Public Health Assessments Completed

AGENCY: Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: This notice announces those sites for which ATSDR has completed public health assessments during the period from October 2002 through December 2002. This list includes sites that are on or proposed for inclusion on the National Priorities List (NPL), and includes sites for which assessments were prepared in response to requests from the public.

FOR FURTHER INFORMATION CONTACT: Robert C. Williams, P.E., DEE, Assistant Surgeon General, Director, Division of Health Assessment and Consultation, Agency for Toxic Substances and Disease Registry, 1600 Clifton Road, NE., Mailstop E–32, Atlanta, Georgia 30333, telephone (404) 498–0007.

SUPPLEMENTARY INFORMATION: The most recent list of completed public health assessments was published in the Federal Register on December 4, 2002 (67 FR 72216). This announcement is the responsibility of ATSDR under the regulation, Public Health Assessments and Health Effects Studies of Hazardous Substances Releases and Facilities (42 CFR part 90). This rule sets forth ATSDR’s procedures for the conduct of public health assessments under section 104(i) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), as amended by the Superfund Amendments and Reauthorization Act (SARA) (42 U.S.C. 9604(i)).

Availability

The completed public health assessments and addenda are available for public inspection at the Division of Health Assessment and Consultation, Agency for Toxic Substances and Disease Registry, Building 1825, Century Blvd, Atlanta, Georgia (not a mailing address), between 8 a.m. and 4:30 p.m., Monday through Friday except legal holidays. The completed public health assessments are also available by mail through the U.S. Department of Commerce, National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, Virginia 22161, or by telephone at (703) 605–6000. NTIS charges for copies of public health assessments and addenda. The NTIS order numbers are listed in parentheses following the site names.

Public Health Assessments Completed or Issued

Between September 1, 2002 and December 31, 2002, public health assessments were issued for the sites listed below:

NPL Sites

Arkansas
Mountain Pine Pressure Treating (PB2003–100516).

Florida
Naval Air Station Cecil Field (a/k/a USN Air Station Cecil Field) (PB2003–101531).

Illinois
Lisle Residential Wells I (a/k/a Lockformer Company) (PB2003–100143).

Louisiana

New Hampshire
Gardner-Roussell Park and Dr. Norman W. Crisp Elementary School (a/k/a Dr. Crisp School/Gardner Roussell Park) (PB2003–100503).

New Jersey


New York
Huntington Landfill (a/k/a Huntington Town Landfill) (PB2003–100504).
Peter Cooper-Markham (a/k/a Peter Cooper Corporation (MARKHAMS)) (PB2003–100154).

Smithtown Groundwater Contamination (a/k/a Smithtown Ground Water Contamination) (PB2003–100147).

Pennsylvania
Naval Air Warfare Center (a/k/a Naval Air Development Center (8 Waste Areas)) (PB2003–100510).

Non NPL Petitioned Sites

None


Georgi Jones, Director, Office of Policy and External Affairs, Agency for Toxic Substances and Disease Registry.
14. Office of Operations Management (FAY)

- Analyzes and evaluates project time lines, schedules, and new methodologies. Evaluates and recommends project management alternatives to the Deputy Administrator/COO and the Agency.
- Prepares and presents recommendations to the Administrator, Deputy Administrator/COO and other high level CMS and Department officials on planning, leadership, implementation and policy issues concerning modifications to existing and proposed operating policies that will improve the administration and operations of programs and the Agency as a whole.
- Collaborates with appropriate CMS component(s) to collect and disseminate data on health care and insurance market trends that affect CMS’ business risk profile. The Risk Management Staff has the lead for monitoring indicators of risk associated with the operations of CMS and our business partners.
- Surveys risk assessment techniques in use in the private and public sectors and identifies and applies the most useful ones for CMS. Helps develop new risk assessment techniques and keeps abreast of methodological developments in the professional literature.
- Promotes and teaches risk assessment methods to business owners throughout CMS. Promotes awareness of the importance of risk analysis as a component of business planning and trains CMS staff in specific techniques and their applicability in particular situations.
- Provides consulting services internally to Agency management and staff to identify processes or contracts that need improvement, to develop improvement strategies, and to monitor processes and improvements over time.
- Participates in agency-wide initiatives to streamline operations, improve accountability and performance, and implement management best practices. Provides leadership, training, and coaching in the implementation of the initiatives.
- Promotes a continuous improvement ethos.

Specific Project Management Functions

- Develops, in conjunction with staff in CMS centers and offices, major project plans, implementation schedules and post implementation evaluations.
- Promotes project planning principles throughout the Agency and provides technical guidance to the Agency on project planning and management techniques.
- Reports to the COO and senior officials on progress of Agency priority projects. Negotiates with and supports project and component heads regarding project schedules, progress, etc.
- Prepares and presents recommendations to senior officials regarding major projects.
- Analyzes and evaluates project time lines, schedules, and new methodologies. Evaluates and recommends project management alternatives to the Deputy Administrator/COO and the Agency.
- Collaborates with the Risk Management Staff, Operational Review Staff, and CMS senior management to identify and address enterprise-wide risk factors that lead to ineffective or inefficient operations.
- Conducts process control analysis and tracking to ensure projects are running smoothly.
- Prepares and presents recommendations to the Administrator, Deputy Administrator/COO and other high level CMS and Department officials on planning, leadership, implementation and policy issues concerning modifications to existing and proposed operating policies that will improve the administration and operations of programs and the Agency as a whole.

