

entries entered into the automated system were entries dealing with FDA-regulated products. The number of respondents is a count of filers who

submit entry data for foreign-origin FDA-regulated products. The estimated reporting burden is based on information obtained by FDA contacting

some potential respondents. Disclaimer entries are not FDA commodities.

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

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

Section of the Act	No of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Section 801 for FY 2002 Updated	3,406	652	2,955,595	.14	413,833

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

Dated: May 16, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 03N-0198]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Medicated Feed Mill License

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension for an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information for medicated feed mill licensing requirements.

**DATES:** Submit written or electronic comments on the collection of information by July 22, 2003.

**ADDRESSES:** Submit electronic comments on the collection of

information via the Internet at: <http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm>. Submit written comments on the collection of information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

#### FOR FURTHER INFORMATION CONTACT:

Denver Presley, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. A collection of information is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites

comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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

In the **Federal Register** of November 19, 1999 (64 FR 63195), FDA published a final rule implementing the feed mill licensing provisions of the Animal Drug Availability Act (the ADAA) of 1966 (Public Law 104-250). The rule added a new part 515 to title 21 CFR to provide the requirements for medicated feed mill licensing.

The rule set forth the information to be included in medicated feed mill license applications and supplemental applications. Also, it set forth criteria for, among other things, the approval and refusal to approve a medicated feed mill license application, as well as the criteria for the revocation and/or suspension of a license.

Respondents to this collection of information are individuals or firms that manufacture medicated animal feed.

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

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

21 CFR Section	No. of Recordkeepers	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	25.00