4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-1181]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medicated Feed Mill License Application; Extension

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0337. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3794, Jonnalynn.capezzuto@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medicated Feed Mill Licensing Application--21 CFR Part 515 (OMB Control Number 0910-0337)--Extension

The Animal Drug Availability Act (ADAA) of October 9, 1996, amended section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b) to replace the system for the approval of specific medicated feed with a general licensing system for feed mills. Before passage of the ADAA, medicated feed manufacturers were required to obtain approval of Medicated Feed Applications (MFAs) in order to manufacture certain types of medicated feeds. An individual 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.

In the Federal Register of December 21, 2012 (77 FR 75635), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received; however, it was unrelated to the information collection.

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	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 (515.30(c))	1	1	1	4	4
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	No. of Recordkeepers	No. of Responses per Recordkeeper	Total Annual Records	Average Burden per Recordkeeper	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

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

Estimated annual reporting burden on industry is 29 hours as shown in table 1. Industry estimates it takes about 15 minutes (0.25) to submit the application. We estimate 100 original and supplemental applications, and voluntary revocations for a total of 25 hours (100 submissions x 0.25 (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 (0.03 hour) for each of approximately 950 licensees. Total burden for reporting and recordkeeping would be 57.5 hours.

Dated: May 6, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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