

Purpose: This study group is charged with locating, evaluating, cataloguing, and copying documents that contain information about historical chemical or radionuclide releases from facilities at the Los Alamos National Laboratory since its inception. The purpose of this meeting is to review the goals, methods, and schedule of the project, discuss progress to date, provide a forum for community interaction, and serve as a vehicle for members of the public to express concerns and provide advice to CDC.

Matters To Be Discussed: Agenda items include a presentation from the National Center for Environmental Health (NCEH) and its contractor regarding the draft Interim Report of the project, the status of project work, and the outlook for continued CDC work at Los Alamos. There will be time for public input, questions, and comments.

Agenda items are subject to change as priorities dictate.

Contact Person for Additional Information: Phillip R. Green, Public Health Advisor, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, NCEH, CDC, 1600 Clifton Road, N.E. (MS-E39), Atlanta, GA 30333, telephone (404) 498-1717, fax (404) 498-1811.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and ATSDR.

Dated: March 5, 2004.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 04-5445 Filed 3-10-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Citizens Advisory Committee on Public Health Service Activities and Research at Department of Energy (DOE) Sites: Savannah River Site Health Effects Subcommittee (SRSHES)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR) announce the following meeting.

Name: Citizens Advisory Committee on Public Health Service Activities and Research at Department of Energy Sites: Savannah River Site Health Effects Subcommittee (SRSHES).

Time and Date: 8 a.m.-3:30 p.m., April 6, 2004.

Place: Adam's Mark Hotel Columbia, 1200 Hampton Street, Columbia, South Carolina 29201, telephone 803-771-7000, fax 803-254-2911.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people.

Background: Under a Memorandum of Understanding (MOU) signed in December 1990 with DOE, and replaced by MOUs signed in 1996 and 2000, the Department of Health and Human Services (HHS) was given the responsibility and resources for conducting analytic epidemiologic investigations of residents of communities in the vicinity of DOE facilities, workers at DOE facilities, and other persons potentially exposed to radiation or to potential hazards from non-nuclear energy production use. HHS delegated program responsibility to CDC.

In addition, a memo was signed in October 1990 and renewed in November 1992, 1996, and in 2000, between ATSDR and DOE. The MOU delineates the responsibilities and procedures for ATSDR's public health activities at DOE sites required under sections 104, 105, 107, and 120 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or "Superfund"). These activities include health consultations and public health assessments at DOE sites listed on, or proposed for, the Superfund National Priorities List and at sites that are the subject of petitions from the public; and other health-related activities such as epidemiologic studies, health surveillance, exposure and disease registries, health education, substance-specific applied research, emergency response, and preparation of toxicological profiles.

Purpose: This subcommittee is charged with providing advice and recommendations to the Director, CDC, and the Administrator, ATSDR, regarding community concerns pertaining to CDC's and ATSDR's public health activities and research at this DOE site. The purpose of this meeting is to provide a forum for community interaction and serve as a vehicle for community concerns to be expressed as advice and recommendations to CDC and ATSDR.

Matters to be Discussed: Agenda items include: a Report by Advanced Technologies and Laboratories International, Inc.; CDC Presentation on Completed Dose Reconstruction Projects at Other Sites; and Update from the National Institute for Occupational Safety and Health.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Phillip Green, Executive Secretary, SRSHES, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, National Center for Environmental Health, CDC, 1600 Clifton Road, NE., (E-39), Atlanta, Georgia 30333, telephone (404) 498-1800, fax (404) 498-1811.

The Director, Management Analysis and Services Office, has been delegated the authority to sign Federal Register notices pertaining to announcements of meetings and other committee management activities for both CDC and ATSDR.

Dated: March 5, 2004.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS-10003, CMS-2728, and CMS-R-39]

Agency Information Collection Activities: Submission for OMB Review; 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.

1. Type of Information Collection

Request: Extension of a currently approved collection; **Title of Information Collection:** Medicare+Choice Appeals Notices, "Notice of Denial of Medical Coverage", "Notice of Denial Payment"; **Form No.:** CMS-10003 (OMB# 0938-0829); **Use:** Section 1852(g)(1)(B) requires M+C organizations to provide determinations to deny coverage (i.e., medical services or payment) in writing and include a statement in understandable language of the reasons for the denial and a

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/pract/default.asp>, or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@hcf.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]

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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/pract/default.asp>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@hcf.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]

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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