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]

BILLING CODE 4163–18–P

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]

BILLING CODE 4163–19–P

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

women of childbearing age who desire to prevent or postpone pregnancy. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for LEA'S SHIELD (U.S. Patent No. 4,703,752) from Shlome Gabbay, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 3, 2003, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of LEA'S SHIELD represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for LEA'S SHIELD is 5,596 days. Of this time, 5,418 days occurred during the testing phase of the regulatory review period, while 178 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)) involving this device became effective*: November 19, 1986. FDA has verified the applicant's claim that the date the investigational device exemption required under section 520(g) of the act for human tests to begin became effective November 19, 1986.

2. *The date the application was initially submitted with respect to the device under section 515 of the act (21 U.S.C. 360e)*: September 18, 2001. FDA has verified the applicant's claim that the premarket approval application (PMA) for LEA'S SHIELD (PMA P010046) was initially submitted September 18, 2001.

3. *The date the application was approved*: March 14, 2002. FDA has verified the applicant's claim that PMA P010046 was approved on March 14, 2002.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,825 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by September 27, 2004. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by January 25, 2005. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information 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 document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 24, 2004.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 04–17209 Filed 7–28–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0558]

Compliance Policy Guide, Guidance Levels for Radionuclides in Domestic and Imported Foods, Availability; and Supporting Document, Supporting Document for Guidance Levels for Radionuclides in Domestic and Imported Foods, Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a compliance policy guide (CPG) entitled ''Guidance Levels for Radionuclides in Domestic and Imported Foods.'' This document is intended to make FDA offices and the industry aware of FDA's guidance for enforcement concerning radionuclide activity concentration in domestic food in interstate commerce or food offered for import. This CPG rescinds and replaces CPG Sec. 560.750 Radionuclides in Imported Foods—Levels of Concern (CPG 7119.14). The agency also is announcing the availability of a final supporting document entitled ''Supporting Document for Guidance Levels for Radionuclides in Domestic and Imported Foods.''

DATES: Submit written or electronic comments concerning the CPG or the final supporting document at any time.

ADDRESSES: Submit written requests for single copies of the CPG entitled ''Guidance Levels for Radionuclides in Domestic and Imported Foods'' and/or the final supporting document entitled ''Supporting Document for Guidance Levels for Radionuclides in Domestic and Imported Foods'' to Paul South (see **FOR FURTHER INFORMATION CONTACT**). Send two self-addressed adhesive labels to assist that office in processing your request. Submit written comments 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*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to these documents.

FOR FURTHER INFORMATION CONTACT: Paul South, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1640.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 14, 2004 (69 FR 2146), FDA announced the availability of a draft CPG entitled ''Guidance Levels for Radionuclides in Domestic and Imported Foods,'' and a draft supporting document entitled ''Supporting Document for Guidance Levels for Radionuclides in Domestic and Imported Foods.'' After considering comments received on these documents, FDA has finalized the CPG and supporting document. The CPG rescinds and replaces CPG Sec. 560.750 Radionuclides in Imported Foods—Levels of Concern (CPG 7119.14).

FDA received five comments on the draft CPG. The comments represented the views of individual consumers, a Federal agency, a State health department, and a foreign government. One comment was rejected because it was outside the scope of the draft CPG. The majority of comments supported the proposed guidance levels while a number of comments suggested changes or modification to other aspects of the draft CPG. After considering carefully the comments received, the agency revised the draft CPG to include a reference to methods for radionuclide analysis of foods.

The CPG is being issued as level 1 guidance consistent with FDA's good