Specific Operational Review Functions

- Identifies operational vulnerabilities in CMS and develops and executes an internal audit plan for each fiscal year, subject to approval by the Deputy Administrator and other senior leadership of CMS.
- Plans and conducts targeted internal audits and makes recommendations to strengthen internal audits and improve the operations of the Agency. The subjects of these reviews will be determined through regular periodic consultation with the Project Management Staff, Risk Management Staff, and the Director of the Office of Operations Management, and the Deputy Administrator. Drafts written reports summarizing conclusions and presents findings to appropriate officials for follow-up actions.
- Monitors the implementation of corrective actions relative to ORS recommendations, as well as those resulting from selected OIG/GAO audits to assure results and accountability.
- Reviews and evaluates enterprise-wide programs, projects, and processes to assess their effectiveness and efficiency, compliance with laws, regulations, or adequacy of management processes.
- Provides consulting services internally to Agency management and staff to identify processes or contracts that need improvement, to develop improvement strategies, and to monitor processes and improvements over time.
- Participates in agency-wide initiatives to streamline operations, improve accountability and performance, and implement management best practices. Provides leadership, training, and coaching in the implementation of the initiatives.
- Promotes a continuous improvement ethos.
- Collaborates with the Risk Management Staff, Project Management Staff, and CMS senior management to identify and address enterprise-wide risk factors that lead to ineffective or inefficient operations.
- Serves as the Agency focal point for implementation of OMB Circular A–76 and Federal Activities Reform Act and Competitive Outsourcing Initiative.
- Coordinates the development of the Agency’s submission to the OMB mandated Performance Assessment Rating Tool that links Agency program performance to the budget process. Serves as Agency liaison with the Department and OMB.

Special Racial and Ethnic Health Initiatives Functions

- Develops and sustains external contacts and partnerships regarding racial and ethnic health issues. Works collaboratively with the DHHS Office of Minority Health with responsibility for coordinating CMS activities with Departmental and White House initiatives that are directed by Executive Orders. Collaborates with the academic community, professional societies, civic, and social groups and non-government agencies concerning health problems of special populations.
- Provides direction in setting priorities, establishing goals and objectives, defining appropriate interventions, and assisting in determining evaluation tools for racial and ethnic health activities.
- Coordinates consolidated reporting on communication and educational activities targeting racial and ethnic populations.

Faith-Based and Community Initiatives Functions

- Coordinates a comprehensive effort to incorporate faith-based and other community organizations into CMS programs and initiatives.
- Develops and coordinates effective outreach and education efforts to
disseminate information regarding CMS programs, contracting opportunities, and other initiatives to faith-based and other community organizations.

19. Office of Health Insurance Portability and Accountability Act Standards (FHA)

- Develops, implements and administers the enforcement of the Health Insurance Portability and Accountability Act (HIPAA) including portability, transactions, code sets, identifiers, and security.
- Develops, implements and administers the enforcement of the Administrative Simplification Compliance Act (ASCA).
- Develops regulations to enforce the provisions of the HIPAA and the ASCA. Also develops regulations and guidance materials on HIPAA standards.
- Educates and reaches out to the public and internal CMS staff on HIPAA issues. Formulates and coordinates a public relations campaign, prepares and delivers presentations and speeches, responds to inquiries on HIPAA issues, and liaisons with industry representatives.
- Works with Federal departments and agencies to identify and adopt universal messaging and clinical health data standards, and represents CMS and HHS in national projects supporting the national health enterprise architecture and the National Health Information Infrastructure.
- Provides technical assistance regarding HIPAA standards and their implementation.
- Collaborates with the Department, especially the Office for Civil Rights, on HIPAA policy issues.
- Coordinates and provides guidance on legislative and regulatory issues.
- Provides assistance and guidance for HIPAA-related budget formulation and execution activities.
- Oversees the enforcement of the insurance portability provisions of HIPAA related to non-Federal governmental health plans and States.

Dated: November 21, 2002.

Ruben J. King-Shaw, Jr.,
Deputy Administrator and Chief Operating Officer, Centers for Medicare & Medicaid Services.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0259]

Agency Information Collection Activities; Announcement of OMB Approval; Telephone Questionnaire Administration to Control Subjects Recruited into FDA Lyme Vaccine Safety Study, “A Case-Control Study of HLA Type and T-Cell Reactivity to Recombinant Outer Surface Protein A and Human Leukocyte Function-Associated Antigen-1”

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled Telephone Questionnaire Administration to Control Subjects Recruited into FDA Lyme Vaccine Safety Study, “A Case-Control Study of HLA Type and T-Cell Reactivity to Recombinant Outer Surface Protein A and Human Leukocyte Function-Associated Antigen-1” 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 October 18, 2002 (67 FR 64937), 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 0910–0501. The approval expires on June 30, 2004. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.


Margaret M. Dotzel,
Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Contaminants and Natural Toxicants Subcommittee of the Food Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Contaminants and Natural Toxicants Subcommittee of the Food Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA’s regulatory issues.

Date and Time: The meeting will be held on March 18, 2003, from 8 a.m. to 6 p.m.; and on March 19, 2003, from 8:30 a.m. to 3 p.m.


Contact Person: Jeanne E. Latham, Center for Food Safety and Applied Nutrition (HFS–800), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1756, or FDA Advisory Committee Information Line, 1–800–741–8138 301–443–0572 in the Washington, DC area, code 10564. Please call the Information Line for up-to-date information on this meeting.

Agenda: The meeting’s purpose is to discuss the scientific issues and principles involved in assessing and evaluating Enterobacter sakazakii contamination in powdered infant formula, risk reduction strategies based on available data, and research questions and priorities. To ensure the presence of the most relevant expertise, the membership of the subcommittee, which has expertise in contaminants, will be augmented by consultants with expertise in infant formula.

The background material for this meeting will be posted on the Internet when available or one working day before the meeting at http://www.cfsan.fda.gov/~lrd/vidtel.html.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by March 3, 2003. Oral