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

guidance practices regulation (21 CFR 10.115). The CPG represents the agency's current thinking on its enforcement process concerning the adulteration of food with radionuclides. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding 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.'' Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the CPG, the final supporting document, and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the CPG and final supporting document may be accessed from the home pages of the Center for Food Safety and Applied Nutrition at *http://www.cfsan.fda.gov* and the Office of Regulatory Affairs at *http://www.fda.gov/ora/*.

Dated: July 22, 2004.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 04–17208 Filed 7–28–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Program Exclusions: Correction

AGENCY: Office of Inspector General, HHS.

ACTION: Notice of program exclusions; correction.

SUMMARY: The HHS Office of Inspector General published a document in the **Federal Register** of February 14, 2003, imposed exclusions. The document contained an incorrect exclusion type.

FOR FURTHER INFORMATION CONTACT: Jacqueline Freeman, (410) 786–5197.

Correction

In the **Federal Register** of February 14, 2003, in FR Doc. 68 FR 7569, on page 7569, in the second column, correct the ''exclusion type'' caption to read:

Fraud/Kickbacks/Other Prohibited Acts/Settlement Agreements

L & L Psychological Svcs, P C, Old Greenwich, CT, 10/31/2002.

Michael W. Lonski, Old Greenwich, CT, 10/31/2002.

Michael Lonski, PhD, P C, Old Greenwich, CT, 10/31/2002.

Dated: July 20, 2004.

Katherine B. Petrowski,

Director, Exclusions Staff, Office of Inspector General.

[FR Doc. 04–17230 Filed 7–28–04; 8:45 am]

BILLING CODE 4150–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[USCG–2004–17696]

Main Pass Energy Hub LLC Liquefied Natural Gas Deepwater Port License Application; Preparation of Environmental Impact Statement

AGENCY: Coast Guard, DHS; and Maritime Administration, DOT.

ACTION: Notice of intent; notice of public meeting; and request for public comments.

SUMMARY: The U.S. Coast Guard and the Maritime Administration announce that the Coast Guard intends to prepare an environmental impact statement as part of the environmental review of the license application for the proposed Main Pass Energy Hub deepwater port, to be located approximately 16 miles southeast of Venice, Louisiana with its associated onshore and offshore components. Publication of this notice begins a public scoping process that will help determine the scope of issues to be addressed in the environmental impact statement and identify the significant environmental issues related to this license application. Finally, this notice solicits public involvement in the scoping process, and announces public meetings and a public comment period to facilitate that involvement.

DATES: The public meetings will be held August 10, 11, and 12, 2004, from 3 p.m. to 7 p.m. in Mobile, Alabama, Pascagoula, Mississippi, and New Orleans, Louisiana, respectively. Each meeting will consist of an informational open house, from 3 p.m. to 4:30 p.m., and a public scoping meeting, from 5 p.m. to 7 p.m. All meeting spaces will be wheelchair-accessible. Comments and related material must reach the docket on or before August 30, 2004.

ADDRESSES:

The Mobile, Alabama informational open house and public meeting will be held at:

Mobile Government Plaza, 205 Government Street, Mobile, Alabama 36644, (251) 574–5058.

The Pascagoula, Mississippi informational open house and public meeting will be held at:

Jackson County Fairgrounds Assembly Hall, 2902 Shortcut Road, Pascagoula, Mississippi 39567, (228) 762–6043.

The New Orleans, Louisiana informational open house and public meeting will be held at:

New Orleans Marriott Hotel, 555 Canal Street, New Orleans, Louisiana 70130, 504–581–1000.

You need not attend the meetings in order to comment. You may also submit comments identified by docket number USCG–2004–17696 to the Docket Management Facility at the U.S. Department of Transportation. To avoid duplication, please use only one of the following methods:

(1) Electronically through the Web site for the Docket Management System, at *http://dms.dot.gov*.

(2) By mail to the Docket Management Facility, U.S. Department of Transportation, Room PL–401, 400 Seventh Street SW., Washington, DC 20590–0001.

(3) By fax to the Docket Management Facility at (202) 493–2251.

(4) By delivery to Room PL–401 on the Plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, from 9 a.m. to 5 p.m., Monday through Friday, except Federal holidays. The telephone number is (202) 366–9329.

(5) By the Federal eRulemaking Portal at *http://www.regulations.gov/*.

The Docket Management Facility maintains the public docket for this notice. Comments and material received from the public will become part of this docket and will be available for inspection or copying in Room PL–401 on the Plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, from 9 a.m. to 5 p.m. Monday through Friday, except Federal holidays. This docket may also be found on the Internet at *http://dms.dot.gov*.