U.S. Food and Drug Administration
Medicated Feed Mill License Application

OMB Control Number 0910-0337

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

   This information collection supports implementation of the Food and Drug Administration's (FDA, us or we) medicated feed mill license regulations. 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 (§ 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 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.

   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.
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 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 the web 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

   FDA is the only Federal agency that collects this information as a result of the mandatory reporting requirements in section 512(m) of the FD&C Act. Each medicated feed manufacturing facility is required to submit an application to obtain a license. The information provided in an application is site specific; there is no duplication of effort.

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 15 of the 29 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/oc/industry/.

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 associated with this collection of information.

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

   In accordance with 5 CFR 1320.8(d), we published a 60-day notice for public comment in the *Federal Register* of December 26, 2018 (83 FR 66280). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

   We do not provide any payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

    This information collection request (ICR) is collecting personally identifiable information (PII). PII is collected in the context of the individuals' professional capacity. The PII submitted for Form FDA 3448 (Medicated Feed Mill License Application) is name, address, telephone number, fax number, and email address. This ICR involves the submission to FDA of medicated feed mill license applications. The FD&C Act and

FDA's regulations specify the information that must be submitted to FDA in a medicated feed mill license application.

FDA further determined that although PII is collected the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, FDA does not use name or any other personal identifier to routinely retrieve records from the information collected. FDA also minimized the PII to be collected to protect the privacy of the individuals.

In preparing this Supporting Statement, FDA staff consulted with the FDA Privacy Office to ensure appropriate handling of information collected.

All files are maintained in a secured area. Confidentiality of the information submitted under these reporting requirements is protected under 21 CFR part 20. Only information that is releasable under the agency's regulations in 21 CFR part 20 would be released to the public. This information is also safeguarded by section 301(j) of the FD&C Act and would be protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)).

11. Justification for Sensitive Questions

This information collection does not involve any questions of a personally sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

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	Average Burden per Response	Total Hours
Medicated Feed Mill License Application using Form FDA 3448 (515.10(b))	14	1	14	0.25 (15 minutes)	4
Supplemental Feed Mill License Application using Form FDA 3448 (515.11(b))	54	1	54	0.25 (15 minutes)	14
Voluntary Revocation of Medicated Feed Mill License (515.23)	29	1	29	0.25 (15 minutes)	7
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	Average Burden per Recordkeeping	Total Hours
Maintenance of Records for Approved Labeling for Each "Type B" and "Type C" Feed (510.305)	837	1	837	0.03 (2 minutes)	25

[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 14 medicated feed mill license applications, 54 supplemental applications, 29 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 29 hours. In table 2, we estimate that 837 licensees will keep the records required by § 510.305 expending a total of 25 hours annually. We estimate the total annual burden for reporting and recordkeeping to be 54 hours.

21 CFR 515.10(b) -- Reporting
Specifies requirements for submitting a completed medicated feed mill license application.

21 CFR 515.11(b) -- Reporting
Specifies requirements for submitting supplemental medicated feed mill license applications for a change in ownership and/or a change in address for the facility.

21 CFR 515.23 -- Reporting
Sets forth written requirements for voluntary revocation of a medicated feed mill license by the sponsor of that facility on the grounds that the facility is no longer manufacturing medicated animal feed.

21 CFR 515.30(c) – Reporting
Details requirements for filing a request for a hearing by a sponsor to give reasons why a medicated feed mill license should not be refused or revoked.

21 CFR 510.305(a) and (b) -- Recordkeeping
Requires an applicant to maintain a copy of the approved license and the 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.

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 2019, approximately $24.23/hour. Increasing this wage by 30% to account for overhead costs ($7.27), we estimate the average hourly cost to respondents to be $31.50/hour. Thus, we estimate the overall cost burden incurred by the respondents to be $1,701.00 (54 burden hours x $31.50/hour = $1,701.00).

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/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 98 original applications, supplemental applications and voluntary revocations, as well as one hearing request, to be $3,205.74. We estimate that we expend approximately 40 minutes to process each of the 98 submissions, for a total of 65.33 hours, rounded to 65 hours. In addition, we estimate that we expend approximately 4 hours to review and evaluate one hearing request, for a total of 69 hours. We estimate the average hourly wage for personnel to review and evaluate these submissions to be at the GS-13-1 level in the locality pay area of Washington-Baltimore-Arlington, DC-MD-VA-WV-PA in 2019, approximately $46.46/hour. Thus, the estimated annualized cost to the Federal government is $3,205.74 (69 hours x $46.46/hr = $3,205.74).

15. Explanation for Program Changes or Adjustments

    Our estimated burden for the information collection reflects an overall decrease of 2 hours and a corresponding decrease of 56 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.