FOOD AND DRUG ADMINISTRATION

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

OMB Control No. 0910-0152

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Under section 501 of the Federal Food, Drug, and Cosmetic Act (the 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.

We request extension of OMB approval of the information collection provisions in the following citations:

Registered Licensed Commercial Feed Mills

21 CFR 225.42(b)(5) through (b)(8) - Recordkeeping - Specifies recordkeeping requirements for procedures for the receipt, storage and inventory control of medicated feeds.

21 CFR 225.58(c) and (d) - Recordkeeping - Specifies recordkeeping requirements for 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.

21 CFR 225.80(b)(2) - Recordkeeping - Requirement that verified medicated feed label (s) be kept for one year.

21 CFR 225.102(b)(1) through (b)(5) - Recordkeeping - Specifies recordkeeping requirements for master record files and production records for medicated feeds.

21 CFR 225.110(b)(1) and (b)(2) - Recordkeeping - Specifies recordkeeping requirements for maintenance of distribution records for medicated feeds.

21 CFR 225.115(b)(1) and (b)(2) - Recordkeeping - Specifies recordkeeping requirements for maintenance of complaint files by the medicated feed manufacturer.

Registered Licensed Mixer-Feeders

21 CFR 225.42(b)(5) through (b)(8) - Recordkeeping - Specifies recordkeeping requirements for procedures for receipt, storage and inventory control of medicated feeds.

21 CFR 225.58(c) and (d) - Recordkeeping - Specifies recordkeeping requirements for the results of periodic assays of medicated feeds that are in accord with label specifications and also those medicated feeds not within documented permissible assay limits.

21 CFR 225.80(b)(2) - Recordkeeping - Requirement that verified medicated feed label(s) be kept for one year.

21 CFR 225.102(b)(1) through (b)(5) - Recordkeeping - Specifies recordkeeping requirements for master record files and production records for medicated feeds...

Nonregistered Unlicensed Commercial Feed Mills

21 CFR 225.142 - Recordkeeping - Specifies recordkeeping requirements for adequate recordkeeping procedures for identification, storage and inventory control (receipt and use) of Type A medicated articles and Type B medicated feeds.

21 CFR 225.158 - Recordkeeping - Specifies recordkeeping requirements for 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.

21 CFR 225.180 - Recordkeeping - Specifies recordkeeping requirements for 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.

21 CFR 225.202 - Recordkeeping - Specifies recordkeeping requirements for formulation, production, and distribution of medicated feeds.

Nonregistered Unlicensed Mixer-Feeders

21 CFR 225.142 - Recordkeeping - Specifies recordkeeping requirements for adequate recordkeeping procedures for identification, storage and inventory control (receipt and use), of Type A medicated articles and Type B medicated feeds.

21 CFR 225.158 - Recordkeeping - Specifies recordkeeping requirements when the results of laboratory assays of drug components indicate that the medicated feed is not in accord with the permissible assay limits.

21 CFR 225.180 - Recordkeeping - Specifies recordkeeping requirements for identification, storage and inventory control of labeling in a manner that prevent label mix-ups and assures that correct labels are used for medicated feeds.

21 CFR 225.202 - Recordkeeping - Specifies recordkeeping requirements for formulation, production, and distribution of medicated feeds.

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 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. We also review the records during the conduct of follow-up investigations of drug residues in edible products of treated animals.

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 three years.

4. Efforts to Identify Duplication and Use of Similar Information

There is no duplication of effort in this area. Each manufacturer is responsible for the labeling and recordkeeping for the products they manufacture. There are no similar records that could substitute for those required by these regulations. In addition, no duplication of Federal regulations concerning medicated feed manufacturing is likely because of the clear Congressional authorization in section 501(a)(2)(B) of the FD&C Act that FDA promulgate regulations for drugs, including medicated feeds, as opposed to the U.S. Department of Agriculture.

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% 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 http://www.fda.gov/oc/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 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.

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

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

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the Federal Register of October 17, 2016 (81 FR 71508). FDA received one letter in response to the notice, which contained multiple comments. One comment was generally supportive of the recordkeeping provisions of part 225. Another comment suggested that we should collect data from manufacturers of medicated feed, and described several benefits of having this information. Our regulations in part 225 require recordkeeping to document procedures required during the manufacturing process to assure that proper quality control is maintained. The regulations do not require manufacturers to submit this information to us on a routine basis but, rather, to make the information available to us upon inspection. To the extent that the comments recommend changes to our cGMP regulations for medicated feed, which can only be accomplished by rulemaking, the comments were outside the scope of the four collection of information topics on which the notice requested comments and will not be discussed in this document.

9. Explanation of Any Payment or Gift to Respondents

This information collection does not provide for payment or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

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

This information collection does not involve questions that are of a personally sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

FDA estimates the burden of this collection 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 Recordkeeper	Total Hours
225.42(b)(5) through (b)(8), requires records of receipt, storage and inventory control of medicated feeds.	877	260	228,020	1	228,020
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.	877	45	39,465	.50	19,732.50
225.80(b)(2), requires that verified medicated feed label(s) be kept for one year.	877	1,600	1,403,200	.12	168,384
225.102(b)(1) through (b)(5), requires records of master record files and production records for medicated feeds.	877	7,800	6,840,600	.08	547,248
225.110(b)(1) and (b)(2), requires maintenance of distribution records for medicated feeds.	877	7,800	6,840,600	.02	136,812
225.115(b)(1) and (b)(2), requires maintenance of complaint files by the medicated feed manufacturer.	877	5	4,385	.12	526.20
Total					1,100,722.70

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 Recordkeeper	Total Hours
225.42(b)(5) through (b)(8), requires records of receipt, storage and inventory control of medicated feeds.	100	260	26,000	.15	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	.50	1,800
225.80(b)(2), requires that verified medicated feed label(s) be kept for one year.	100	48	4,800	.12	576
225.102(b)(1) through (b)(5), requires records of master record files and production records for medicated feeds.	100	260	26,000	.40	10,400
Total					16,676

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 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.	4,186	4	16,744	1	16,744

21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeper	Total Hours
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	.12	48,223
225.202, requires records of formulation, production, and distribution of medicated feeds.	4,186	260	1,088,360	.65	707,434
Total					789,145

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

21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeper	Total Hours
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	.12	13,056
225.202, requires records of formulation, production, and distribution of medicated feeds.	3,400	260	884,000	.33	291,720
Total					331,976

We based our estimate of time required for record preparation and maintenance on our communications with industry. We derived additional information needed to calculate the total burden hours (i.e., number of recordkeepers, number of medicated feeds being manufactured, etc.) from our records and experience.

12b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Feed Mill Worker	2,159,321	$15.41[2]	$33,275,136.61

[2]Bureau of Labor Statistics, National Industry-Specific Occupation Employment and Wage Estimates for Records Clerks, May 2015

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/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 $34.06 per hour, the GS-12/Step-5 rate for the year 2017. Thus, we estimate the cost to the Federal Government for the review of records to be $34.06 per review ($34.06 /hour x 1 hour). Assuming we review records for 680 inspections per year, we estimate that the total annual cost to the Federal Government would be $23,160.80 ($34.06 x 680 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 increased from 840 to 877. This results in an increase in the number of annual responses of 68,088, with a corresponding increase in hours of 79,199.

16. Plans for Tabulation and Publication and Project Time Schedule

There is no intent on the part of the Federal Government to publish this data, nor is any general statistical analysis by the Federal Government anticipated.

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.