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.

225-04-4003

Memorandum of Understanding
Between
University of California
Lawrence Livermore National Laboratory
and
United States Food and Drug Administration
Office of Regulatory Affairs
for
Collaborative Research and Development
for
Homeland Security

I. Purpose, Objectives and Goals:

a. **Purpose.** This Memorandum of Understanding (MOU) establishes the framework for collaborative research and development and emergency triage response efforts between the University of California Lawrence Livermore National Laboratory (UC LLNL) and its Laboratories and Centers and the Food and Drug Administration (FDA) Office of Regulatory Affairs and its Laboratories on the subject of Homeland Security. Research and development efforts specifically targeted under this MOU are focused on, but not limited to, food safety and rapid risk assessment. The MOU is intended to expedite research and development of new methods and technologies that can be implemented in support of Homeland Security efforts by federal, state or local government entities as well as authorized private sector organizations to avert and/or mitigate the effects of terrorist activities in the United States.

Both UC LLNL and FDA believe that this collaboration will contribute to more efficient resource utilization, avert or minimize duplication, and accelerate method and technology advancement in the Homeland Security arena. The two organizations further believe that successful collaboration will leverage beneficial results via method and technology transfer in support of human health, while ensuring a safe food supply for the United States of America.

b. **Objectives.** FDA and UC LLNL will work collaboratively to expedite development of methods and technologies that are needed to address Homeland Security issues.

c. **Goals.**

i. Identify method and technology needs, formulate research and development projects that address food security needs, and

establish Interagency Agreements (IAGs) or other extramural arrangements that describe how personnel and resources of FDA and UC LLNL will be effectively utilized to perform research and development projects addressing Homeland Security issues such as early detection of impending terrorist attacks or the aftermath of terrorist attacks.

ii. Perform collaborative research and development projects in an expeditious manner.

iii. Provide products from the research and development projects in a form and format that can be easily used and understood by the targeted public and private sector organizations involved in Homeland Security activities.

II. Background and Program Scope:

a. **Background.** Terrorist attacks against the United States and the consequent war on terrorism being waged by the U.S., its allies and many countries around the world have provided great impetus for the development of methods and technologies that can be utilized to detect and/or neutralize terrorist threats. One of the greatest concerns facing the United States and other nations is the deliberate use of chemical, biological, nuclear or radiological weapons by terrorist organizations. Following the tragic events of September 11, 2001, the U.S. Food and Drug Administration, the University of California Lawrence Livermore National Laboratory, and other federal agencies, as well as universities and emergency response organizations in the public and private sector, began addressing the need for new methods and technologies related to Homeland Security.

b. **Program Scope.** Under this MOU the two organizations – UC LLNL and FDA – will meet on an annual basis to identify areas of research and development, and emergency related to Homeland Security that can be efficiently addressed through a collaborative approach.

III. Responsibilities:

a. **The Food and Drug Administration,** consistent with agency regulations governing the release of information, agrees to:

i. Work with UC LLNL to: (1) identify research and development needs in the area of Homeland Security; (2) develop, formulate and establish IAGs [this MOU will be incorporated by reference in each

related IAG] between specific UC LLNL Laboratories and Centers and one or more FDA Laboratories; and (3) describe specific research and development projects that will be jointly pursued by FDA and UC LLNL.

ii. Participate in joint technical activities (e.g., workgroups, or scientific panels) with representatives from UC LLNL, and other organizations which may be established to provide technical advice and guidance on issues related to Homeland Security.

iii. Enter into IAGs that address research and development needs, under which FDA personnel from one or more FDA Laboratories will work cooperatively on projects of mutual interest and formulated as described above with UC LLNL as time (the Food and Drug Administration has priority) and resources permit.

iv. In special cases and subject to approval by the Director of the appropriate FDA Laboratory, work with UC LLNL to address the research and development needs of a third party (either public or private).

v. Assign a Management Point of Contact and Technical Lead(s) for interactions with the UC LLNL.

vi. Provide, in cooperation with UC LLNL's Management Point of Contact, an annual executive summary report on the progress made under this MOU for each of the IAG's or other cooperative activities that are developed as part of this agreement (MOU).

vii. Record, produce and maintain minutes of meetings as described in this MOU.

b. The University of California Lawrence Livermore National Laboratory, consistent with agency regulations governing the release of information agrees to:

i. Work with FDA to: (1) identify research and development needs in the area of Homeland Security; (2) develop, formulate and establish IAG's [this MOU will be incorporated by reference in each related IAG] between one or more FDA Laboratories and UC LLNL Laboratories and Centers; and (3) describe specific research and development projects that will be jointly pursued by UC LLNL and FDA.

ii. Participate in joint technical activities associated with specific IAG's (e.g., workgroups, or scientific panels) with representatives from FDA and other organizations which may be established to provide technical advice and guidance on issues related to Homeland Security.

iii. Enter into IAGs that address research and development needs, under which UC LLNL personnel will work cooperatively on projects of mutual interest and formulated as described above with FDA as time (the UC LLNL mission has priority) and resources permit.

iv. In special cases and subject to approval by the Director of the appropriate UC LLNL Laboratory or Center, work with FDA to address the research and development needs of a third party (either public or private).

v. Cooperate in making facilities available in cases where emergency response activities are required.

vi. Assign a Management Point of Contact and Technical Lead(s) for interactions with the FDA.

