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

Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On June 20, 1997, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before November 6, 1997, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: September 11, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–26563 Filed 10–6–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0411]

Bovine Spongiform Encephalopathy (BSE) in Products for Human Use; Guidance for Industry on the Sourcing and Processing of Gelatin to Reduce Potential Risk; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''The Sourcing and Processing of Gelatin to Reduce the Potential Risk Posed by Bovine Spongiform Encephalopathy (BSE) in FDA-Regulated Products for Human Use.'' This guidance is intended to provide information to industry on reducing the risk of transmission of BSE in gelatin for human use.

DATES: Submit written comments on this guidance by December 22, 1997.

ADDRESSES: Submit written requests for single copies of the guidance document to the Executive Secretariat (HF–40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request. Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Linda H. Gangloff, Executive Secretariat (HF–40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4450.

SUPPLEMENTARY INFORMATION: In 1994, representatives of the gelatin industry presented preliminary data to FDA concerning an experimental study of the infectivity of tissue infected with a transmissible spongiform encephalopathy (TSE). TSE's are rare, fatal, neurological diseases that occur in a number of animals (e.g., scrapie in sheep) and in humans (e.g., Creutzfeldt-Jakob disease). Based on the data presented, FDA decided that recommendations concerning bovine ingredients from countries that have reported BSE in FDA-regulated products would not include gelatin. A notice in the **Federal Register** of August 29, 1994 (59 FR 44584), summarized FDA's recommendations to reduce any potential BSE risk to humans from FDA-regulated products and clarified that FDA did not object at that time to gelatin for human use produced from bovine materials from countries reporting BSE.

FDA is committed to amending previous guidance to industry as new information becomes available. On April 23 and 24, 1997, FDA's TSE Advisory Committee discussed information on gelatin manufacturing practices and final results of the research study. At the end of the meeting, a majority of the advisory committee members agreed that current scientific evidence did not justify continued exemption of gelatin from restrictions recommended by FDA for other bovine-derived materials from BSE countries. They also stated that the potential risk of BSE transmission from bovine-derived gelatin varies depending on the country of origin of the raw materials, type of tissue used, the gelatin processes used, and the route of administration or exposure.

FDA has adopted ''Good Guidance Practices'' (GGP's) that set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). The guidance announced in this document is issued as a Level 1 guidance consistent with GGP's. The agency is accepting public comments, but it is implementing this guidance immediately because of public health concerns related to the use of gelatin. This guidance represents the agency's current thinking on reducing the potential risk of transmission of BSE related to the use of gelatin in FDA-regulated products for human use. It does not create or confer any rights for or on any person and does not operate to bind the FDA or the public. An alternative approach may be used if such an approach satisfies the requirements of the applicable statute, regulations, or both.

Interested persons may, on or before December 22, 1997, submit to the Dockets Management Branch (address above) written comments regarding this notice. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this