Dated: October 1, 1997.

Carolyn J. Russell,

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

[FR Doc. 97–26496 Filed 10–6–97; 8:45 am]

BILLING CODE 4163–70–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

Citizens Advisory Committee on Public Health Service (PHS) Activities and Research at Department of Energy (DOE) Sites: Hanford Health Effects Subcommittee (HHES); Meeting Cancellation

This notice announces the cancellation of a previously announced meeting.

Federal Notice Citation of Previous Announcement: 62 FR 6539, February 12, 1997.

Previously Announced Times and Dates: 9 a.m.–5 p.m., and 6:30 p.m.–8:30 p.m., December 11, 1997; 9:30 a.m.–3:30 p.m., December 12, 1997.

Change in the Meeting: This meeting has been cancelled.

Contact Person for More Information: James K. Carpenter, Executive Secretary, Citizens Advisory Committee on PHS Activities and Research at DOE Sites: HHES, ATSDR, 1600 Clifton Road, NE, M/S E–32, Atlanta, Georgia 30333, telephone 404/639–6027.

Dated: October 1, 1997.

Carolyn J. Russell,

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

[FR Doc. 97–26497 Filed 10–6–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Institute for Occupational Safety and Health; Occupational Exposure to Inorganic Lead: Request for Comments and Information

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS).

ACTION: Request for Comments and Information Relevant to Occupational Exposure to Inorganic Lead.

SUMMARY: NIOSH is reviewing its recommendations contained in the document Criteria for a Recommended Standard....Occupational Exposure to Inorganic Lead, Revised Criteria—1978 [NIOSH 1978]. The evaluation of recent literature indicates that the NIOSH recommended exposure limit (REL) of 100 g/m^3 as an 8-hour time-weighted average (TWA) in that document does not sufficiently protect workers from the adverse effects of exposure to inorganic lead. NIOSH is requesting comments and information relevant to the evaluation of the potential health risks associated with occupational exposure to inorganic lead, as well as case reports or other data that demonstrate adverse health effects in workers exposed to inorganic lead at or below the OSHA permissible exposure limit (PEL) of 50 g/m^3 as an 8-hour TWA and any information pertinent to evaluating the technical feasibility of establishing a more protective REL for inorganic lead. NIOSH is also soliciting information on worker blood lead levels (BLLs) including data on methodologies used in measuring BLLs in the workplace and information that can be used for comparing airborne inorganic lead concentrations to observed BLLs.

NIOSH intends to analyze the feasibility of developing preventive measures including an REL that would provide better protection for workers. In the interim, NIOSH plans to adopt the more protective current OSHA PEL as its REL.

DATES: Written comments to this notice should be submitted to Diane Manning, NIOSH Docket Office, 4676 Columbia Parkway, M/S C–34, Cincinnati, Ohio 45226, on or before December 8, 1997. Comments may also be faxed to Diane Manning at (513) 533–8285 or submitted by email to dmm2@cdc.gov as WordPerfect 6.0/6.1 files.

FOR FURTHER INFORMATION CONTACT: Technical information may be obtained from Dr. Henryka Nagy, NIOSH, CDC, 4676 Columbia Parkway, M/S C–32, Cincinnati, Ohio 45226, telephone (513) 533–8369.

SUPPLEMENTARY INFORMATION: NIOSH has conducted a literature review of the health effects data on inorganic lead exposure and finds evidence that some adverse effects on the adult reproductive, cardiovascular, and hematologic systems, and on the development of children of exposed workers can occur at BLLs as low as 10 g/dl with no apparent threshold. At BLLs below 40 g/dl, many of the health effects associated with lead exposure would not necessarily be evident by routine physical examinations, but represent early stages in a continuum of disease development. The risk of developing adverse health effects appears to increase as BLLs rise above 40 g/dl.

In the NIOSH 1978 criteria document entitled Occupational Exposure to Inorganic Lead [NIOSH 1978], NIOSH recommended that exposure to inorganic lead be limited to 100 g/m^3 as an 8-hour TWA. This exposure limit was expected to maintain BLLs below 60 g/dl and to prevent clinical health effects to the hematologic system, the central and peripheral nervous systems, the reproductive system, and the kidneys. NIOSH also expressed concern about possible health effects that may occur below 60 g/dl:''In adhering to the 60 g/dl figure, NIOSH has not relinquished its concerns for possible effects that may occur below 60 g/dl. Adherence to this 60 g/dl figure should not be interpreted as a firm NIOSH opposition to establishing a lower blood lead standard. In fact, NIOSH endorses a lower blood lead standard as a future goal to provide greater assurance of safety.

In 1978, the Occupational Safety and Health Administration (OSHA) promulgated an occupational inorganic lead standard for general industry that incorporates a PEL of 50 g/m^3 which is intended to maintain worker BLLs below 40 g/dl. OSHA also included provisions for reducing the PEL for work shifts that exceed 8 hours, medical monitoring of workers exposed to airborne inorganic lead concentrations at or above the action level of 30 g/m^3, and medical removal of workers with BLLs greater than 50 g/dl. Workers are permitted to return to jobs involving inorganic lead exposure only after their BLLs have declined to 40 g/dl.

