4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-N-0496]

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 revision 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: Either electronic or written comments on the collection of information must be submitted 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. 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 received 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-2026-N-0496 for "Agency Information Collection Activities; Proposed Collection; Comment Request; 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, 240-402-7500.

- 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, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Kelly Covington, Office of Operations, Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740, 240-402-5661, 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 parts 225 & 226

OMB Control Number 0910-0152 and 0910-0154--Revision

This information collection supports implementation of section 501 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 351), which governs current good manufacturing practice (CGMP) for drugs, including medicated feeds and Type A medicated articles. Medicated feeds are administered to animals for the prevention, cure, mitigation, or treatment of disease or for growth promotion and feed efficiency. A Type A medicated article is

an animal feed product containing a concentrated drug diluted with a feed carrier substance. A Type A medicated article is intended solely for use in the manufacture of another Type A medicated article or a Type B or Type C medicated feed.

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.

Manufacturers are required to establish, maintain, and retain records for Type A medicated articles including records to document procedures required under the manufacturing process to assure that proper quality control is maintained under part 226. Type A medicated articles which are not manufactured in accordance with these regulations are considered adulterated under section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)).

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 the systems and procedures used by manufacturers of medicated feeds are adequate to ensure 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.

The information collection provisions approved under OMB control number 0910-0152 and 0910-0154 are similar in that they support FDA's CGMP regulations for medicated feeds. Thus, with this notice, FDA proposes to consolidate these collections of information into one OMB control number for all reporting associated with CGMPs for medicated feeds. FDA further proposes to consolidate all the regulations into a summary. FDA has combined the commercial feed mills and the mixer feeders, as the requirements for licensed medicated feedmills are the same for commercial feed mills and mixer feeders. FDA will continue to separate the licensed feed mills vs. the non-licensed feed mills, as the recordkeeping requirements for non-licensed feedmills require less burden than licensed feedmills. As with the licensed facilities, we will combine the commercial feedmills with the mixer/feeders as the requirements and burdens remain the same. The number of non-licensed feedmills were updated with our current inventory data utilizing production code for manufacturers of medicated feeds.

Because we are proposing to combine all reporting associated with CGMPs for medicated feeds into one collection, we are consolidating the burden under OMB control number 0910-0152 and discontinuing OMB control number 0910-0154.

Description of Respondents: Respondents to this collection of information are manufacturers of medicated feeds, commercial feed mills, and licensed mixer/feeders.

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

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

21 CFR Section, Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
225.42, 225.58, 225.80, 225.102, 225.110, and 225.115; Recordkeeping and maintenance of records for components used in the manufacture of the medicated feeds and premixes, laboratory controls, packaging and labeling, master formula and batch-production, distribution records and complaint files.	768	2919	2,241,792	.305 (18.3 minutes)	683,747

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

Table 2. – Estimated Annual Recordkeeping Burden (Nonregistered Non-licensed Commercial Feed Mills)

21 CFR Section, Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
225.142, 225.158, 225.180, and 225.202; Recordkeeping and maintenance of records for components used in the manufacture of the medicated feeds and premixes, laboratory controls, packaging and labeling, production and distribution records	1658	91	150,878	1.44	217,265

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

Table 3. – Estimated Annual Recordkeeping Burden (Nonregistered Non-licensed Mixer/Feeders)

21 CFR Section, Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
225.142, 225.158, 225.180, and 225.202; Recordkeeping and maintenance of records for components used in the manufacture of the medicated feeds and premixes, laboratory controls, packaging and labeling, production and distribution records	3,400	91	309,400	1.36	420,784

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

Table 4. – Estimated Annual Recordkeeping Burden (Manufacturers of Type A Medicated Feeds)

21 CFR Section, Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
226.42, 226.58, 226.80, 226.102, 226.110, and 226.115; Recordkeeping and maintenance of records for components used in the manufacture of the medicated premixes, laboratory controls, packaging and labeling, master formula and batch-production, distribution records and complaint files.	65	1,370	89,050	~ 1 hour	89,050

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

After review of the information collection, we have adjusted our estimated burden of the number of CGMP for medicated feeds recordkeepers by 2,722. The reduction accurately reflects the current number of firms that hold a medicated feed mill license and the number of firms that are listed in the FDA database as manufacturing with medicated feeds and meet the definition of a commercial feed manufacturing facility. With this update, we note a corresponding decrease of 13,731,017 records and a decrease of 913,153 hours.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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