must submit to FDA a Notice of Claimed Investigational Exemption (INAD), before shipping the new animal drug for clinical tests in animals. The INAD must contain, among other things, the following specific information: (1) Identity of the new animal drug, (2) labeling, (3) statement of compliance of any nonclinical laboratory studies with good laboratory practices, (4) name and address of each clinical investigator, (5) the approximate number of animals to be treated or amount of new animal drug(s) to be shipped, and (6) information regarding the use of edible tissues from investigational animals. Part 511 also requires that records be established and maintained to document the distribution and use of the investigational drug to assure that its use is safe, and that distribution is controlled to prevent potential abuse. The agency utilizes these required records under its Bio-Research Monitoring Program to monitor the validity of the studies submitted to FDA to support new animal drug approval and to assure that proper use of the drug is maintained by the investigator.

Investigational new animal drugs are used primarily by drug industry firms, academic institutions, and the government. Investigators may include individuals from these entities as well as research firms and members of the medical profession. Respondents to this collection of information are the persons who use new animal drugs investigationally.

In the **Federal Register** of November 10, 2004 (69 FR 65198), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

FDA estimates the burden for 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
511.1(b)(4)	190	4.09	778	8	6,224
511.1(b)(5)	190	0.58	110	140	15,400
511.1(b)(6)	190	.01	20	1	20
511.1(b)(8)(ii)	190	.005	1	20	20
511.1(b)(9)	190	.10	20	8	160
Total					21,824

[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	Total Annual Records	Hours per Recordkeeper	Total Hours
511.1(a)(3)	190	2.11	400	9	3,600
511.1(b)(3)	190	4.20	798	1	798
511.1(b)(7)(ii)	400	3.00	1,200	3.5	4,200
511.1(b)(8)(i)	190	6.38	1,200	3.5	4,200
Total					12,798

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

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: April 13, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–7823 Filed 4–19–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0469]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Adverse Experience Reporting for Licensed Biological Products; and General Records

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 May 20, 2005.

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: Jonna Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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.

Adverse Experience Reporting for Licensed Biological Products; and General Records—(OMB Control Number 0910–0308—Extension)

Under the Public Health Service Act (42 U.S.C. 262), FDA is required to ensure the marketing of only those biological products that are safe and effective. FDA must, therefore, be informed of all adverse experiences occasioned by the use of licensed biological products. FDA issued the adverse experience reporting (AER) requirements in part 600 (21 CFR part 600) to enable FDA to take actions necessary for the protection of the public health in response to reports of adverse experiences related to licensed biological products. The primary purpose of FDA's AER system is to flag potentially serious safety problems with licensed biological products, focusing especially on newly licensed products. Although premarket testing discloses a general safety profile of a biological product's comparatively common adverse effects, the larger and more diverse patient populations exposed to the licensed biological product provides the opportunity to collect information on rare, latent, and long-term effects. Reports are obtained from a variety of sources, including patients, physicians, foreign regulatory agencies, and clinical investigators. Information derived from the AER system contributes directly to increased public health protection because such information enables FDA to recommend important changes to the product's labeling (such as adding a new warning), to initiate removal of a biological product from the market when necessary, and to assure the manufacturer has taken adequate corrective action, if necessary.

The regulation in § 600.80(c)(1) requires the licensed manufacturer to report each adverse experience that is both serious and unexpected, whether foreign or domestic, as soon as possible but in no case later than 15 calendar days of initial receipt of the information by the licensed manufacturer and to submit any followup reports within 15 calendar days of receipt of new information, or as requested by FDA.

Section 600.80(e) requires licensed manufacturers to submit a 15-day alert report obtained from a postmarketing clinical study only if there is a reasonable possibility that the product caused the adverse experience. Section 600.80(c)(2) requires the licensed manufacturer to report each adverse experience not reported under § 600.80(c)(1)(i) at quarterly intervals, for 3 years from the date of issuance of the biologics license, and then at annual intervals. The majority of the periodic reports will be submitted annually since a large percentage of the current licensed biological products have been licensed longer than 3 years. Section 600.80(i) requires the licensed manufacturer to maintain, for a period of 10 years, records of all adverse experiences known to the licensed manufacturer, including raw data and any correspondence relating to the adverse experiences. Section 600.81 requires the licensed manufacturer to submit information about the quantity of the product distributed under the biologics license, including the quantity distributed to distributors at an interval of every 6 months. The semiannual distribution report informs FDA of the quantity, certain lot numbers, labeled date of expiration, the number of doses, and date of release. Under § 600.90, a licensed manufacturer may submit a waiver request that applies to the licensed manufacturer under § § 600.80 and 600.81. A waiver request submitted under § 600.90 must be submitted with supporting documentation.

Manufacturers of biological products for human use must keep records of each step in the manufacture and distribution of products including the recalls of the product. The recordkeeping requirements serve preventative and remedial purposes. These requirements establish accountability and traceability in the manufacture and distribution of products, and enable FDA to perform meaningful inspections.

Section 600.12 requires that all records of each step in the manufacture and distribution of a product be made and retained for no less than 5 years after the records of manufacture have been completed or 6 months after the latest expiration date for the individual product, whichever represents a later date. In addition, records of sterilization of equipment and supplies, animal necropsy records, and records in cases of divided manufacturing of a product are required to be maintained. Section 600.12(b)(2) requires complete records to be maintained pertaining to the recall from distribution of any product.

Respondents to this collection of information are manufacturers of biological products. In table 1 of this document, the number of respondents is based on the estimated number of manufacturers that submitted the required information to FDA in fiscal year (FY) 2002 and 2003. Based on information obtained from the Center for Biologics Evaluation and Research's (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 reports for post-marketing studies under § 600.80(e) is included in the total number of 15-day alert reports. FDA received an average of five 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.

In the **Federal Register** of November 3, 2004 (69 FR 64069), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Respondent	Total Hours
600.80(c)(1) and (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 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	Total Annual Records	Hours per Recordkeeper	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 capital costs or operating and maintenance costs associated with this collection of information.

Dated: April 13, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0123]

Agency Information Collection Activities; Proposed Collection; Comment Request; Survey of Need for Online Medical Device Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on a survey of customers who should be served by FDA's Center for Devices and Radiological Health (CDRH) Web site, in order to determine the kind and quality of services they want.

DATES: Submit written or electronic comments on the collection of information by June 20, 2005.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Survey of Need for Online Medical Device Information

Executive Order 12862 directs agencies to identify the customers who are, or should be, served by the agency, and to survey customers to determine the kind and quality of services they want.

This proposed survey will collect data about the information customers want