OSHA concluded in 1978 that a PEL of 50 g/m^3 represented the lowest level for which there was evidence of feasibility in most industries. OSHA also acknowledged that, based on the scientific data, the PEL of 50 g/m^3 did not provide protection from all adverse health effects of inorganic lead toxicity because the hematologic system, the nervous system, the kidneys, and the fetus can be adversely affected by exposures to inorganic lead resulting in BLLs below 40 g/dl (43 FR 52952, November 14, 1978). In May 1993, OSHA published the Interim Final Lead in Construction Standard (58 FR 26590, May 4, 1993). This standard extended the general industry standard for inorganic lead to include workers in the construction industry. No additional analysis of the health data was performed by OSHA in adopting this standard for the construction industry.

NIOSH seeks to obtain materials, including reports and research findings, to evaluate the health risks of occupational exposure to inorganic lead. Examples of requested information include, but are not be limited to, the following:

1. Occupational (environmental) exposure data.

2. Data on the effectiveness of engineering controls, work practices, training, personal protective equipment and other activities used to limit workers' exposure.

3. Identification of industries or occupations where intermittent or low concentrations of inorganic lead may occur.

4. Descriptions of work practices and engineering controls used to reduce workplace exposure.

5. Case reports or other health data that demonstrate adverse health effects in workers exposed to inorganic lead at or below the OSHA PEL and any information pertinent to evaluating the feasibility of establishing a more protective exposure limit. Case reports and health data should be submitted without personal identifiers.

6. Information regarding methods for BLL determination that could be used routinely in the workplace (e.g., determination of BLLs using portable equipment). NIOSH is evaluating whether the routine biological monitoring of inorganic lead exposed workers (through BLLs) may be a more appropriate measure than airborne concentrations for estimating the potential for developing adverse health effects.

This information will be used by NIOSH to determine the need for developing new recommendations for lowering the occupational exposure to inorganic lead and improving strategies for monitoring inorganic lead exposure.

All information received in response to this notice will be available for public examination and copying at the NIOSH Docket Office, 4676 Columbia Parkway, Cincinnati, Ohio 45226.

References

43 FR 52952, November 14, 1978. Chapter XVII—Occupational Safety and Health Administration, Department of Labor; Part 1910—Occupational safety and health standards: occupational exposure to lead.

58 FR 26590, May 4, 1993. Occupational Safety and Health Administration: lead exposure in construction; interim final rule. (To be codified at 29 CFR 1926.)

NIOSH [1978]. Criteria for a recommended standard . . . occupational exposure to inorganic lead, revised criteria. Rockville, MD: U.S. Department of Health, Education, and Welfare, Public Health Service, Center for Disease Control, National Institute for Occupational Safety and Health, DHEW (NIOSH) Publication No. 78–158.

Dated: September 29, 1997.

Linda Rosenstock, MD., MPH.,

Director, National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–26516 Filed 10–6–97; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Oak Ridge Workshop; Energy-Related Health Research Needs; Notice of a Meeting

The National Center for Environmental Health (NCEH) of the Centers for Disease Control and Prevention (CDC), in collaboration with the Department of Energy (DOE), the National Institute for Occupational Safety and Health, CDC, and the Agency for Toxic Substances and Disease Registry (ATSDR) announces the following meeting.

Name: Oak Ridge Workshop on Energy-Related Health Research Needs.

Times And Dates: 2 p.m.-9 p.m., October 30, 1997. 8:30 a.m.–12 noon, October 31, 1997.

Place: Ramada Inn and Suites, 420 South Illinois Avenue, Oak Ridge, Tennessee 37830, telephone 423/483–4371, FAX 423/483–5972.

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

Purpose: To solicit individual input from scientists, representatives of State and local health departments, DOE facility managers, workers, and the public regarding health research needs in and around the Oak Ridge DOE facility. The results of this workshop and similar workshops at other locations will be used to set the short- and long-range research plan for health studies at DOE facilities.

Matters To Be Discussed: The workshop will be divided into three breakout sessions which will include the following topics: (1) worker health studies, (2) environmental health studies, and (3) communications and community involvement.

Agenda items are subject to change as priorities dictate.

Due to circumstances beyond our control, it was necessary to reschedule the original meeting dates of September 22–23, 1997, to October 30–31, 1997.

Contact Person for More Information: Michael J. Sage, Deputy Chief, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, NCEH, CDC, 4770 Buford Highway, NE, (F–35), Atlanta, Georgia 30341–3724, telephone 770/488–7040, FAX 770/488–7044.

Dated: October 1, 1997.

Carolyn J. Russell,

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

[FR Doc. 97–26495 Filed 10–6–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97M–0416]

Johnson and Johnson Professional, Inc.; Premarket Approval of the S–ROM Poly-Dial Constrained Liner

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Johnson and Johnson Professional, Inc., Raynham, MA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the S–ROM Poly-Dial Constrained Liner. After reviewing the recommendation of the Orthopedic and Rehabilitation Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of June 20, 1997, of the approval of the application.

DATES: Petitions for administrative review by November 6, 1997.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration,12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Hany W. Demian, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2036.

SUPPLEMENTARY INFORMATION: On December 26, 1996, Johnson and Johnson Professional, Inc., Raynham, MA, 02767–0350, submitted to CDRH an application for premarket approval of the S–ROM Poly-Dial Constrained Liner. The device is a constrained acetabular liner and is indicated for use as a component of a total hip dislocation due to a history of prior dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease, or intraoperative instability.

On June 10, 1997, the Orthopedic and Rehabilitation Devices Panel of the