United States Food and Drug Administration

Current Good Manufacturing Practice Regulations for Medicated Feeds

OMB Control No. 0910-0152

SUPPORTING STATEMENT

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, Agency, us or we) regulations. 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 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. Respondents to this collection of information are commercial feed mills and mixer/feeders.

We therefore request OMB extension of OMB approval of 0910-0152 found in 21 CFR part 225; Current Good Manufacturing Practice Regulations for Medicated Feed 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. The records are used by manufacturers of medicated feeds 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. We review the records during the conduct of periodic plant inspections. This permits us to determine whether the medicated feed products have been consistently processed in conformance with appropriate CGMP controls. We use the records required 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. 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

By feed mill size, most respondents (to the USDA study referenced below) had feed mills that produced from 1,000 to 9,999 tons per year. Only 56 feed mills had production of over 100,000 tons per year, yet they produced 53 percent of the total.[1] Based on this, we estimate that 75 percent of the 8,563 medicated feed manufacturers (reported in tables 1 through 4), or 6,422 respondents, are small businesses, and we have kept their particular needs in mind during the development of these regulations. The recordkeeping is no more burdensome for small businesses than for large. The requirements are the minimum requirements for CGMPs. We aid 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/industry.

6. Consequences of Collecting the Information Less Frequently

Data collection occurs occasionally. Under a CGMP system, the frequency of data collection by each processor would occur periodically during medicated feed manufacturing operations, but that frequency of observation and recording would vary considerably for different manufacturers and different medicated feed products. Less frequent recordkeeping would reduce or nullify the effectiveness of the regulation to provide assurance to both the medicated feed manufacturer and FDA that the medicated feed meets standards for safety and meets the claimed identity, strength, quality, and purity standards. We do not collect CGMP records as a routine matter. Records remain on file at each medicated feed manufacturing facility. We would examine the records during a periodic inspection or during

[1] "Feed Mill Operations of Agricultural Cooperatives," U.S. Department of Agriculture Research Report #207, September 2005

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 March 4, 2020 (85 FR 12790). No comments were received.

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

In preparing this Supporting Statement, we consulted with our Privacy Office to ensure appropriate handling of information collected.

This information collection request (ICR) collects personally identifiable information (PII). PII is collected in the context of the individuals' professional capacity. The PII collected as part of inspections includes name, address, email address, phone number and fax number.

FDA further determined that although PII is collected the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, FDA does not use name or any other personal identifier to retrieve records from the information collected. FDA also minimized the PII to be collected to protect the privacy of the individuals.

Company records describing manufacturing procedures, which may be consulted during a facility inspection, and CGMP records that we may copy or take possession of often contain trade secret and confidential commercial information. Confidential commercial information is protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), by section 301(j) of the FD&C Act, and by part 20 of the regulations (21 CFR part 20).

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)[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 Non-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
225.142 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 Non-licensed 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

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

12b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Feed Mill Worker[1]	2,173,254.50	26.51	$57,612,976.80

[1]May 2019 National Industry-Specific Occupational Employment and Wage Estimates, Bureau of Labor Statistics and including 30% for benefits (https://www.bls.gov/OES/Current/oes434199.htm)

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 collection.

14. Annualized Cost to the Federal Government

Our review of the records would generally occur as part of our inspection activities. We estimate that our review of the records would take one hour per inspection. We estimate the hourly cost for the review to be $46.88 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 2020. Thus, we estimate the cost to the Federal Government for the review of records to be $46.88 per review ($46.88 /hour x 1 hour). Assuming we review records for 200 inspections per year, we estimate that the total annual cost to the Federal Government would be $9,376.00 ($46.88 x 200 inspections).

15. Explanation for Program Changes or Adjustments

This information collection reflects a change due to the Agency estimate. Specifically, the number of recordkeepers has decreased from 877 to 825. This results in a decrease in the number of annual responses of 95,691 with a corresponding decrease in hours of 65,266.

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.