DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–0496]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Current Good Manufacturing Practice Regulations for Type A Medicated Articles and Medicated Feeds

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by July 20, 2026.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control numbers for this information collection are 0910–0152 and 0910–0154. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Kelly Covington, Center for Veterinary Medicine, 5001 Campus Drive, College Park, MD 20740, 240–402–5661, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Current Good Manufacturing Practice Regulations for Type A Medicated Articles and Medicated Feeds

OMB Control Numbers 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 practices (CGMPs) for Type A medicated articles and CGMPs for drugs, including medicated feeds.

A Type A medicated article consists of one or more new animal drugs with or without carrier and with or without inactive ingredients. It is intended solely for use in the manufacturing of another Type A medicated article or in the manufacturing of a Type B or Type C medicated feed. See *21 CFR 558.3(b)(2).* Under part 226 (21 CFR part 226), 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 ensure that proper quality control is maintained. 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)).

Medicated feeds are administered to animals for the prevention, cure, mitigation, or treatment of disease or for growth promotion and feed efficiency. Under part 225 (21 CFR 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 mis formulation 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 medicated feed mill license is required when the manufacturing process 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 numbers 0910–0152 and 0910–0154 are similar in that they support FDA's current good manufacturing practices. Thus, with this notice, FDA proposes to consolidate these collections of information into one OMB control number for all reporting associated with CGMPs for Type A medicated articles and CGMPs for medicated feeds. FDA further proposes to consolidate each regulation into a summary. As part of this consolidation FDA has combined the commercial feed mills and the mixer/feeders into a single category, as the requirements for licensed medicated feed mills in 21 CFR part 225 are the same for both facility types. FDA will continue to distinguish between the licensed and the non-licensed feed mills, because non-licensed feed mills are subject to less burdensome recordkeeping requirements than licensed feed mills. As with the licensed facility category, non-licensed commercial feed mills and mixer/feeders have also been combined as the requirements and associated burdens remain the same. The number of non-licensed medicated feed mills have been updated with our current inventory data utilizing production codes to identify manufacturers of medicated feeds. FDA will also continue to maintain a distinct category for Type A medicated article manufacturers subject to the recordkeeping requirements under part 226.

Because we are proposing to combine all reporting associated with CGMPs for Type A medicated articles and 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.

In the **Federal Register** of February 25, 2026 (91 FR 9285), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received. While the comment did not address the collection of information topics solicited, it did point out an error in the definition of a Type A medicated article.

The commenter is correct, and we have updated the definition in this notice to align with the definition of a Type A medicated article in 21 CFR 558.3(b)(2).

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

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

manufacturers of Type A medicated articles.

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN

[Registered licensed commercial feed mills] [1]

21 CFR section, activity	Number of respondents	Number 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	2,919	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] [1]

21 CFR section, activity	Number of recordkeepers	Number 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	1,658	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] [1]

21 CFR section, activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	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 articles] [1]

21 CFR section, activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	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 the number of recordkeepers of CGMPs for medicated feeds 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.

[FR Doc. 2026–12237 Filed 6–17–26; 8:45 am]

BILLING CODE 4164–01–P