Dated: March 4, 1999.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 99–5866 Filed 3–9–99; 8:45 am]

BILLING CODE 4163–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0747]

Agency Information Collection Activities; Announcement of OMB Approval; Customer/Partner Satisfaction Surveys

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 24, 1998 (63 FR 71294), 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 0910–0360. The approval expires on March 31, 2002. A copy of the supporting statement for this information collection is available on the Internet at ''http://www.fda.gov/ohrms/dockets''.

Dated: March 4, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–5903 Filed 3–9–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0482]

Agency Information Collection Activities; Submission for OMB 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 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: Submit written comments on the collection of information by April 9, 1999.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (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—21 CFR 600.80, 600.81, and 600.90; and General Records—21 CFR 600.12 (OMB Control Number 0910–0308)—Extension

Under the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 201 *et seq.*) and the Public Health Service Act (42 U.S.C. 262 and 264), FDA is required to ensure the marketing of only those biological products that are shown to be safe and effective. Under the authority of section 301(e) of the act (21 U.S.C. 331(e)), FDA issued regulations for adverse experience reports related to the use of licensed biological products. FDA issued the adverse experience reporting requirements 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 adverse experience reporting system flags potentially serious safety problems with licensed biological products, focusing especially on newly licensed products. Although premarket testing discloses a general safety profile of a new drug'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 adverse experience reporting 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.

Manufacturers of biological products for human use must also keep records of each step in the manufacture and distribution of products including any 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 (21 CFR 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.

Section 600.80(c)(1) (21 CFR 600.80(c)(1)) requires the licensed manufacturer to report each adverse experience that is both serious and unexpected, regardless of source, as soon as possible but in any case within 15 working days of initial receipt of the information. 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 paragraph (c)(1) at quarterly intervals, for 3 years from the date of issuance of the product 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 manufacturers 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 (21 CFR 600.81) requires the licensed manufacturer to submit information about the quantity of the product distributed under the product license, including the quantity distributed to distributors at an interval of every 6 months. The semiannual distribution report informs FDA of the quantity, the lot number, and the dosage of different products. Section 600.90 (21 CFR 600.90) requires a licensed manufacturer to submit a waiver request with supporting documentation when asking for waiving the requirement that applies to them under §§ 600.80 and 600.81.

In the **Federal Register** of July 10, 1998 (63 FR 37394), a 60-day notice for public comment on the information collection provisions was published. Two comments were received in response to the 60-day notice.

Both comments agreed there is practical value in this proposed collection of information. However they questioned the estimate of the annual responses and provided estimates of burden hours for § 600.80(c)(2). Based on these comments and further internal research, the estimated annual reporting burden has been revised as follows. A periodic report submitted under § 600.80(c)(2) may include one or more, even hundreds, of individual MedWatch and Vaccine Adverse Event Reporting System (VAERS)–1 Forms. These forms are attached to the report. The original estimate of periodic reports (5,903) included the number of individual attached forms, whereas the current estimate (1,129) reflects only the number of periodic reports received regardless of the number of attachments. More than half of these reports are monthly reports on plasma derivatives that should take on the average 2 hours each to complete. The balance of the reports are quarterly and annual reports that may each require an average of 28 hours to prepare. The burden hours required to complete the MedWatch Form for § 600.80(c)(1), (e), and (f) are reported under OMB Control No. 0910–0291. The VAERS–1 Form is exempt from compliance with paperwork reduction requirements under the National Childhood Vaccine Injury Act (42 U.S.C. 300aa–1) (section 321 of Pub. L. 99–660).

Both comments questioned the statement that there are no capital, operating, or maintenance costs associated with maintaining records of adverse experience reports for 10 years. FDA believes there are no maintenance costs associated with the storage/retention of records because respondents already have the facilities and the infrastructure for ongoing record retention, and that existing and emerging data storage technology minimizes space and costs of long-term record retention.

