affiliates, partners, and parent firms, may qualify for a fee waiver for their first PMA, and for lower rates for subsequent PMAs, PMRs, supplements, and 510(k)s.

Even if a firm qualified under MDUFMA as a small business in FY 2004, it must obtain a new small business certification and decision number for FY 2005 and for each subsequent fiscal year. This can be initiated any time after the publication of this document. For FY 2005, firms that have not received an FY 2005 small business qualification decision number from FDA will not be permitted to submit the reduced small business fees. FDA urges firms to apply for this qualification at least 60 days before they intend to submit their application and fee.

To qualify, you are required to submit the following:

(1) Certified copies of your Federal Income Tax Return for the most recent taxable year (2003 or later), including certified copies of the income tax returns of your affiliates, partners, and parent firms.

(2) A certified list of all parents, partners, and affiliate firms since October 1, 2002.

You can find information for determining if an applicant qualifies for a small business first-time PMA waiver and lower rates for subsequent applications on the FDA Web site at *http://www.fda.gov/oc/mdufma*. At that Web site, under the heading ''Guidance Documents,'' click on the link ''Qualifying as a Small Business.'' This Web site provides detailed instructions and the address for mailing documentation to support qualification as a small business under MDUFMA.

VI. Procedures for Paying Application Fees

Any application or supplement subject to fees under MDUFMA that is received on or after October 1, 2004, through September 30, 2005, is subject to the FY 2005 fee rate. The later of the date that the application is received in the reviewing center's document room or the date that the check is received by the US Bank determines whether the fee rates for FY 2004 or 2005 apply. FDA must receive the correct fee at the time that an application is submitted, or the application will not be accepted for filing or review.

FDA requests that you follow the steps in the following paragraphs before submitting a medical device application subject to a fee. Please pay close attention to these procedures to ensure that FDA links the fee with the correct application. (Note: In no case should the check for the fee be submitted to FDA with the application.)

A. Step One—Secure a Payment Identification Number and Medical Device User Fee Cover Sheet From FDA Before Submitting Either the Application or the Payment. Note: FY 2005 Fee Rates Will be Available on the Cover Sheet Web Site Beginning on August 25, 2004

Log onto the MDUFMA Web site at *http://www.fda.gov/oc/mdufma* and, under the forms heading, click on the link ''User Fee Cover Sheet.'' Complete the Medical Device User Fee Cover Sheet. Be sure you chose the correct application submission date range. (Two choices will be offered from August 25 until the middle of October 2004. One choice is for applications that will be received on or before September 30, 2004, which will be subject to FY 2004 fee rates. A second choice is for applications that will be received on or after October 1, 2004, which will be subject to FY 2005 fee rates.) After completing data entry, print a copy of the Medical Device User Fee Cover Sheet and note the unique Payment Identification Number located in the upper right-hand corner of the printed cover sheet.

B. Step Two—Electronically Transmit a Copy of the Printed Cover Sheet With the Payment Identification Number to FDA's Office of Financial Management

Once you are satisfied that the data on the cover sheet is accurate, electronically transmit that data to FDA according to instructions on the screen. Since electronic transmission is possible, applicants are required to set up a user account and use passwords to assure data security in the creation and electronic submission of cover sheets.

C. Step Three—Mail Payment and a Copy of the Completed Medical Device User Fee Cover Sheet to the St. Louis Address Specified Below

- Make the payment in U.S. currency by check, bank draft, or U.S. Postal money order payable to the Food and Drug Administration. (The tax identification number of the Food and Drug Administration is 53–0196965, should your accounting department need this information.)
- Please write your application's unique Payment Identification Number, from the upper right-hand corner of your completed Medical Device User Fee Cover Sheet, on your check, bank draft, or U.S. Postal money order.
- Mail the payment and a copy of the completed Medical Device User Fee Cover Sheet to: Food and Drug Administration, P.O. Box 956733, St. Louis, MO 63195–6733.

If you prefer to send a check by a courier such as FEDEX or UPS, the courier may deliver the checks to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101.

(Note: This address is for courier delivery only. Contact the US Bank at 314–418–4821 if you have any questions concerning courier delivery.)

It is helpful if the fee arrives at the bank at least 1 day before the application arrives at FDA. FDA records the official application receipt date as the later of the following:

- The date the application was received by FDA.
- The date US Bank receives the payment. US Bank is required to notify FDA within 1-working day, using the Payment Identification Number described previously.

D. Step Four—Submit your Application to FDA With a Copy of the Completed Medical Device User Fee Cover Sheet

Please submit your application and a copy of the completed Medical Device User Fee Cover Sheet to one of the following addresses:

- Medical device applications should be submitted to: Food and Drug Administration, Center for Devices and Radiological Health, Document Mail Center (HFZ–401), 9200 Corporate Blvd., Rockville, MD 20850.
- Biologic applications should be sent to: Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center (HFM–99), suite 200N, 1401 Rockville Pike, Rockville, MD 20852–1448.

Dated: July 21, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–17440 Filed 7–30–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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). The meeting will be open 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 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]

BILLING CODE 4160–01–S

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.