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.

New Animal Drug Application, Form 356 V—21 CFR Part 514 (OMB Control Number 0910–0032)—Extension

FDA has the responsibility under the Federal Food, Drug and Cosmetic Act (the act), for the approval of new animal drugs that are safe and effective. Section 512(b) of the act (21 U.S.C. 360b(b)) requires that a sponsor submit and receive approval of a new animal drug application (NADA) before interstate marketing is allowed. The regulations implementing statutory requirements for NADA approval have been codified under 21 CFR part 514. NADA applicants generally use a single form, FDA 356 V. The NADA must contain, among other things, safety and effectiveness data for the drug, labeling, a list of components, manufacturing and controls information, and complete information on any methods used to determine residues of drug chemicals in edible tissues. While the NADA is pending, an amended application may be submitted for proposed changes. After an NADA has been approved, a supplemental application must be submitted for certain proposed changes, including changes beyond the variations provided for in the NADA and other labeling changes. An amended application and a supplemental application may omit statements concerning which no change is proposed. This information is reviewed by FDA scientific personnel to ensure that the intended use of an animal drug, whether as a pharmaceutical dosage form, in drinking water, or in medicated feed, is safe and effective. The respondents are pharmaceutical firms that produce veterinary products and commercial feed mills.

In the **Federal Register** of May 19, 2004 (69 FR 28930), FDA published a 60-day notice soliciting comments on the collection of information requirements. In response to that notice, no comments were received.

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 Response	Total Annual Responses	Hours per Response	Total Hours
514.1 and 514.6	190	7.39	1,405	211.6	297,298
514.8	190	7.39	1,405	30	42,150
514.11	190	7.39	1,405	1	1,405
558.5(i)	1	1	1.0	5	5
Total					340,858

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

The estimate of the burden hours required for reporting are based on FY 2003 data. The burden estimate includes original NADAs, supplemental NADAs and amendments to unapproved applications.

The burden estimate for obtaining a waiver (filing a petition) from labeling requirements for certain drugs intended for use in animal feed or drinking water was derived from data by FDA's Division of Animal Feeds in the Center for Veterinary Medicine.

Dated: October 27, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–24446 Filed 11–2–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0383]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Recommended Glossary and Educational Outreach to Support Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Recommended Glossary and Educational Outreach to Support Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 5, 2004 (69 FR 47448), 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 0910–0553. The approval expires on October 31, 2007. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: October 27, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–24447 Filed 11–2–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0245]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Current Good Manufacturing Practice Regulations for Medicated Feeds

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 2, 2004.

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.

Current Good Manufacturing Practice Regulations for Medicated Feeds—21 CFR Part 225—(OMB Control Number 0910–0152)—Extension

Under section 501 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 351), FDA has the statutory authority to issue current good manufacturing practice (cGMP) regulations for drugs, including medicated feeds. Medicated feeds are administered to animals for the prevention, cure, mitigation, or treatment of disease or growth promotion and feed efficiency. Statutory requirements for cGMPs have been codified under part 225 (21 CFR part 225). Medicated feeds that are not manufactured in accordance with these regulations are considered adulterated under section 501(a)(2)(B) of the act. Under part 225, a manufacturer is required to establish, maintain, and retain records for a medicated feed, including records to document procedures required during the manufacturing process to assure that proper quality control is maintained. Such records would, for example, contain information concerning receipt and inventory of drug components, batch production, laboratory assay results (i.e. batch and stability testing), labels, and product distribution.

This information is needed so FDA can monitor drug usage and possible misformulation of medicated feeds, to investigate violative drug residues in products from treated animals and investigate product defects when a drug is recalled. In addition, FDA will use the cGMP criteria in part 225 to determine whether or not the systems and procedures used by manufacturers of medicated feeds are adequate to assure that their feeds meet the requirements of the act as to safety and also meet their claimed identity, strength, quality, and purity, as required by section 501(a)(2)(B) of the act.

A license is required when the manufacturer of a medicated feed involves the use of a drug or drugs which FDA has determined requires more control because of the need for a withdrawal period before slaughter or carcinogenic concerns. Conversely, for those medicated feeds for which FDA has determined that the drugs used in their manufacture need less control, a license is not required and the recordkeeping requirements are less demanding.

In the **Federal Register** of June 14, 2004 (69 FR 33040), FDA published a 60-day notice, soliciting comments on the collection of information requirements for this clearance. In response, no comments were received.

Respondents to this collection of information are commercial feed mills and mixer-feeders.

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN (REGISTERED LICENSED COMMERCIAL FEED MILLS)[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeper	Total Annual Records	Hours per Recordkeeper	Total Hours
225.42(b)(5) through (b)(8)	1,150	260	299,000	1	299,000
225.58(c) and (d)	1,150	45	51,750	.5	28,875
225.80(b)(2)	1,150	1,600	1,840,000	.12	220,800
225.102(b)(1)	1,150	7,800	8,970,000	.08	717,600
225.110(b)(1) and (b)(2)	1,150	7,800	8,970,000	.015	134,550
225.115(b)(1) and (b)(2)	1,150	5	5,750	.12	690
Total					1,397,825

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