Both comments recommended ways to enhance the quality, utility, and clarity of the information to be collected, and to minimize the burden of the collection of information on the respondents. FDA is in the process of revising its safety reporting and recordkeeping regulations and will consider these comments in developing its rulemaking. FDA has provided notice and requested comments on several proposed rules. In the **Federal Register** of October 27, 1994 (59 FR 54046), FDA published a proposed rule to amend its postmarketing expedited and periodic safety reporting requirements, as well as others, to implement international standards and to facilitate the reporting of adverse drug experiences. In the **Federal Register** of October 27, 1997 (62 FR 52237), FDA published a final rule amending its expedited safety reporting regulations to implement certain recommendations in the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) E2A guidance on definitions and standards for expedited reporting (58 FR 37408, July 9, 1993). At this time, the agency is further considering recommendations in the ICH E2A guidance for additional amendments to its postmarketing expedited safety reporting regulations. With respect to the proposed amendments to the periodic adverse drug experience reporting requirements in the proposal of October 27, 1994, FDA has decided to repropose these amendments based on recommendations in the ICH E2C guidance on periodic safety update reports (62 FR 27470, May 19, 1997). In developing the reproposal, FDA will also consider comments submitted in response to the proposed rule of October 27, 1994, regarding periodic adverse experience reports. FDA is also considering rulemaking concerning the electronic submission of postmarketing expedited and periodic safety reports using standardized medical terminology, data elements, and electronic transmission standards recommended by ICH. The respondents to the collection of information discussed here will, therefore, have further opportunity to provide comment on these rulemaking initiatives.

Description of Respondents: Respondents to this collection of information are manufacturers of biological products.

Reporting Burden: The total number of respondents in the chart, is based upon information submitted to FDA in fiscal year (FY) 1996, which shows that 69 licensed manufacturers (excluding 3 manufacturers who received waivers from Adverse Event Reporting (AER) requirements, produced 242 licensed biological products. The 69 licensed manufacturers excludes those manufacturers who only produce blood and blood components or in vitro diagnostic licensed products and are exempt from the AER regulations. In FY 1996, licensed manufacturers submitted approximately 1,616 15-day alert reports under § 600.80(c)(1) and (e); 1,129 periodic reports under § 600.80(c)(2); and 464 distribution reports under § 600.81. The MedWatch Form that is used to submit the information provided under § 600.80(c)(1), (e), and (f) has received approval under OMB Control No. 0910–0291.

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 (e)	69	23.4	1,616	1	1,616
600.80(c)(2)	69	16.4	1,129	28	31,612

TABLE 1.—Estimated Annual Reporting Burden[1]—Continued

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
600.81	69	6.7	464	1	464
600.90	3	1	3	1	3
Total					33,695

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

Recordkeeping Burden: There are approximately 391 licensed manufacturers of biological products. The number of recordkeepers under § 600.12(a), (c), (d), and (e) is estimated to be 102. That number excludes the 189 manufacturers of blood and blood components whose recordkeeping is conducted under 21 CFR 606.160, which is approved under OMB Control No. 0910–0116. FDA expects that the total number of AER records kept by the respondent will parallel the total number of reports submitted to FDA. The total number of annual records, therefore, is based on reporting information provided to FDA by manufacturers. Based on FY 1996 data, the total annual records are estimated as follows: Under § 600.12(a), (c), (d), and (e), the number of lots released was 9,027; under § 600.12(b)(2), the number of recalls was 710; and under § 600.80(i), the total number of AER reports received was 2,745. Based on FDA's experience, the agency estimates that the total number of hours per recordkeeper under § 600.12(a), (c), (d), and (e) would be 32 hours per lot multiplied by 88.5 lot records on the average per recordkeeper, totaling 2,832 hours; the total number of hours per recordkeeper under § 600.12(b)(2) would be 24 hours per recall multiplied by 1.8 recalls on the average per recordkeeper, totaling 43 hours; and the total number of hours per recordkeeper under § 600.80(i) would be 1 hour per report multiplied by 39.8 AER records on the average per recordkeeper, totaling 40 hours.

TABLE 2.—Estimated Annual Recordkeeping Burden[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
600.12(a), (c), (d) and (e)	102	88.5	9,027	2,832	288,864
600.12(b)(2)	391	1.8	710	43	16,813
600.80(i)	69	39.8	2,745	40	2,760
Total					308,437

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

Dated: March 4, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–5904 Filed 3–9–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–1771]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection;

Title of Information Collection: Attending Physicians Statement and Documentation of Medicare Emergency and Supporting Regulations in 42 CFR Sections 424.101 and 424.103;

Form No.: HCFA–1771 (OMB# 0938–0023);

Use: Payment, by Medicare, may be made for certain Part A inpatient hospital services and Part B outpatient services provided in a nonparticipating U.S. or foreign hospital, when services are necessary to prevent the death or serious impairment to the health of an individual. This form is used to document the attending physician's statement that the hospitalization was required due to an emergency and give clinical support for the claim;

Frequency: On occasion;

Affected Public: Business or other for profit;

Number of Respondents: 2,000;

Total Annual Responses: 2,000;

Total Annual Hours: 500.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards