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]

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