Medicated Feed Mill Licensing
Supporting Statement
OMB Control No. 0910-0337

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The Animal Drug Availability Act (ADAA) of October 9, 1996, amended section 512 of the FD&C Act to replace the system for the approval of specific medicated feeds with a general licensing system for feed mills.

Before passage of the ADAA, medicated feed manufacturers were required to obtain approved MFAs in order to manufacture certain types of medicated feeds. An individually approved MFA was required for each and every applicable medicated feed. The ADAA streamlined the paperwork process for gaining approval to manufacture medicated feeds by replacing the MFA system with a facility license for each medicated feed manufacturing facility. Implementing regulations are at 21 CFR Part 515.

FDA is requesting OMB approval for information collection under the following citations:

21 CFR 515.10(b) Reporting

Specifies requirements for submitting a completed medicated feed mill license application using Form FDA 3448.

21 CFR 515.11(b) Reporting

Specifies requirements for supplemental medicated feed mill license applications for a change in ownership and/or a change in address for the facility using Form FDA 3448

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(b) Recordkeeping

Requires maintenance of approved labeling for each Type B and Type C medicated animal feed being manufactured.

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

FDA uses the information required from the medicated feed manufacturing facility, in accordance with 21 CFR 515, in a process to determine if a medicated feed mill license application will be approved or refused. Form FDA 3448, "Medicated Feed Mill License Application" will be used to certify the information.

3. Use of Improved Information Technology and Burden Reduction

The CVM webpage contains assembled lists (alphabetical and by State, Country or Province) of licensees drawn from our computerized data base. It also contains information on the licensing process and the license application, Form FDA 3448. Currently this information collection does not employ electronic capability. The license application is still submitted in paper form. The application is available in a "fillable" form on the web but must be printed and submitted with an original signature.

4. Efforts to Identify Duplication and Use of Similar Information

Each medicated feed manufacturing facility is requested to submit data to obtain a license. Data collected is site specific; there is no duplication of efforts.

5. Impact on Small Business or Other Small Entities

The proposed collection of information carries the same burden for small or large firms. The data collection is minimal.

6. Consequences of Collecting the Information Less Frequently

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

All of the reporting requirements are consistent with 5 CFR 1320.5

8. Efforts to Obtain Comments on the Information Collection before Submission to OMB.

FDA published a notice in the **Federal Register** on December 21, 2012 (77 FR 75635). One comment was received but is not related to the information collection.

9. Explanation of Any Payment or Gift to Respondents

There are no payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

Information will be kept confidential in accordance with FDA's public information regulations in 21 CFR Part 20.

11. Justification for Sensitive Questions

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

12. Estimates of Hour Burden Hours and Costs

12a. Annualized Burden Hour Estimate

FDA estimates 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))	20	1	20	.25	5
Supplemental Feed Mill License Application Using Form FDA 3448 (515.11(b))	40	1	40	.25	10
Voluntary Revocation of Medicated Feed Mill License (515.23)	40	1	40	.25	10
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 maintenance costs associated with this information collection.

Table 2 - Estimated Annual Recordkeeping Burden[1]

21 CFR	No. of Record-keepers	No. of Responses per Record-keeper	Total Annual Records	Average Burden per Record-keeper	Total Hours
Maintenance of Records for Approved Labeling for Each "Type B" and "Type C" Labeling (510.305)	950	1	950	0.03 (2 minutes)	28.5 (rounded to 29 in ICRAS/ ROCIS)

[1]There are no capital costs or maintenance costs associated with this information collection.

The estimated annual reporting burden on industry is 29 hours as shown in the table above. Industry estimates it takes about 15 minutes (.25) to submit the application. We estimate 100 original and supplemental applications, and voluntary revocations for a total of 25 hours (100 submissions x .25 (15 minutes)). An additional 4 hours is added for the rare notice of opportunity for a hearing to not approve or revoke an application. Finally, we estimate 28.5 hours for maintaining and retrieving labels as required by 21 CFR 510.305. We estimated (2 minutes) (.03 hour) for each of approximately 950 licensees. Total burden for reporting and recordkeeping would be 57.5 hours (rounded to 58 in ICRAS/ROCIS).

12b. <u>Annualized Cost Burden Estimate</u>

Type of Respondent	**Total Burden Hours**	**Hourly Wage Rate**	**Total Respondent Costs**
First Line Supervisor[1]	57.5	$29	$1667.50

13. <u>Estimate of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs</u>

There are no additional cost burdens to respondents and recordkeepers.

1 First line supervisor of farm, fishery, or forestry occupation, May 2012, National Occupational Employment Wage Estimates, Bureau of Labor Statistics, Department of Labor. ($22.31 median per hour wage + 30% benefits=$29.00 per hour.)

14. Annualized Cost to the Federal Government

We estimate that it takes 40 minutes to process each of the approximately 100 original applications, supplemental applications and voluntary revocations in a year. This would result in approximately 66 hours (2/3 hour x 100 applications). Sixty-six hours x $42.66 per hour for a GS-13 step 1 reviewer equals $2,844. Plus 4 hours at $42.66 for the handling of hearing requests equals $2,844 plus $171 for a total of $3,015.

15. Explanation of Program Changes or Adjustments

Over the past three years, the estimated annual number of responses decreased from 1,206 to 1,051 due to the natural fluctuation in the number of license applications received each year. The decrease in these responses resulted in a decrease in burden (an adjustment) from 70 hours to 58 (a difference of 12 hours).

16. Plans for Tabulation and Publication and Project Time Schedule.

Information is not to be published for statistical use. However, the list of licensees is available on the CVM website on the Internet.

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

Display of the OMB Expiration Date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.