

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

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**Orthopaedic and Rehabilitation Devices 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:* Orthopaedic and Rehabilitation Devices 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 8, 2001, from 9:30 a.m. to 4:30 p.m., and August 9, 2001, from 9:30 a.m. to 4 p.m.

*Location:* Holiday Inn, Walker/Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

*Contact:* Hany W. Demian, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2036, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12521. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* The committee will discuss and make recommendations on the reclassification of metal on metal total hip arthroplasty devices. Also, the committee will discuss, make recommendations, and vote on premarket approval application (PMA) for a metacarpophalangeal finger joint prosthesis.

Background information for each day's topic, including the agenda and questions for the committee, will be available to the public 1 business day before the meeting, on the Internet at <http://www.fda.gov/cdrh/panelmtg.html>. Material for the August 8 meeting will be posted on August 7, 2001; material for the August 9 meeting will be posted on August 8, 2001.

*Procedure:* On August 8, 2001, from 9:30 a.m. to 3:30 p.m., and on August 9, 2001, from 9:30 a.m. to 4 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 August 1, 2001. Oral presentations from the public will be scheduled between approximately 9:30 a.m. and 10 a.m. on August 8, 2001, and between approximately 9:30 a.m. and 10 a.m. on August 9, 2001. On both days, near the end of the committee deliberations for the reclassification petition and the PMA, a 30-minute open public session will be conducted for interested persons to address issues specific to the submission before the committee. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before August 1, 2001, 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 8, 2001, from 3:30 p.m. to 4:30 p.m., the meeting will be closed to the public to permit FDA to present to the committee trade secret and/or confidential information (5 U.S.C. 552b(c)(4)) regarding present and future FDA issues.

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

Dated: 7-20-01  
July 20, 2001.

Linda A. Suydam  
Linda A. Suydam,  
Senior Associate Commissioner.

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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