your request, including your address, phone number, OMB number, and CMS 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 CMS Paperwork Clearance Officer designated at the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances, Attention: Melissa Musotto, Room C5–14–03, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: January 8, 2004.

John P. Burke, III,

Paperwork Reduction Act Team Leader, Office of Strategic Operations and Strategic Affairs, Division of Regulations Development and Issuances.

[FR Doc. 04–982 Filed 1–15–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS–2786M, R, and S–Y, CMS–10097, CMS–R–204, CMS–9044, CMS–P–0015A, CMS–R–13]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS) (formerly known as 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.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Fire Safety Survey Report Forms and Supporting Regulations in 42 CFR 488.26 and 442.30; *Form No.:* CMS–2786 M, R, and S–Y (OMB# 0938–0242); *Use:* CMS surveys facilities to determine compliance with the Life Safety Code of 2000. The providers must make documentation proving compliance available to the surveyors; *Frequency:* Annually; *Affected Public:* Business or other for-profit, not-for-profit institutions; *Number of Respondents:* 27,900; *Total Annual Responses:* 27,900; *Total Annual Hours:* 2325.

2. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Medicare Contractor Provider Satisfaction Survey; *Form No.:* CMS–10097 (OMB# 0938–NEW); *Use:* CMS needs standard data about Medicare provider's satisfaction with their Medicare contractors, who are charged with all Medicare claims processing and related activities on behalf of the Agency. Respondents will be staff representatives of hospitals, skilled nursing facilities, rural health clinics, home health agencies, end-stage renal disease clinics, physicians, non-physicians, durable medical equipment suppliers, laboratories and ambulance providers. The survey will be used as a mechanism for evaluating and improving Medicare providers' satisfaction with their Medicare contractors. The results will provide CMS with a comprehensive review of contractor-provider business relations from the perspective of the ''customer'' or provider. The information will help the Agency appropriately address provider concerns about Medicare Contractors' performance, aid in business/contracting decisions, and assist or guide contractors in identifying/implementing ''best practices'' or quality improvement initiatives.; *Frequency:* On occasion; *Affected Public:* Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 6,052; *Total Annual Responses:* 6,052; *Total Annual Hours:* 3,331.

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Data Collection for the Second Generation Social Health Maintenance Organization Demonstration; *Form No.:* CMS–R–204 (OMB# 0938–0709; *Use:* The Centers for Medicare and Medicaid Services will continue to use the data collected under this effort to support the operational needs of the Congressionally-mandated and administratively extended Second Generation of the Social Health Maintenance Organization Demonstration; *Frequency:* Annually; *Affected Public:* Individuals or households; *Number of Respondents:* 15,000; *Total Annual Responses:* 15,000; *Total Annual Hours:* 3,000.

4. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Provider Reimbursement Manual, Part 1—Chapter 27, Sections 2721, 2722 and 2725, Request for Exception to End Stage Renal Disease Composite Rates and Supporting Regulations in 42 CFR 413.170 and 413.184; *Form No.:* CMS–9044 (OMB# 0938–0296); *Use:* This information collection describes the information End Stage Renal Disease facilities must submit in justifying an exception request to their composite rate for outpatient dialysis services; *Frequency:* On occasion; *Affected Public:* Business or other for-profit, not-for-profit institutions, and Federal government; *Number of Respondents:* 125; *Total Annual Responses:* 125; *Total Annual Hours:* 6,000.

5. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Current Beneficiary Survey (MCBS): Rounds 38–46; *Form No.:* CMS–P–0015A (OMB# 0938–0568); *Use:* The MCBS is a continuous, multipurpose survey of a nationally representative sample of aged and disabled persons enrolled in Medicare. The survey provides a comprehensive source of information on beneficiary characteristics, needs, utilization, and satisfaction with Medicare-related activities; *Frequency:* Other: 3 times a year; *Affected Public:* Individuals or households, business or other for-profit, and not-for-profit institutions; *Number of Respondents:* 16,500; *Total Annual Responses:* 49,500; *Total Annual Hours:* 50,325.

6. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Conditions of Coverage for Organ Procurement Organizations (OPOs) and Supporting Regulations in 42 CFR, Sections 486.304, 486.306, 486.307, 486.310, 486.316, 486.318, and 486.325; *Form No.:* CMS–R–13 (OMB# 0938–0688); *Use:* Organ Procurement Organizations are required to submit accurate data to CMS concerning population and information on donors and organs on an annual basis in order to assure maximum effectiveness in the procurement and distribution of organs; *Frequency:* Annually; *Affected Public:* Not-for-profit institutions; *Number of*

Respondents: 59; *Total Annual Responses:* 59; *Total Annual Hours:* 118.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at *http://cms.hhs.gov/regulations/pra/default.asp,* or e-mail your request, including your address, phone number, OMB number, and CMS 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 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Brenda Aguilar, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: January 8, 2004.

John P. Burke, III,

Paperwork Reduction Act Team Leader, CMS Reports Clearance Officer, Office of Strategic Operations and Strategic Affairs, Division of Regulations Development and Issuances.

[FR Doc. 04–983 Filed 1–15–04; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0295]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Establishing and Maintaining a List of U.S. Dairy Product Manufacturers/ Processors With Interest in Exporting to Chile

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Establishing and Maintaining a List of U.S. Dairy Product Manufacturers/ Processors With Interest in Exporting to Chile'' 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 October 8, 2003 (68 FR 58114), 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 0910–0509. The approval expires on December 31, 2006. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: January 6, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–942 Filed 1–15–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0267]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Postmarketing Studies for Licensed Biological Products; Status Reports

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 February 17, 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: JonnaLynn P. 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.

Postmarketing Studies for Licensed Biological Products; Status Reports—(OMB Control Number 0910–0433)—Extension

Section 130(a) of the Food and Drug Administration Modernization Act (Public Law 105–115) amended the Federal Food, Drug, and Cosmetic Act (the act) by adding a new provision (section 506B of the act (21 U.S.C. 356b)) requiring reports of postmarketing studies for approved human drugs and licensed biological products. Section 506B of the act provides FDA with additional authority to monitor the progress of postmarketing studies that applicants have made a commitment to conduct and requires the agency to make publicly available information that pertains to the status of these studies. Under section 506B(a) of the act, applicants that have committed to conduct a postmarketing study for an approved human drug or licensed biological product must submit to FDA a status report of the progress of the study or the reasons for the failure of the applicant to conduct the study. This report must be submitted within 1 year after the U.S. approval of the application and then annually until the study is completed or terminated. The reporting requirements for applicants of approved new drug applications and abbreviated new drug applications are under §314.81(b)(2)(vii) (21 CFR 314.81(b)(2)(vii)). The collection of information requirements for § 314.81(b)(2)(vii) are approved under OMB control number 0910–0001. The reporting requirements for applicants of approved biologics license applications (BLAs) or supplements to an application are under § 601.70 (21 CFR 601.70). Section 601.70 requires applicants of approved biologics license applications or supplements to an application to submit to FDA postmarketing status reports for studies of clinical safety, clinical efficacy, clinical pharmacology, and nonclinical toxicology that are required by FDA or that an applicant of a BLA commits to conduct, in writing, at the time of approval of an application or a supplement to an application, or after approval of an application or a supplement. Information submitted in a status report for §601.70(b) is limited to that which is needed to sufficiently identify each applicant that has committed to conduct a postmarketing study, the status of the study that is being reported, and the reasons, if any,