

**ACTION:** Notice.

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

**DATES:** Submit written comments on the collection of information by September 8, 2003.

**ADDRESSES:** OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. 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: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

**FOR FURTHER INFORMATION CONTACT:** Denver Presley, Office of Management Programs (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 License Application—21 CFR Part 515 (OMB Control Number 0910-0037)—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 of 1966 (Public Law 104-250). The rule added a new 21 CFR part 515 to provide the requirements for medicated feed mill licensing.

The rule sets forth the information to be included in medicated feed mill license applications and supplemental applications. It also sets forth the 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 Respondents	Annual Frequency per Responses	Total Annual Responses	Hours per Response	Total Hours
515.10	7	1	7	0.25	1.75
515.11	100	1	100	0.25	25.00
515.23	25	1	25	0.25	6.25
515.30	0.15	1	0.15	24.00	3.60
Total Burden Hours					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 Recordkeepers	Annual Frequency per Record-keeping	Total Annual Records	Hours per Recordkeeper	Total Hours
510.305	1,160	1	1,160	0.03	34.80

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

The estimated number of respondents is derived from agency data on the number of medicated feed manufacturers entering the market each year, changing ownership or address, requesting voluntary revocation of a medicated feed mill license, and those involved in revocation and/or suspension of a license. The estimate of the time required for this reporting requirement is based on the agency communication with industry.

Dated: August 4, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2003N-0324]

**Certain Antibiotic New Animal Drug Products and Use Combinations Subject to Listings in the New Animal Drug Regulations; Drug Efficacy Study Implementation; Notice of Opportunity for Hearing**

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

**ACTION:** Notice of opportunity for hearing.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the effective conditions of use for certain drug products and use combinations in

the following four categories: Bacitracin methylene disalicylate single-ingredient Type A medicated articles, oxytetracycline and neomycin fixed-combination Type A medicated articles, and combination drug Type B and Type C medicated feeds for poultry containing bacitracin. The agency is also proposing to withdraw the new animal drug applications (NADAs) for those products or use combinations lacking substantial evidence of effectiveness, following a 90-day opportunity to supplement the NADAs with labeling conforming to the relevant findings of effectiveness. For applications proposed to be withdrawn, the agency is providing an opportunity for hearing. Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to remove certain obsolete or redundant sections of the new animal