covering the costs of data collection of their own sample and the sharing of all other costs.

The purpose of the survey is to move the national health surveys of both countries toward closer comparability so the health status among residents of countries can be compared in a more concrete manner. This will allow researchers to study the effect of variations in health systems on health care, health status and functional status. This effort can also serve as a model for improving comparability among national health studies generally. A need for such comparability has been noted by the World Health Organization, the Centers for Disease Control and Prevention and the Robert Wood Johnson Foundation who is funding the study in part.

The specific data from the CUJHS may well contribute toward meeting some of the research needs directly. Its longer term impact will be to demonstrate best practices for use in bi-national and multi-national health surveys. The annual burden for this data collection is 2,292 hours.

Respondents	Number of respondents	Number of responses/respondent	Avg. burden/response (in hours)
Screener	7500	1	5/60
Survey	5000	1	20/60

Dated: August 6, 2002.

Nancy E. Cheal,

Acting Associate Director for Policy, Planning and Evaluation, , Centers for Disease Control and Prevention.

[FR Doc. 02–20427 Filed 8–12–02; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS–R–293]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare and Medicaid Services, HHS.

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.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Medicare Telephone Customer Satisfaction Survey; *Form No.:* CMS–R–293 (OMB# 0938–0780); *Use:* In response to the National Partnership for Reinventing Government Performances and Results Act (GPRA), CMS is implementing a number of initiatives to measure and then improve the customer service that is provided by Medicare Call Centers, that service over 21 million calls annually. This particular initiative is to provide the 75+ call centers with suitably trained staff and survey materials to conduct a standardized random sample of beneficiary calls, and then administer a customer satisfaction questionnaire. The goal is to develop a national baseline measure of customer satisfaction with the Medicare telephone service provided by carriers and fiscal intermediaries. The respondents for this study will consist of beneficiaries and their advocates who phone Medicare call centers.; *Frequency:* On occasion, semi -annually, and other (single 800# survey); *Affected Public:* Individuals or households; *Number of Respondents:* 50,000; *Total Annual Responses:* 50,000; *Total Annual Hours:* 3,500

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS'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 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 N2–14–26 7500 Security Boulevard Baltimore, Maryland 21244–1850.

Dated: August 6, 2002.

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. 02–20469 Filed 8–12–02; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS–2746]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare and Medicaid Services, HHS.

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.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* End Stage Renal Disease Death Notification; *Form No.:* CMS–2746 (OMB# 0938–0448); *Use:* The form is completed by all Medicare approved ESRD facilities upon the death of an ESRD patient. Its primary purpose is to collect fact and cause of death. Reports of deaths are used to show cause of death and demographic characteristics of these patients.; *Frequency:* On occasion, weekly; *Affected Public:* Business or other for-profit, Not-for-profit institutions, Federal Government; *Number of Respondents:* 4,500; *Total Annual Responses:* 63,989; *Total Annual Hours:* 1,088.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS'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 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 N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: August 6, 2002.

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. 02–20470 Filed 8–12–02; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0400]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Regulations Requiring Manufacturers to Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the 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: Submit written comments on the collection of information by September 12, 2002.

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: Stuart Shapiro, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Karen Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

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.

Regulations Requiring Manufacturers to Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients—(OMB Control Number 0910–0392)—Reinstatement

FDA regulations require pediatric studies of certain new and marketed drugs and biological products to ensure that those products that are likely to be commonly used in children or that represent a meaningful therapeutic benefit over existing treatments contain adequate pediatric labeling for the approved indications at the time of, or soon after, approval (see 63 FR 66632, December 2, 1998). Many drugs and biological products represent treatments that are the best available treatment for children, but most of them have not been adequately tested in the pediatric population. As a result, product labeling frequently fails to provide directions for safe and effective use in pediatric patients. The regulations are intended to increase the number of drugs and biological products, with clinically significant use in children, that carry adequate labeling for use in that subpopulation. Specifically, the regulations are intended to address the following concerns: (1) Avoidable adverse drug reactions in children—drug reactions that occur because of the use of inadvertent drug overdoses or other drug administration problems that could have been avoided with better information on appropriate pediatric use; and (2) undertreatment of children with a potentially safe and effective drug because the physician either prescribed an inadequate dosage or regimen, prescribed a less effective drug, or did not prescribe a drug, due to the physician's uncertainty about whether the drug or the dose was safe and effective in children.

The regulations contain the following reporting requirements that are subject to the PRA:

21 CFR 201.23(a)—Manufacturers of marketed drug products submit an application containing data adequate to assess whether the drug product is safe and effective in pediatric populations; applicants develop a pediatric formulation for FDA approval.

21 CFR 201.23(c)—Applicants request a full waiver of the requirements under § 201.23(a) by certifying that necessary studies are impossible or highly impractical or there is evidence that the product would be ineffective or unsafe in all pediatric age groups. Applicants request a partial waiver of the requirements under § 201.23(a) by certifying that: (1) The product does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in that age group, it is not likely to be used in a substantial number of patients in that age group, and the absence of adequate labeling could not pose significant risks to pediatric patients; or (2) necessary studies are impossible or highly impractical, or there is strong evidence that the product would be ineffective or unsafe in that age group, or the applicant can demonstrate that reasonable attempts to produce a pediatric formulation necessary for that age group have failed.

21 CFR 312.47(b)(1)(iv)—Sponsors submit background information on the sponsor's plan for phase 3, including plans for pediatric studies, including a time line for protocol finalization, enrollment, completion, and data analysis, or information to support any