(CBER's) database system, there were 90 licensed biologics manufacturers. This number excludes those manufacturers who produce blood and blood components and in-vitro diagnostic licensed products because these products are specifically exempt from the regulations under § 600.80(k). The total annual responses are based on the average estimated number of submissions received annually by FDA for FY 2002 and 2003. However, not all manufacturers have submissions in a given year and some may have multiple submissions. There were an estimated 15,126 15-day alert reports, 6,550 periodic reports, and 323 lot distribution reports submitted to FDA. The number of 15-day alert report for postmarketing studies under § 600.80(e) is included in the total number of 15-day alert reports. FDA received an average of 5 waiver requests for FY 2002 and 2003 under § 600.90, all of which were approved for exemption of the AER requirements. The hours per response are based on FDA's experience. The burden hours required to complete the MedWatch Form for § 600.80(c)(1), (e), and (f) are reported under OMB control number 0910–0291.

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
600.80(c)(1) and 600.80(e)	90	168.07	15,126	1	15,126
600.80(c)(2)	90	72.78	6,550	28	183,400
600.81	90	3.59	323	1	355
600.90	5	1	5	1	5
Total					198,886

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

In table 2 of this document, the number of respondents is based on the number of manufacturers subject to those regulations. Based on information obtained from CBER's database system, there were 320 licensed manufacturers of biological products in FY 2002 and 2003. However, the number of recordkeepers listed for § 600.12(a) through (e) excluding paragraph (b)(2) is estimated to be 116. This number excludes manufacturers of blood and blood components because their burden hours for recordkeeping have been reported under § 606.160 in OMB control number 0910–0116. The total annual records is based on the annual average of lots released (6,630), number of recalls made (1,958), and total number of AER reports received (35,484) in FY 2002 and 2003. The hours per record are based on FDA's experience.

FDA estimates the burden of this recordkeeping as follows:

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Response	Total Hours
600.12	116	57.16	6,630	32	212,160
600.12(b)(2)	320	6.12	1,958	24	46,992
600.80(i)	90	394.27	35,484	1	35,484
Total					294,636

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

Dated: October 27, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–24445 Filed 11–2–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0179]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; New Animal Drug Application, Form FDA 356 V

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 (the PRA).

DATES: Fax written comments on the collection of information by December 3, 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.

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]

BILLING CODE 4160–01–S

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*.