

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).

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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).

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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