4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2004-N-0193]

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: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, 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 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 April 7, 2014 (79 FR 19091), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received, it was not responsive to the four elements solicited in the notice and therefore will not be discussed in this document.

FDA estimates the burden for 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 Recordkeeper	Total Hours
225.42(b)(5) through (b)(8)	840	260	218,400	1	218,400
225.58(c) and (d)	840	45	37,800	0.50 (30 minutes)	18,900
225.80(b)(2)	840	1,600	1,344,000	0.12 (7 minutes)	161,280
225.102(b)(1)	840	7,800	6,552,000	0.08 (5 minutes)	524,160
225.110(b)(1) and (b)(2)	840	7,800	6,552,000	.015 (1 minute)	98,280
225.115(b)(1) and (b)(2)	840	5	4,200	0.12 (7 minutes)	504
Total					1,021,524

[1]There are no capital 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 Recordkeeper	Total Hours
225.42(b)(5) through (b)(8)	100	260	26,000	0.15 (9 minutes)	3,900
225.58(c) and (d)	100	36	3,600	0.50 (30 minutes)	1,800
225.80(b)(2)	100	48	4,800	0.12 (7 minutes)	576
225.102(b)(1) through (b)(5)	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 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	4,186	4	16,744	1	16,744
225.158	4,186	1	4,186	4	16,744
225.180	4,186	96	401,856	0.12 (7 minutes)	48,223
225.202	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 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	3,400	4	13,600	1	13,600
225.158	3,400	1	3,400	4	13,600
225.180	3,400	32	108,800	0.12 (7 minutes)	13,056
225.202	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.

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

Dated: June 17, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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