**SUMMARY:** The Food and Drug Administration (FDA) is providing an opportunity for interested persons to provide information for a scientific literature review related to the health effects of dental amalgam in humans. Over the years there has been concern about the safe use of dental amalgam because of the presence of mercury. FDA is publishing this notice to gather recommendations from the scientific and lay communities about peer-reviewed journal articles from 1996 to 2002 that address human health risks from dental amalgam.

**DATES:** Submit information by June 2, 2003.

**ADDRESSES:** Submit written information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic information to http://www.fda.gov/dockets/ecomments.

**FOR FURTHER INFORMATION CONTACT:** Susan Runner, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–5283.

**SUPPLEMENTARY INFORMATION:** Dental amalgam has been in use as a restorative material for approximately 150 years. It consists of an alloy of powdered silver, tin, copper and sometimes smaller amounts of zinc, palladium, or indium. Elemental liquid mercury holds these powders together. There has been concern about the safety of dental amalgam because of its mercury content. In 1993, to address this concern, the Subcommittee on Risk Management of the Committee to Coordinate Environmental Health and Related Programs of the Public Health Service (PHS) completed a major review of the scientific literature on the use and safety of dental amalgam.

The review concluded that there was no evidence that dental amalgam posed a serious health risk in humans except in the very few instances of localized allergic reactions. The World Health Organization as well as the Working Group on Dental Amalgam of the Environmental Health Policy Committee of the PHS reaffirmed this conclusion.

In 1997, the Working Group on Dental Amalgam, with input from a broad cross-section of scientists and dental professionals, issued a joint report. This report indicated that the current body of literature through 1997 does not support claims that individuals with dental amalgam restorations will experience adverse effects, except for rare allergic or hypersensitivity reactions. Adverse effects include neurological, renal, or developmental effects.

There was a review of the peer-reviewed scientific literature on studies of the health effects of dental amalgam in 1993 and 1998. A current review, covering the literature from 1996 through 2002, is in the planning stages. The National Institute of Dental and Craniofacial Research in conjunction with the Centers for Disease Control and Prevention and FDA are sponsoring the review. The purpose of the review is to determine whether any studies published in the peer-reviewed, scientific literature provide new evidence related to the health effects of dental amalgam in humans. An independent group will conduct the review in the latter part of 2003.

The review will include articles from standard bibliometric databases as well as suggestions from the scientific and lay communities.

Scientific and lay communities should provide the following information to recommend an article for consideration:

- Name(s) of author(s),
- Complete title of article,
- Name of peer-reviewed journal,
- Year of publication,
- Volume number of journal,
- Page numbers of article.

Recommended articles should shed light on the possible health effects of dental amalgam in humans. Articles published in peer-reviewed journals should be from the time period between January 1, 1996, and June 1, 2003.

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic information regarding this document. Submit a single copy of electronic information or two paper copies of any mailed information, except individuals may submit one paper copy. Information is to be identified with the docket number found in brackets in the heading of this document. Any received information may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 1, 2003.

**Linda S. Kahan,**

*Deputy Director, Center for Devices and Radiological Health.*

[FR Doc. 03–11648 Filed 5–8–03; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 03F–0182]**

### Food Steris Corp.; Filing of Food Additive Petition

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that Steris Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of ionizing radiation for the control of microbial contamination on dietary supplements up to a maximum absorbed dose of 30 kiloGray (kGy).

**FOR FURTHER INFORMATION CONTACT:** Lane A. Highbarger, Center for Food Safety and Applied Nutrition (HFS–255), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 202–418–3032.

**SUPPLEMENTARY INFORMATION:** Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 2M4741) has been filed by Steris Corp., P.O. Box 147, St. Louis, MO 63166. The petition proposes that the food additive regulations in part 179 *Irradiation in the Production, Processing and Handling of Food* (21 CFR part 179) be amended to provide for the safe use of ionizing radiation for the control of microbial contamination on dietary supplements, and ingredients used in the manufacture of dietary supplements, up to a maximum absorbed dose of 30 kGy.

