



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-4428]

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 or we) 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: Submit written comments (including recommendations) 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 submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review - Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910-0337. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 240-994-7399, 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

Feed manufacturers that seek to manufacture a Type B or Type C medicated 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 (FD&C Act) (21 U.S.C. 360b). Our regulations in 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 preapproval inspection.

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) (21 CFR 515.11(b))). If a licensed facility is no longer manufacturing medicated animal feed under § 515.23 (21 CFR 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) (21 CFR 515.30(c)) to give reasons why a medicated feed mill license should not be refused or revoked.

Under § 510.305 (21 CFR 510.305) we require each applicant to maintain in a single accessible location: (a) a copy of the approved medicated feed mill license (Form FDA 3448) on the premises of the manufacturing establishment; and (b) approved or index listed labeling for each Type B and/or Type C feed being manufactured on the premises of the manufacturing establishment or the facility where the feed labels are generated.

In the *Federal Register* of January 28, 2022 (87 FR 4620), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although two comments were received, the comments were not responsive to the four collection of information topics solicited.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

21 CFR Section and Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Medicated Feed Mill License Application using Form FDA 3448 (§ 515.10(b))	5	1	5	0.25 (15 minutes)	1.25
Supplemental Feed Mill License Application using Form FDA 3448 (§ 515.11(b))	14	1	14	0.25 (15 minutes)	3.5
Voluntary Revocation of Medicated Feed Mill License (§ 515.23)	15	1	15	0.25 (15 minutes)	3.75
Filing a Request for a Hearing on Medicated Feed Mill License (§ 515.30(c))	1	1	1	4	4
Total					12.5

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

Table 2.--Estimated Annual Recordkeeping Burden¹

21 CFR Section and Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Maintenance of Records for Approved Labeling for Each “Type B” and “Type C” Feed (§ 510.305)	795	1	795	0.03 (2 minutes)	24

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

Our estimated burden for the information collection reflects an overall decrease of 17 hours and a corresponding decrease of 105 responses/records. We attribute this adjustment to a decrease in the number of submissions we received over the last few years.

Dated: April 27, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.