4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0511]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medicated Feed Mill License Application

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 0910-0337. 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.

Medicated Feed Mill License Application--21 CFR Part 515--

OMB Control Number 0910-0337--Revision

Feed manufacturers that seek to manufacture feed using Category II, Type A medicated articles or manufacture certain liquid and free-choice feed, using Category I, Type A medicated articles that must follow proprietary formulas or specifications are required to obtain a facility license under section 512 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360b). Our regulations in part 515 (21 CFR part 515) establish the procedures associated with applying for a facility license. We require that a manufacturer seeking a facility license submit a completed medicated feed mill license application using Form FDA 3448 (21 CFR 515.10(b)). We use the information submitted to establish that the applicant has made the certifications required by section 512 of the FD&C Act, to register the mill, and to schedule a pre-approval inspection. We have made minor editorial revisions to Form FDA 3448, including the addition of a dedicated field for the submitter's email address in the contact information section. We estimate that the revisions will not change the amount of time necessary to complete the form.

We require the submission of a supplemental medicated feed mill license application for a change in facility ownership or a change in facility address (§ 515.11(b)). If a licensed facility is no longer manufacturing medicated animal feed under § 515.23, a manufacturer may request voluntary revocation of a medicated feed mill license. An applicant also has the right to file a request for hearing under § 515.30(c) to give reasons why a medicated feed mill license should not be refused or revoked.

In the **Federal Register** of March 9, 2016 (81 FR 12509), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment, which was not responsive to the comment request.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

21 CFR Section and Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Avg. Burden per Response	Total Hours
Medicated Feed Mill License Application using Form FDA 3448 (515.10(b))	20	1	20	0.25 (15 minutes)	5
Supplemental Feed Mill License Application using Form FDA 3448 (515.11(b))	40	1	40	0.25 (15 minutes)	10
Voluntary Revocation of Medicated Feed Mill License (515.23)	40	1	40	0.25 (15 minutes)	10
Filing a Request for a Hearing on Medicated Feed Mill License (515.30(c))	1	1	1	4	4
Total					29

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

Table 2.--Estimated Annual Recordkeeping Burden[1]

21 CFR Section and Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Avg. Burden per Recordkeeping	Total Hours
Maintenance of Records for Approved Labeling for Each "Type B" and "Type C" Feed (510.305)	890	1	890	0.03 (2 minutes)	27

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

These estimates are based on our experience with medicated feed mill license applications. We estimate that we will receive 20 medicated feed mill license applications, 40 supplemental applications, 40 requests for voluntary revocation, and that these submissions will take approximately 15 minutes per response, as shown in table 1, rows 1 through 3. We estimate that preparing a request for a hearing under § 515.30(c) takes approximately 4 hours, as shown in table 1, row 4. In table 2, we estimate that 890 licensees will keep the records required by 21 CFR 510.305 expending a total of 27 hours annually.

Dated: June 6, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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