The agency has determined under 21 CFR 25.32(j) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: April 16, 2003.

**Alan M. Rulis,**

*Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.*

[FR Doc. 03–11496 Filed 5–8–03; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### The Sixth Annual FDA–Orange County Regulatory Affairs (OCRA) Educational Conference ''FDA and OCRA: Understanding the Changing Landscape''

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of meeting.

The Food and Drug Administration (FDA) is announcing its sixth annual educational conference entitled ''FDA and OCRA: Understanding the Changing Landscape'' cosponsored with OCRA. The conference is intended to provide the drug, device and biologics industries with an opportunity to interact with FDA reviewers and compliance officers from FDA's centers and district offices, as well as other industry experts. The main focus of this interactive conference will be product approval, compliance, and risk management in the three medical product areas. Industry speakers, interactive questions and answer, and workshop sessions will also be included to assure open exchange and dialogue on the relevant regulatory issues.

*Date and Time*: The meeting will be held on June 4 and 5, 2003, from 7:30 a.m. to 5 p.m.

*Location*: The meeting will be held at The Irvine Marriott, 18000 Von Karman Ave., Irvine, CA.

*Contact*: Ramlah Oma, Food and Drug Administration, 19900 MacArthur Blvd., suite 300, Irvine, CA 92612, 949–798–7611, FAX 949–798–7656, or OCRA, Attention to detail (ATD), 111 East Avenida San Gabriel, San Clemente, CA 92672, 949–366–1056, FAX 949–366–1057, Web site: http://www.ocra-dg.org. (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after the document publishes in the **Federal Register**.)

*Registration and Meeting Information*: See OCRA Web site at http://www.ocra-dg.org. Contact ATD at 949–366–1056.

*Before May 20, 2003, registration fees are as follows*: $425.00 for members, $500.00 for nonmembers, and $275.00 for FDA/government/full-time students with proper identification. After May 20, 2003, $495.00 for members, $575.00 for nonmembers, and $325.00 for FDA/government/full-time students with proper identification.

If you need special accommodations due to a disability, please contact Ramlah Oma at least 10 days in advance.

Dated: May 2, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 03–11651 Filed 5–8–03; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Psychopharmacologic Drugs Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee*: Psychopharmacologic Drugs Advisory Committee.

*General Function of the Committee*: To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time*: The meeting will be held on June 16, 2003, from 8 a.m. to 5 p.m.

*Location*: Marriott Washingtonian Center, Grand Ballroom, 9751 Washingtonian Blvd., Gaithersburg, MD.

*Contact Person*: Jayne E. Peterson, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, e-mail: petersonj@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12544. Please call the Information Line for up-to-date information on this meeting.

*Agenda*: On June 16, 2003, the committee will discuss the white blood cell (WBC) monitoring schedule for patients being treated long-term with clozapine. Currently, the WBC monitoring schedule is weekly for the first 6 months of continuous therapy and biweekly thereafter. The committee will consider the question of whether the frequency of WBC monitoring can be diminished further following some period of biweekly monitoring. When available, background materials for this meeting will be posted 1-business day prior to the meeting on the FDA Web site at: www.fda.gov/ohrms/dockets/ac/acmenu.htm. (Click on the year 2003 and scroll down to Psychopharmacologic Drugs Advisory Committee.)

*Procedure*: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by June 9, 2003. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before June 9, 2003, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Jayne Peterson at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 5, 2003.

**Peter J. Pitts,**

*Associate Commissioner for External Relations.*

[FR Doc. 03–11649 Filed 5–8–03; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 02N–0528]**

### Risk Management; Public Workshop; Reopening of Comment Period

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop; reopening of comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is reopening until May 30, 2003, the comment period for three concept papers entitled ''Premarketing Risk Assessment,'' ''Risk Management Programs,'' and ''Risk Assessment of Observational Data: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment.'' The document that requested public input, review, and comments for the three concept papers was published in