The estimate of the time required for reporting requirements, record preparation and maintenance for this collection of information is based on agency communication with industry. Additional information needed to make a final calculation of the total burden hours (i.e. the number of respondents, the number of recordkeepers, the number of INAD applications received, etc.) is derived from agency records.

Dated: November 3, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–24991 Filed 11–9–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0481]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Food Additive Petitions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Food Additive Petitions'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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: In the **Federal Register** of June 4, 2004 (69 FR 31617), 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 0910–0546. The approval expires on November 30, 2006. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: November 3, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–24992 Filed 11–9–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0244]

Agency Information Collection Activities: Submission for Office of Management and Budget Review; Comment Request, Current Good Manufacturing Practice Regulations for Type A Medicated Articles

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 (the PRA).

DATES: Fax written comments on the collection of information by December 10, 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, rm. 4B–41, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the Paperwork Reduction Act of 1995 (PRA) (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 Type A Medicated Articles—21 CFR 226 (OMB Control No. 0910–0154) Extension

Under section 501 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351) (the act), FDA has the statutory authority to issue current good manufacturing practice (cGMP) regulations for drugs, including type A medicated articles. A type A medicated article is a feed product containing a concentrated drug diluted with a feed carrier substance. A type A medicated article is intended solely for use in the manufacture of another type A medicated article or a type B or type C medicated feed. Medicated feeds are administered to animals for the prevention, cure, mitigation, or treatment of disease or for growth promotion and feed efficiency. Statutory requirements for cGMP's for type A medicated articles have been codified in part 226 (21 CFR part 226). Type A medicated articles which are not manufactured in accordance with these regulations are considered adulterated under section 501(a)(2)(B) of the act. Under 21 CFR part 226, a manufacturer is required to establish, maintain, and retain records for Type A medicated articles, including records to document procedures required under 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) and product distribution. This information is needed so that FDA can monitor drug usage and possible misformulation of type A medicated articles. The information could also prove useful to FDA in investigating product defects when a drug is recalled. In addition, FDA will use the cGMP criteria in part 226 to determine whether or not the systems used by manufacturers of Type A medicated articles are adequate to assure that their medicated articles meet the requirements of the act as to safety and also meet the articles, claimed identity, strength, quality and purity, as required by section 501(a)(2)(B) of the act as to safety and also meet the articles claimed identity, strength, quality, and purity, as required by section 501(a)(2)(B) of the act.

In the **Federal Register** of June 4, 2004 (69 FR 31615), the FDA published a 60-day notice, soliciting comment on the collection of information requirements. In response to that notice, no comments were received. The respondents for type A medicated articles are pharmaceutical firms that manufacture both human and veterinary drugs, those firms that produce only veterinary drugs and commercial feed mills.

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

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
226.42	115	260	29,000	0.75	22,425
226.58	115	260	29,000	1.75	52,325
226.80	115	260	29,000	0.75	22,425
226.102	115	260	24,000	1.75	52,325
226.110	115	260	29,000	0.25	7,475
226.115	115	10	1,150	0.5	575
Total					157,550

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

The estimate of the time required for record preparation and maintenance is based on agency communications with industry. Other information needed to calculate the total burden hours (i.e., manufacturing sites, number of type A medicated articles being manufactured, etc.) are derived from agency records and experience.

Dated: November 3, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–24993 Filed 11–9–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0332]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Devices; Third-Party Review Under the Food and Drug Administration Modernization Act

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

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.

Medical Devices; Third-Party Review Under the Food and Drug Administration Modernization Act—(OMB Control Number 0910–0375)—Extension

Section 210 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) established section 523 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360m), directing FDA to accredit persons in the private sector to review certain premarket applications and notifications. Participation in this third-party review program by accredited persons is entirely voluntary. A third party wishing to participate will submit a request for accreditation to FDA. Accredited third-party reviewers have the ability to review a manufacturer's 510(k) submission for selected devices. After reviewing a submission, the reviewer will forward a copy of the 510(k) submission, along with the reviewer's documented review and recommendation to FDA. Third-party reviews should maintain records of their 510(k) reviews and a copy of the 510(k) for a reasonable period of time, usually a period of 3 years. This information collection will allow FDA to continue to implement the accredited person review program established by FDAMA and improve the efficiency of 510(k) review for low to moderate risk devices.

Respondents to this information collection are businesses or other for-profit organizations.

In the **Federal Register** of August 10, 2004 (69 FR 48508), FDA published a 60-day notice requesting public comment on the information collection provisions. 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 Recordkeepers	Annual Frequency per Record	Total Annual Records	Hours per Recordkeeper	Total Hours
Requests for accreditation	15	1	15	24	360
510(k) reviews conducted by accredited third parties	15	14	210	40	8,400
Totals					8,760

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