Medicated Feed Mill License Application

0910-0337

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

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

We request extension of OMB approval of the information collection requirements in the following citations and in Form FDA 3448.

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.

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.

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. 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. However, we assist small businesses in meeting these requirements through our Regional Small Business Representatives and through the scientific and administrative staff within the Center.

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. This is a one time submission.

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 March 9, 2016 (81 FR 12509). We received one comment, which was not responsive to the comment request.

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

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

12a. 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	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	1	1	1	4	4

(515.30(c))					
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 21 CFR 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 890 licensees will keep the records required by 21 CFR 510.305 expending a total of 26.7 hours annually, rounded to 27 hours. We estimate the total annual burden for reporting and recordkeeping to be 56 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 in 2016, approximately $23.02/hour. Increasing this wage by 30% to account for overhead costs ($6.91), we estimate the average hourly cost to respondents to be $29.93/hour. Thus, we estimate the overall cost burden incurred by the respondents to be $1,676 (56 burden hours x $29.93/hour = $1,676.08).

13. Estimates of Other Total Annual Cost Burden to Respondents and Recordkeepers

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

14. Annualized Cost to the Federal Government

We estimate the annualized cost to the Federal government for the review and evaluation of approximately 100 original applications, supplemental applications and voluntary revocations, as well as one hearing request, to be $3,134.65. We estimate that we expend approximately 40 minutes to process each of the 100 submissions, for a total of 66.66 hours, rounded to 67 hours. In addition, we estimate that we expend approximately 4 hours to review and evaluate one hearing request, for a total of 71 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 in 2016, approximately $44.15/hour. Thus, the estimated annualized cost

to the Federal government is $3,134.65 (71 hours x $44.15/hr = $3,134.65).

15. Explanation of Program Changes or Adjustments

Over the past three years, the estimated annual number of responses decreased from 1,051 to 991 due to the natural fluctuation in the number of licensees from 950 to 890. The decrease in these responses resulted in a decrease in burden (an adjustment) from 58 hours to 56 (a difference of 2 hours).

The previously approved ICR submitted to OMB included five ICs entered in ROCIS. Upon this submission we are consolidating the ICs, thereby, reducing the number of ICs in ROCIS to two. The information collection activities, however, remain broken down in this supporting statement document.

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. Reasons Display of OMB Expiration Date is Inappropriate

There are no reasons why display of the expiration date for OMB approval of the information collection would be inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.