

Each public meeting will provide an opportunity for an open comment session where attendees can express their views.

#### IV. Registration and Requests for Oral Presentations

Send registration information (including name, title, firm name, address, telephone, e-mail, and fax number), and written material and requests to make oral presentations, to the appropriate contact person listed in section III of this document by July 31, 1998.

If you need special accommodations due to a disability, please contact the appropriate contact person listed in section III of this document at least 7 days in advance.

#### V. Additional Meetings

The public meeting for the Center for Food Safety and Applied Nutrition (CFSAN) was held on June 24 and 25, 1998. The comment period associated with the CFSAN meeting closed on July 15, 1998. A summary of the views presented at the CFSAN meeting is available on the CFSAN website "<http://www.cfsan.fda.gov>". For information on the CFSAN meeting, contact Tracy S. Summers, Center for Food Safety and Applied Nutrition (HFS-1), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4850, FAX 202-205-5025, e-mail "tsummers@bangate.fda.gov".

An additional public meeting is being planned for September 15, 1998, to obtain stakeholder views on potential recurring themes and the best approach for consolidating these themes agency wide. A separate notice of this meeting will be published in the **Federal Register**.

#### VI. Transcripts

Transcripts of these meetings may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page. The transcript of the meeting will be available for public examination at the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday, as well as on the FDA website "<http://www.fda.gov>".

Dated: July 20, 1998.

**William K. Hubbard,**

Associate Commissioner for Policy Coordination.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Dental Products Panel of the Medical Devices 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). At least one portion of the meeting will be closed to the public.

*Name of Committee:* Dental Products Panel of the Medical Devices 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 August 4, 1998, 10:30 a.m. to 6:30 p.m., and August 5, 1998, 8 a.m. to 3 p.m.

*Location:* Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD.

*Contact Person:* Pamela D. Scott, Center for Devices and Radiological Health (HFZ-480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-827-5283, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12518. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* On August 4, 1998, the committee will discuss: (1) Previously unclassified devices for use in the diagnosis and/or treatment of temporomandibular joint dysfunction and oral-facial pain, (2) devices that FDA believes may fall within a present device classification and those devices that do not fall within a present device classification and thus remain unclassified, and (3) classification of the devices that remain unclassified. On August 5, 1998, the committee will continue discussion of the classification of devices for use in the diagnosis and/or treatment of temporomandibular joint dysfunction and oral-facial pain that remain unclassified. The list of those devices that FDA believes may fall within a present device classification and those devices that do not fall within a present device classification and thus remain unclassified will be placed on the FDA web site at "<http://www.fda.gov/cdrh/degenint.html>".

*Procedure:* On August 4, 1998, from 10:30 a.m. to 5:30 p.m. and on August 5, 1998, from 8 a.m. to 3 p.m., the meeting is open to the public. 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 July 31, 1998. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. on August 4, 1998, and between approximately 8:10 a.m. and 8:40 a.m. on August 5, 1998. Near the end of committee deliberations, a 30-minute open public session will be conducted for interested persons to address issues specific to the classification before the committee. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 31, 1998, 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.

*Closed Committee Deliberations:* On August 4, 1998, from 5:30 p.m. to 6:30 p.m., the meeting will be closed to permit discussion of trade secret and/or confidential information regarding dental device issues (5 U.S.C. 552b(c)(4)). The meeting will discuss classified device issues.

FDA regrets that it was unable to publish this notice 15 days prior to the August 4 and 5, 1998, Dental Products Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Dental Products Panel of the Medical Devices Advisory Committee were available at this time, the Commissioner concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice. I11Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 21, 1998.

**Michael A. Friedman,**

Deputy Commissioner for Operations.

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