United States Food and Drug Administration

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

OMB Control Nos. 0910-0152 and 0910-0154 -- REVISION

SUPPORTING STATEMENT

Terms of Clearance: None.

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

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 consists of one or more new animal drugs with or without carrier and with or without inactive ingredients. 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 Title 21, Code of Federal Regulations, part 225, CGMP for Medicated Feeds requirements (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. 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 21 CFR part 226, CGMP for Type A Medicated Articles. 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)).

The above 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 21 CFR 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 number 0910-0152 and 0910-0154 are similar in that they support FDA's CGMP regulations. 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 are the same for both facility types. FDA will continue to distinguish between licensed fand 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 feed mills had been updated with our current inventory data utilizing production codes to identify manufacturers of medicated feeds. FDA will 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.

We therefore request OMB extension of OMB approval of the reporting associated with CGMPs for Type A medicated articles and CGMPs for medicated feeds found in 21 CFR part 225 and 21 CFR part 226 as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

The required records are used by both the respondents and the FDA. Records are used by manufacturers of medicated feeds and Type A medicated articles to verify that appropriate control measures have been maintained, or that appropriate corrective actions were taken if the control measures were not maintained. Such verification activities are essential to ensure that the CGMP system is working as planned. This permits us to determine whether the regulated products have been consistently processed in conformance with appropriate CGMP controls and monitor drug usage and possible misformulation of Type A medicated articles. We use the records required in 21 CFR part 225 and part 226 to determine whether the systems and procedures used by manufacturers of medicated feeds are adequate to ensure that their feeds and medicated articles meet the requirements of the FD&C Act as to safety, and that they meet their claimed identity, strength, quality, and purity, as required by section 501(a)(2)(B) of the FD&C Act. We would examine the records during a periodic inspection or during an investigation.

3. Use of Improved Information Technology and Burden Reduction

The regulation does not specifically prescribe the use of automated, electronic, mechanical, or other technological techniques or other forms of information technology as necessary for use by firms. Companies are free to use whatever forms of information technology may best assist them in retaining the appropriate records and making them available to regulatory officials. We estimate that about ninety percent (90%) of respondents will keep some of the required records electronically in the next 3 years.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

The recordkeeping is no more burdensome for small businesses than for large. The requirements are the minimum requirements for CGMPs. FDA aids small businesses in complying with our requirements through our Regional Small Business Representatives and through the scientific and administrative staffs within the agency. We have provided a Small Business Guide on our website at https://www.fda.gov/animal-veterinary/resources-you/cvm-small-business-assistance.

6. Consequences of Collecting the Information Less Frequently

Under a CGMP system, manufacturers and processors collect data periodically during manufacturing operations, however the frequency varies considerably across different manufacturers and medicated feed products and Type A medicated articles. Reducing the frequency of recordkeeping would reduce or nullify the effectiveness of the regulation in providing assurances - both to manufacturers and to FDA - that medicated feed and Type A medicated article meet standards for safety and meet the claimed identity, strength, quality, and purity requirements. FDA does not collect CGMP records as a routine matter. Rather, records are maintained on file at each facility and are reviewed by FDA during periodic inspections or during an investigation.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances associated with this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

FDA published a 60-day notice for public comment in the *Federal Register* of February 25, 2026 (91 FR 9285). 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 the 30 Day notice and this Supporting Statement to align with the definition of a Type A medicated article in 21 CFR 558.3(b)(2).

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

The Privacy Act of 1974 (5 U.S.C. 552a)

In preparing this Supporting Statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. This ICR collects personally identifiable information (PII) in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII submitted is name, address, email address, phone number, and fax number. Information collected

is maintained in a Privacy Act system of records as described in HHS/FDA System of Records Notice (SORN) 09-10-0002 for Regulated Industry Employee Enforcement Records. Through appropriate instruction, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

The Freedom of Information Act (FOIA)

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

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

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

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

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

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

12b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Records Clerk[1]	1,410,846	$31.37	$44,258,239.02

[1]May 2024 National Industry-Specific Occupational Employment and Wage Estimates, Bureau of Labor Statistics (43-4199) and including 30% for benefits (https://data.bls.gov/oes/#/industry/000000)

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information.

14. Annualized Cost to the Federal Government

Our review of the records at feed mills would generally occur as part of our inspection activities. We estimate that our review of the records would take 2 hours per inspection. We estimate the hourly cost for the review to be $55.62 per hour, based on the GS-12/Step-5 rate in the pay area of Washington-Baltimore-Arlington, DC-MD-VA-WV-PA for the year 2026. Thus, we estimate the cost to the Federal Government for the review of records to be $ $111.24 per review ($55.62 /hour x 2 hours). Assuming we review records for 200 inspections per year, we estimate that the total annual cost to the Federal Government would be $22,248 ($111.24 x 200 inspections).

Our review of the records at Type A medicated article manufacturers would generally occur as part of our inspection activities. We estimate that our review of the records would take 36 hours per inspection. We estimate the hourly cost for the review to be $55.62 per hour, based on the GS-12/Step-5 rate in the pay area of Washington-Baltimore-Arlington, DC-MD-VA-WV-PA for the year 2026. Thus, we estimate the cost to the Federal Government for the review of records to be $2,002.32 per review ($55.62 /hour x 36 hours). Assuming we review records for 21 inspections

per year, we estimate that the total annual cost to the Federal Government would be $42,048.72 ($2,002.32 x 21 inspections).

15. Explanation for Program Changes or Adjustments*

After review of the information collection, we have reduced 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.

16. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB expiration date will be displayed.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.