

Infected Women and Their Families in Botswana was published in the **Federal Register** on July 20, 2004, volume 69, number 138, pages 43421–43425. The notice is amended as follows:

- Page 43421, second column, the correct Catalog of Federal Domestic Assistance number is 93.941.
- Page 43421, second column, the correct application due date is August 19, 2004.

Dated: July 23, 2004.

William P. Nichols,

Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 04–17281 Filed 7–28–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Board on Radiation and Worker Health (ABRWH), National Institute for Occupational Safety and Health (NIOSH)

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) announces the following subcommittee and committee meetings:

Name: Advisory Board on Radiation and Worker Health (ABRWH), National Institute for Occupational Safety and Health (NIOSH), and Subcommittee for Dose Reconstruction and Site Profile Reviews of ABRWH, NIOSH.

Times and Dates: 1 p.m.–4 p.m., August 23, 2004, Subcommittee. 9 a.m.–8:30 p.m., August 24, 2004, Full Committee. 8 a.m.–4 p.m., August 25, 2004, Full Committee.

Place: Shilo Inn Suites, 780 Lindsay Boulevard, Idaho Falls, Idaho 83402, telephone 208/523–0088, fax 208/525–8420.

Status: Open to the public, limited only by the space available. The subcommittee meeting room accommodates approximately 20 people and the committee meeting room accommodates approximately 65 people.

Background: The Advisory Board on Radiation and Worker Health (“the Board”) was established under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) of 2000 to advise the President, through the Secretary of Health and Human Services (HHS), on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Board include providing advice on the development of probability of causation guidelines which have been promulgated by HHS as a final rule, advice on methods of dose reconstruction which have also been promulgated by HHS as a final rule, evaluation of the scientific validity and quality of dose reconstructions conducted by

the NIOSH for qualified cancer claimants, and advice on petitions to add classes of workers to the Special Exposure Cohort.

In December 2000 the President delegated responsibility for funding, staffing, and operating the Board to HHS, which subsequently delegated this authority to the CDC. NIOSH implements this responsibility for CDC. The charter was issued on August 3, 2001, and renewed on August 3, 2003.

Purpose: This board is charged with (a) providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this Program; and (c) upon request by the Secretary, HHS, advise the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class.

Matters To Be Discussed: Agenda for this meeting will focus on a subcommittee working session; program status reports from NIOSH and Department of Labor; site profile status; Privacy Act and FACA requirements; conflict of interest and quality assurance plan; use of uncertainty in dose reconstruction; scientific research issues update; subcommittee status; and a Board working session. There will be an evening public comment period scheduled for August 24, 2004, and a public comment period at midday on August 25, 2004.

The agenda is subject to change as priorities dictate.

Contact Person for More Information: Larry Elliott, Executive Secretary, ABRWH, NIOSH, CDC, 4676 Columbia Parkway, Cincinnati, Ohio 45226, telephone 513/533–6825, fax 513/533–6826.

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 the Agency for Toxic Substances and Disease Registry.

Dated: July 22, 2004.

Alvin Hall,

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

[FR Doc. 04–17214 Filed 7–28–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002E–0342]

Determination of Regulatory Review Period for Purposes of Patent Extension; LEA’S SHIELD

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for LEA’S SHIELD and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that medical device.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Claudia V. Grillo, Office of Regulatory Policy (HFD–013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240–453–6699.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product’s regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA’s determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA recently approved for marketing the medical device LEA’S SHIELD. LEA’S SHIELD is indicated for use by