United States Food and Drug Administration

Medicated Feed Mill License Application

OMB Control No. 0910-0337 -- EXTENSION

SUPPORTING STATEMENT

Terms of Clearance: None.

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection helps support implementation of statutory and regulatory provisions related to medicated animal feed mill licensing. 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 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))), or a change in facility name. 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.

2. Purpose and Use of the Information Collection

We use the information submitted to establish that the applicant has completed the certifications required by section 512 of the FD&C Act, to register the mill as a drug establishment, and allow CVM to schedule a preapproval inspection. Medicated feed manufacturing facilities will not be allowed to enter the market if the information is not submitted. 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 and may be accessed on our website at: https://www.fda.gov/about-fda/reports-manuals-forms/forms

Through technical amendment (89 FR 51966), 21 CFR 515 was revised to allow for electronic submission of Form FDA 3448. We have added a dedicated email address (MedicatedFeedsTeamMail@fda.hhs.gov) to facilitate electronic submission of applications consistent with our regulations in 21 CFR part 11 (Electronic Records; Electronic Signatures). We estimate 80% of submissions will be electronic. Information collection associated with electronic records is currently approved under OMB control number 0910-0303.

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 23 of the 34 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

The information collection schedule is consistent with statutory and regulatory authorities.

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 November 29, 2024 (89 FR 94740). No comments were received.

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

Data will be kept private to the extent provided by law. In preparing this Supporting Statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected.

The Privacy Act of 1974

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.

The Freedom of Information Act

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

21 CFR Section; Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
515.10(b), 515.11(b); Medicated Feed Mill License Application and Supplemental Applications using Form FDA 3448	34	1	34	0.25 (15 minutes)	8.5
515.23; Voluntary Revocation of Medicated Feed Mill License	14	1	14	0.25 (15 minutes)	3.5
515.30; Filing a Request for a Hearing on Medicated Feed Mill License	1	1	1	4	4
Total			49		16

We estimate that respondents will spend 15 minutes to assemble the necessary information, prepare, and submit an application for a feed mill license or revocation of a feed mill license. We estimate that respondents will spend 4 hours to prepare their request for a hearing.

Table 2.--Estimated Annual Recordkeeping Burden

21 CFR Part; Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
510.305; Maintenance of Records for Approved Labeling for Each "Type B" and "Type C" Feed	779	1	779	0.03 (2 minutes)	23

12b. Annualized Cost Burden Estimate

We estimate that the average hourly wage for respondents is equivalent to a GS-11 Step 2 level in the locality pay area of Washington-Baltimore-Arlington, DC-MD-VA-WV-PA in 2024, approximately $40.98/hour. Increasing this wage by 30% to account for overhead costs ($12.29), we estimate the average hourly cost to respondents to be $53.27/hour. Thus, we estimate the overall cost burden incurred by the respondents to be $2,077.53 (39 burden hours x $53.27/hour = $2,077.53).

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 49 original applications, supplemental applications and voluntary revocations, as well as one hearing request, to be $1,711.08. We estimate that we expend approximately 40 minutes to process each of the 48 submissions, for a total of 32.16 hours, rounded to 32 hours. In addition, we estimate that we expend approximately 4 hours to review and evaluate one hearing request, for a total of 36 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 2024, approximately $47.53/hour. Thus, the estimated annualized cost to the Federal government is $1,711.08 (36 hours x $47.53/hr = $1,711.08).

15. Explanation for Program Changes or Adjustments

We base our estimates on our recent experience with the existing medicated feed mill license application process. Our estimated burden for the information collection reflects an overall increase of 2.5 hours. We attribute this adjustment to a slight increase in the overall 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.