description of the reconsideration and appeals processes. These notices fulfill the statutory requirement.; *Frequency:* On occasion and other: distribution; *Affected Public:* Individuals or households, business or other for-profit, not-for-profit institutions; *Number of Respondents:* 211; *Total Annual Responses:* 71,200; *Total Annual Hours:* 7,120.

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* End Stage Renal Disease Medical Evidence Report Medicare Entitlement and/or Patient Registration and Supporting Regulations in 42 CFR 405.2133; *Form No.:* CMS–2728 (OMB# 0938–0046); *Use:* This form captures the necessary medical information required to determine Medicare eligibility of an end stage renal disease claimant. It also captures the specific medical data required for research and policy decisions on this population as required by law.; *Frequency:* weekly, monthly, quarterly, semi-annually and annually; *Affected Public:* Individuals or households, business or other for-profit, not-for-profit institutions; *Number of Respondents:* 100,000; *Total Annual Responses:* 100,000; *Total Annual Hours:* 75,000.

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Home health Medicare Conditions of Participation (CoP) Information Collection Requirements and Supporting Regulations in 42 CFR 484.10, 484.12, 484.14, 484.16, 484.18, 484.36, 484.48, and 484.52; *Form No.:* CMS–R–39 (OMB# 0938–0365); *Use:* 42 CFR part 484 outlines Home Health Agency Medicare CoP to ensure HHAs meet the Federal patient health and safety regulations; *Frequency:* Annually; *Affected Public:* Business or other for-profit, not-for-profit institutions, Federal government, and State, local or tribal government; *Number of Respondents:* 7,422; *Total Annual Responses:* 7,422; *Total Annual Hours:* 854,891.

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; Fax (202)395–6929.

Dated: March 4, 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. 04–5412 Filed 3–10–04; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS–R–297]

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:* Request for Employment Information; *Form No.:*CMS–R–297 (OMB# 0938–0787); *Use:* This information is needed to determine whether a beneficiary can enroll in part B under section 1837(i) of the Act and/or qualify for a reduction in the premium amount under section 1839(b) of the Act.; *Frequency:* On occasion; *Affected Public:* Business or other for-profit; *Number of Respondents:* 5000; *Total Annual Responses:* 5000; *Total Annual Hours:* 750.

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://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 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: March 4, 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. 04–5413 Filed 3–10–04; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Industry Exchange Workshop on FDA Clinical Trial Requirements; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) Detroit District, in cooperation with the Society of Clinical Research Associates, (SoCRA) is announcing a workshop on FDA clinical trial statutory and regulatory requirements. Topics for discussion include: Pre-IND(investigational new drug application) meetings and FDA meeting process, medical device, drug and biological product aspects of clinical research, investigator initiated research, informed consent requirements, adverse event reporting, how FDA conducts bioresearch inspections, ethics in subject enrollment, FDA regulation of Institutional Review Boards, FDA and

confidence in the conduct of clinical research, and what happens after the FDA inspection. This 1 1/2-day workshop for the clinical research community targets sponsors, monitors, clinical investigators, institutional review boards and those who interact with them for the purpose of conducting FDA regulated clinical research. The workshop will include both industry and FDA perspectives on proper conduct of clinical trials regulated by FDA.

Date and Time: The public workshop is scheduled for Wednesday, April 21, 2004 from 8:30 a.m. to 4:45 p.m. and Thursday, April 22, 2004, from 8:45 a.m. to 12:30 p.m.

Location: The public workshop will be held at the Livonia, Michigan Holiday Inn, 17123 Laurel Park Dr. North, Livonia, MI 48152.

Contact: Nancy Bellamy, FDA, 300 River Pl., suite 5900, Detroit, MI 48207, 313–393–8143, FAX: 313–393–8139, e-mail *nbellamy@ora.fda.gov* or Marie Falcone, Industry and Small Business Representative, FDA, rm. 900 U.S. Customhouse, 200 Chestnut St., Philadelphia, PA 19106, 215–597–2120, ext. 4003, FAX: 215–597–5798, e-mail: *mfalcone@ora.fda.gov*.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number) and $485 (member) or $560 (non-member) registration fee made payable to SoCRA, P.O. Box 101, Furlong, PA 18925. To register via the Internet go to *http://www.socra.org/FDA__Conference.htm*. FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.

Registrar will also accept payment by major credit cards. For more information on the meeting, or for questions on registration, contact 800-SoCRA92 (800–762–7292), or 215–345–7369 or via e-mail to *socramail@aol.com*. Attendees are responsible for their own accommodations. To make reservations at the Holiday Inn Livonia at the reduced conference rate, contact the Holiday Inn at 734–464–1300 or at hotel FAX: 734–464–1596 before March 23, 2004.

The registration fee will be used to offset the expenses of hosting the conference, including meals, refreshments, meeting rooms, and materials. Space is limited, therefore interested parties are encouraged to register early. Limited onsite registration may be available. Please arrive early to ensure prompt registration.

If you need special accommodations due to a disability, please contact Marie Falcone at least 7 days in advance of the workshop.

SUPPLEMENTARY INFORMATION: The ''FDA Clinical Trials Statutory and Regulatory Requirements'' workshop helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health by educating researchers on proper conduct of clinical trials. FDA has made education of the research community a high priority to assure the quality of clinical data and protect research subjects.

The workshop helps to implement the objectives of section 406 of the FDA Modernization Act (21 U.S.C. 393) and the FDA Plan for Statutory Compliance, which includes working more closely with stakeholders and ensuring access to needed scientific and technical expertise. The workshop also furthers the goals of the Small Business Regulatory Enforcement Fairness Act (Public Law 104–121) by providing outreach activities by Government agencies directed to small businesses.

Dated: March 5, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–5489 Filed 3–10–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; National Center for Complementary and Alternative Medicine Office of Communications and Public Liaison Communications Program Planning and Evaluation

SUMMARY: Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Center for Complementary and Alternative Medicine (NCCAM), the National Institutes of Health (NIH), will submit to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. A notice of this proposed information collection was previously published in the **Federal Register** on September 12, 2003, page 53743, and allowed 60 days for public comment. In response to the notice, NCCAM received one request to learn more about the overall evaluation plans. The purpose of this notice is to announce a final 30 days for public comment. NIH may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection

Title: NCCAM Office of Communications and Public Liaison Communications Programs Planning and Evaluation. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* NCCAM provides the public, patients, families, health care providers, complementary and alternative medicine (CAM) practitioners, and other with the latest scientifically based information on CAM and information about NCCAM's programs through a variety of channels. NCCAM requests permission to collect data from individuals and organizations in order to conduct (1) Formative research and (2) evaluation of activities, using both qualitative and quantitative methods. OCPL communications goals include raising awareness of issues unique to CAM so that consumers and health care providers can make better, more informed decisions, and establishing NCCAM as the source for credible, authoritative CAM information. The response data collected under this generic clearance will be used to improve communication activities through (1) Identifying key audiences, (2) developing program plans to meet the needs of diverse audiences, (3) developing messages and evaluating how well they resonate with intended audiences, and (4) evaluating how well communications program reach their intended audiences. *Frequency of Response:* Periodically or as needed. *Affected Public:* Individuals and households; nonprofit institutions; Federal government; State, local, or tribal government. *Type of Respondents:* Members of the public, health care professionals, representatives of organizations. The annual reporting burden is as follows. *Estimated Number of Respondents:* 2,440. *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours per Response:* 0.29. *Estimated Annual Total Burden Hours Requested:* 713. There are no capital costs, operating costs, or maintenance costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the