratory assays of drug components indicate that the medicated feed is not in accord with the permissible assay limits. | 3,400 | 1 | 3,400 | 4 | 13,600 |
| 225.180 requires identification, storage, and inventory control of labeling in a manner that prevents label mix-ups and assures that correct labels are used for medicated feeds. | 3,400 | 32 | 108,800 | 0.12 (7 minutes) | 13,056 |
| 225.202 requires records of formulation, production, and distribution of medicated feeds. | 3,400 | 260 | 884,000 | 0.33 (20 minutes) | 291,720 |
| Total | | | | | 331,976 |

Our estimated burden for the information collection reflects a decrease of 65,265.20 hours. We attribute this adjustment to a decrease in the number of respondents for Registered Licensed Commercial Feed Mills. Medicated Feed Mill licensing is voluntary. Firms may

withdraw if they go out of business or if they change the source of the drug and a license is not required.

Dated: February 27, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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