ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30–Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 18, 2003 (68 FR 36676), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0513. The approval expires on July 31, 2006. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: August 4, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–20199 Filed 8–7–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1993P–0174]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Requirements for Liquid Medicated Animal Feed and Free-Choice Medicated Animal Feed

AGENCY: Food and Drug Administration, HHS.

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.

Waiver From Labeling Requirements for New Animal Drugs Intended for Use in Liquid Medicated Animal Feed

Proposed § 558.5(i) specifies procedures for obtaining a waiver from labeling requirements for certain drugs intended for use in animal feed or drinking water but not approved for use in liquid medicated feed. The request for waiver must include a copy of the product label; a description of the formulation; and information to establish that the physical, chemical, or other properties of the product are such that diversion to use in liquid medicated feeds is unlikely. This information would be collected if the manufacturer or sponsor chose not to include the required warning ''FOR USE IN_____ ONLY, NOT FOR USE IN LIQUID MEDICATED FEEDS'' on its product label. The sponsor or manufacturers would then need to satisfy the requirements of the waiver section of the regulation. All other data collections are covered under OMB control number 0910–0032.

Medicated feed manufacturing facilities and sponsors of new animal drugs used in the manufacture of medicated feed.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Proposed 21 CFR Section	No. of Respondents	Annual Frequency per Responses	Total Annual Responses	Hours per Response	Total Hours
558.5(i)	1	1	1	5	5

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

The burden estimate for this reporting requirement was derived from data by our Division of Animal Feeds, Center for Veterinary Medicine, FDA. Only one respondent was used in these figures because although this particular waiver has been part of the regulations since 1973, it has never been utilized. We estimated it would take 5 hours to compile the required information because of the time necessary to explain why the drug would not be diverted to use in liquid feed.

Dated: August 4, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–20200 Filed 8–7–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0198]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Requirements for Medicated Feed Mill License

AGENCY: Food and Drug Administration, HHS.

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[1]

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

[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	Annual Frequency per Record-keeping	Total Annual Records	Hours per Recordkeeper	Total Hours
510.305	1,160	1	1,160	0.03	34.80

[1] 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.

[FR Doc. 03–20201 Filed 8–7–03; 8:45 am]

BILLING CODE 4160–01–S

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