4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0601]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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) 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: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0152. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, 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 Medicated Feeds--21 CFR Part 225

OMB Control Number 0910-0152--Extension

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. Respondents to this collection of information are commercial feed mills and mixer-feeders.

In the Federal Register of October 17, 2016 (81 FR 71508), FDA published a 60-day notice requesting public comment on the proposed collection of information. 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.

FDA estimates the burden of this collection of information 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 Recordkeeping	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

21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
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 (30 minutes)	19,732.5
225.80(b)(2), requires that verified medicated feed label(s) be kept for 1 year	877	1,600	1,403,200	.12 (7 minutes)	168,384
225.102(b)(1), requires records of Master Record Files and production records for medicated feeds	877	7,800	6,840,600	.08 (5 minutes)	547,248
225.110(b)(1) and (b)(2), requires maintenance of distribution records for medicated feeds	877	7,800	6,840,600	.02 (1 minute)	136,812
225.115(b)(1) and (b)(2), requires maintenance of complaint files by the medicated feed manufacturer	877	5	4,385	.12 (7 minutes)	526.2
Total					1,100,722.7

[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 (b)(8), requires records of receipt, storage, and inventory control of medicated feeds	100	260	26,000	.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	.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	.12 (7 minutes)	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 (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 Unlicensed 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	.12 (7 minutes)	48,223
225.202, requires records of formulation, production, and distribution of medicated feeds	4,186	260	1,088,360	.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 Unlicensed Mixer-Feeders)[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	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	.12 (7 minutes)	13,056
225.202, requires records of formulation, production, and distribution of medicated feeds	3,400	260	884,000	.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.

We based our estimate of the 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. The burden has not changed since the last OMB approval.

Dated: July 12, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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