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

A. JUSTIFICATION`

1. Circumstances Making the Information Collection Necessary.

The Animal Drug Availability Act (ADAA) of October 9, 1996, amended section 512 of the Federal Food Drug and Cosmetic Act (the act) (21 U.S.C. 360(b) to replace the existing "Medicated Feed Application (MFA) System" for approval of specific medicated feeds with a "General Licensing System." The "General Licensing System" streamlined the paperwork process whereby individually approved MFAs were no longer required to be submitted by medicated feed manufacturers for each and every applicable medicated feed. The provisions for ADAA are implemented under part 515, (21 CFR part 515) .

Under ADAA, the "General Licensing System" requires medicated feed manufacturing facilities to submit a medicated feed mill license application using Form FDA 3448 (attached), in order to obtain approval to manufacture medicated feeds. The specific application requirements include identifying information i.e. business name of company, mailing address, telephone and fax numbers, the FDA registration number and the name, title and signature of the responsible individual or individuals for that facility. After approval of a medicated feed mill license application, a subsequent supplemental application is required to be submitted for a change in ownership and / or a change in mailing address of the facility cite. Each supplemental application should be accompanied by a fully completed Form FDA 3448 with an explanation of the change A medicated feed license issue under ADAA can be revoked on the merits of a written request by the responsible individual holding the license on the basis that the facility no longer manufactures any animal feed previously covered under ADAA. A notice to an applicant for an opportunity for a hearing on a proposal by the Commissioner of FDA to refuse to approve a medicated feed mill license application or to revoke the approval of a medicated feed mill license is also covered under certain provisions of ADAA. An applicant receiving such notice has 30 days to respond

Recordkeeping requirements are provided for under ADAA, i.e, that current approved or index listed Type B and / or Type C medicated feed labeling for each type B or type C medicated feed must be maintained

Thus this information collection extension request is needed to so that manufacturing medicated feed facilities can obtain approval for their medicated feed mill license application.

2. Purpose and Use of the Information

FDA will use the information required from medicated feed facilities to determine compliance with the provisions of ADAA for obtaining approval of medicated feeds, i.e.

whether a medicated feed mill license application will be approved or disapproved. Form FDA 3448 will be used to certify the information.

3. Use of Information Technology and Burden Reduction.

We have assembled lists (alphabetical and by State, Country or Province) of licensees in a computerized data base. These lists are posted on the CVM Home Page on the Internet. The Home Page also contains information on licensing and a license application, Form FDA 3448.

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 October 28, 2009 (74 FR 55556). No comments were received in response to the notice.

9. Explanation of Any Payment or Gift to Respondent

There are no payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondent

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 to Respondents

Estimated annual reporting burden on industry is 38 hours as shown in the Table I below. Industry estimates it takes about 1/4 hour to submit the application. We estimate 135 original and supplemental applications, and voluntary revocations for a total of 34 hours (135 submissions x 1/4 hour). 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 36 hours for maintaining and retrieving labels as required by 21 CFR 510.305. We estimated .03 hours for each of approximately 1000 licensees. Total burden for reporting and recordkeeping is estimated to be 70 hours,(38+32=70)

Table 1 - Estimated Annual Reporting Burden[1]

21 CFR	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
515.10(b)	20	1	20	0.25	5
515.11(b)	75	1	75	0.25	19
515.23	40	1	40	0.25	10
515.30(c)	1.0	1	1.0	4.00	4
Total Burden Hours					38

[1]There are no capital cost or operating and maintanence cost associated with this collection of information

Table 2 - Estimated Annual Recordkeeping Burden[1]

21 CFR	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
510.305	1000	1	1,070	0.03	32

[1] There are no capital cost or operating and maintanence cost associated with this collection information

12b Annualized Cost Burden

Type of Respondents	Total Burden Hours	Hourly Wage rate	Total Respondent Cost
Medicated Feed Manufacturers	70	$35.00	2459

13. Estimate of Other Total Cost Burden to Respondents and Recordkeepers

There are no additional cost burden to respondents and recordkeepers.

14. Annualized Cost to the Federal Government

We estimate that it takes 40 minutes to process each of the approximately 135 original applications, supplemental applications and voluntary revocations in a year. This would result in approximately 90.45 hours (2/3 hour x 135 applications). 90.45 x $50.41 per hour for a GS-14 reviewer equals $4560.

15. Explanation of Program Changes or Adjustments

Based on reevaluation of the burden estimate by CVM, there was a very small adjustment (decrease) of 2 hours since the last extension request.

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 Home Page on the Internet.