

meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: November 6, 2006.

**Alvin Hall,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2006N-0329]

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

**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 December 14, 2006

**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: 202-395-6974.

**FOR FURTHER INFORMATION CONTACT:** Denver Presley, Jr., Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

**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 No. 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 part 515 (21 CFR part 515).

In the **Federal Register** of August 25, 2006 (71 FR 50433), FDA solicited comments on the information collection provisions of this proposed collection. In response to that request, FDA received no comments.

*Description of Respondents:* Medicated feed manufacturers.

FDA estimates the burden for this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	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					36.6

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

21 CFR Section	No. of Record-keepers	Annual Frequency per Record-keeping	Total Annual Records	Hours per Record-keeper	Total Hours
510.305	1,070	1	1,070	0.03	32.10

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimated annual reporting burden on industry is 36.6 hours as shown in table 1 of this document. 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. Thus, the total burden for recordkeeping requirements is 32.10 hours (1,070 x 0.03).

Dated: November 7, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2006D-0441]

**Draft Guidance for Industry: Protocols for the Conduct of Method Transfer Studies for Type C Medicated Feed Assay Methods; Availability**

**AGENCY:** Food and Drug Administration, HHS.