

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 31, 2004, from 8 a.m. to 4:30 p.m.

Location: Hilton Washington DC North/Gaithersburg, Ballroom Salons A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Janet L. Scudiero, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1184, ext. 176, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512521. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote on a premarket approval application for an interspinous process distraction system intended for treatment of patients aged 50 or older suffering from neurogenic intermittent claudication secondary to mild or moderate lumbar spinal stenosis who have undergone a regimen of non-operative treatment. Background information for the topics, 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>.

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 August 17, 2004. Oral presentations from the public will be scheduled for approximately 30 minutes at the beginning of committee deliberations and for approximately 30 minutes near the end of the deliberations. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before August 17, 2004, 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 Shirley Meeks at 301-594-1283, ext.105, 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: July 22, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 04-17446 Filed 7-30-04; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225-04-4004]

Memorandum of Understanding Between the Food and Drug Administration and the Harvard-Massachusetts Institute of Technology Division of Health Sciences and Technology

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between the Food and Drug Administration and the Harvard-Massachusetts Institute of Technology Division of Health Sciences and Technology, to establish the framework for a collaborative partnership on mutually agreed activities in the areas of scientific research and education.

DATES: The agreement became effective March 29, 2004.

FOR FURTHER INFORMATION CONTACT: Mary I. Poos, Office of External Relations (HF-10), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2825.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c),

which states that all written agreements and MOU's between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: July 21, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04-17513 Filed 7-30-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225-04-4003]

Memorandum of Understanding Between the Food and Drug Administration and the University of California, Lawrence Livermore National Laboratory

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between FDA and the University of California (UC), Lawrence Livermore National Laboratory to establish the framework for collaborative research and development and emergency triage response efforts. FDA and UC Lawrence Livermore National Laboratory will work collaboratively to expedite development of methods and technologies that are needed to address Homeland Security issues.

DATES: The agreement became effective February 23, 2004.

FOR FURTHER INFORMATION CONTACT: Karen A. Wolnik, Forensic Chemistry Center (HFR-CE502), Food and Drug Administration, 6751 Steger Dr., Cincinnati, OH 45237, 513-679-2700 ext. 181.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and MOUs between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: July 21, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.