United States Food and Drug Administration

Medicated Feed Mill License Application--21 CFR Part 515

OMB Control No. 0910-0337

SUPPORTING STATEMENT

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, us or we) medicated animal feed mill license regulations. 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 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 preapproval inspection. Form FDA 3448 may be accessed on our website at: https://www.fda.gov/media/70099/download.

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.

We therefore request extension of OMB approval for the information collection provisions of medicated feed mill license reporting found in 21 CFR Part 515; recordkeeping found in 21 CFR Part 510; Form FDA 3448; and discussed in this supporting statement.

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2. Purpose and Use of the Information Collection

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. *Description of Respondents*: Respondents are manufacturers of medicated animal feed. Respondents include individuals; the private sector (for-profit businesses); and State, Local or Tribal governments.

3. Use of Improved Information Technology and Burden Reduction

Form FDA 3448 is available in a "fillable" form on our website but must be printed and submitted with an original signature. As a result, no license applications will be submitted electronically in the next three years. We are exploring various electronic submission methods for Form FDA 3448.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

The reporting requirements are those mandated by section 512(m) of the FD&C Act and there is no statutory exception for small businesses. The same information is requested from large and small firms and is the minimal amount needed. Assuming that about half the respondents are small businesses, we estimate that 18 of the 35 respondents reported in table 1 are small businesses. FDA aids small businesses in complying with its requirements through the Agency's Regional Small Business Representatives and through the scientific and administrative staffs within the Agency. FDA also provides a Small Business Guide on the Agency's website at http://www.fda.gov/ForIndustry/SmallBusinessAssistance/default.htm.

6. Consequences of Collecting the Information Less Frequently

Data collection occurs occasionally. Medicated feed manufacturing facilities will not be allowed to enter the market if the information is not submitted. Applications are submitted only once and therefore cannot be collected less frequently.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this information collection.

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

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

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

In preparing this Supporting Statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected.

This ICR collects personally identifiable information (PII). PII is collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII submitted via Form FDA 3448 (Medicated Feed Mill License Application) is name, address, telephone number, fax number, and email address. FDA determined that although PII is collected it is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, the contractor or FDA do not use name or any other personal identifier to routinely retrieve records from the information collected.

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

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

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

[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	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

[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 5 medicated feed mill license applications, 14 supplemental applications, 15 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. The total reporting burden is estimated to be 12.5 hours. In table 2, we estimate that 795 licensees will keep the records required by § 510.305 expending a total of 24 hours annually. We estimate the total annual burden for reporting and recordkeeping to be 36.5 hours.

12b. Annualized Cost Burden Estimate

We estimate that the average hourly wage for respondents is equivalent to a GS-7-4 level in the locality pay area of Washington-Baltimore-Arlington, DC-MD-VA-WV-PA in 2022, approximately $26.69/hour. Increasing this wage by 30% to account for overhead costs ($8.00), we estimate the average hourly cost to respondents to be $34.69/hour. Thus, we estimate the

overall cost burden incurred by the respondents to be $1,266.18 (36.5 burden hours x $34.69/hour = $1,266.18).

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or Capital Costs

There are no capital, start-up, operating, or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

We estimate the annualized cost to the Federal government for the review and evaluation of approximately 35 original applications, supplemental applications and voluntary revocations, as well as one hearing request, to be $1,162.08. We estimate that we expend approximately 40 minutes to process each of the 35 submissions, for a total of 23.34 hours, rounded to 23 hours. In addition, we estimate that we expend approximately 4 hours to review and evaluate one hearing request, for a total of 27 hours. We estimate the average hourly wage for personnel to review and evaluate these submissions to be at the GS-12-1 level in the locality pay area of Washington-Baltimore-Arlington, DC-MD-VA-WV-PA in 2022, approximately $43.04/hour. Thus, the estimated annualized cost to the Federal government is $1,162.08 (27 hours x $43.04/hour = $1,162.08).

15. Explanation for Program Changes or Adjustments

Our estimated burden for the information collection reflects an overall decrease of 17.5 hours and a corresponding decrease of 105 responses/records. We attribute this adjustment to a net decrease in the number of submissions we received over the last few years.

16. Plans for Tabulation and Publication and Project Time Schedule

We have no plans to tabulate and publish information from this information collection. However, we maintain a listing of approved medicated feed mill licenses on our website.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA will display the OMB expiration date as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.