

**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 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 Medicated Feed Applications (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.

We are 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 515.305(b) Recordkeeping

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

being manufactured.

2. Purpose and Use of the Information

We will use the information required from the medicated feed manufacturing facility, in accordance with 21 CFR 515.10(b), to determine if a medicated feed mill license application will be approved or denied. 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.

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 36.6 hours as shown in the table below. Industry estimates it takes about 1/4 hour to submit the application. We estimate 132 original and supplemental applications, and voluntary revocations for a total of 33 hours (132 submissions x 1/4 hour). An additional 3.6 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 1,070 licensees. Total burden for reporting and recordkeeping would be 68.70 hours.

Table 1 - Estimated Annual Reporting Burden

21 CFR	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
515.10(b)	7	1	7	0.25	1.75
515.11(b)	100	1	100	0.25	25
515.23	25	1	25	0.25	6.25
515.30(c)	0.15	1	0.15	24	3.6
Total Burden Hours					36.6

Table 2 - Estimated Annual Recordkeeping Burden

21 CFR	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
510.305	1,070	1	1,070	0.03	32.10

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

Total annual cost burden is included in the preceding paragraph. There are no additional costs to respondents.

14. Annualized Cost to the Federal Government

We estimate that it takes 40 minutes to process each of the approximately 132 original applications, supplemental applications and voluntary revocations in a year. This would result in approximately 88 hours (2/3 hour x 132 applications).

15. Explanation of Program Changes or Adjustments

The number of recordkeepers has been revised based on the number of licensees at the time of this reporting.

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.