IV. Memorandum of Understanding (MOU) Administration:

a. **Reports.** The status of work performed (associated with specific IAG's) under this MOU will be reviewed on an annual basis. The FDA Coordinator of Counter Terrorism Laboratory Response Development/Office of Regulatory Affairs, will take the lead and be responsible for organizing meetings (planning meetings and annual meetings), developing agenda and recording results of the meetings. Minutes of the meetings will be produced by FDA and be distributed to meeting participants as well as to the Director of the appropriate FDA Laboratory and in turn the Commissioner, FDA and to the UC LLNL. A central file (retained by the FDA) will be maintained.

b. **Information Releases:** The Associate Commissioner for Regulatory Affairs, FDA, and UC LLNL (or their designees) will jointly review and approve information regarding MOU activities (meetings, new developments, etc.) prior to public release. IAGs prepared under this agreement will stipulate specific procedures for the coordination, handling and public disclosure of information. All information disclosures concerning activities under this MOU or subsequent IAGs will comply with agency regulations governing the release of information. Where particular

information protocols apply to a particular laboratory, or network of laboratories, those protocols will be followed by both parties to this MOU.

c. **Security Classification:** The highest security classification applied by either FDA or UC LLNL will govern the handling of information and reports under this MOU, as appropriate. The security classification and procedures will be stipulated in each IAG.

d. **Facility Security, Health, Safety and Environmental Compliance:** When working at a host's facility, the guest employee will follow the security, health, safety and environmental policies and regulations of that facility.

e. **Reimbursement Policy:** Each party to this agreement will handle and expend its own funds. The responsibilities assumed by each party are contingent upon funds being available from which expenditures legally may be met.

f. **Annual Management Meetings:** UC LLNL and FDA will meet yearly to plan and coordinate research and development activities, and emergency response triage activities under this MOU. Such meetings will be held at a mutually agreed upon location and on a date that is compatible with the planning and budgeting cycle of each organization. At this meeting, recommendations for adjustments to current activities, projects, and budget priorities will be proposed and agreed upon by the Management Points of Contact for submission to the appropriate UC LLNL and FDA administrators for further action.

g. **Semi-Annual Technical Discussion:** UC LLNL and FDA will meet twice a year to discuss technical progress under each IAG or activity. These reviews will require technical information exchange by UC LLNL and FDA Technical Leads. These meetings may include individuals from outside of UC LLNL and FDA as mutually agreed to by the respective Management Points of Contact.

h. **Technical Lead Responsibilities:** Technical Leads for each IAG or activity will strive to engage in:

- Providing technical information exchange consistent with agency regulations governing the exchange or release of information
- Delivering written or verbal technical evaluations of progress
- Conducting visit to sites where research is underway
- Organizing and Participating in technical workshops and scientist-to-scientist meetings

- Reporting on any exceptional accomplishments from, or impediments to, successful program or project execution
- Recommending improvements for the MOU activities

i. **Approvals:** All IAGs and activities conducted to carry out this MOU must be agreed to and approved by the UC LLNL and FDA prior to commencement of any technical work.

j. **Inventions and Licensing:** Activities conducted to carry out this MOU and any IAGs or other extramural arrangements may result in products or processes that are patentable or otherwise proprietary. The organization whose work results in the invention shall disclose the invention to the other organization and may then prepare, file, and prosecute patent applications. If protection is granted, the inventing organization will manage the invention in accordance with its rules and regulations subject to a government use license. Inventions resulting from joint research and development by both UC LLNL and FDA employees shall be handled as jointly agreed to at the time of the disclosure.

V. Period of Agreement:

a. This MOU shall be effective for five years from the date of the last signature unless canceled in writing by (either/any) of the participating organizations with 90 days notice.

b. This MOU will be reviewed annually by the Management Points of Contact to determine if any changes or amendments should be incorporated. Such changes or amendments will be formally incorporated in the MOU by mutual agreement.

VI. Names and Addresses of Parties:

University of California
Lawrence Livermore National Laboratory
7000 East Avenue
Livermore, CA 94550

Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

VII. General Provisions:

a. Nothing in this MOU supersedes any other memorandum of understanding held by either party.

b. This MOU in no way restricts the parties from participating in similar activities or arrangements with other public or private agencies, organizations, or individuals.

c. This MOU describes in general terms, the basis upon which the parties intent to cooperate. It does not create binding, enforceable obligations against any party.

VIII. Signatures:

Approved and Accepted for the Food and Drug Administration by

John M. Taylor
Associated Commissioner for Regulatory Affairs
U.S. Food & Drug Administration

4/14/04
Date

Approved and Accepted for the University of California
Lawrence Livermore National Laboratory by:

Harold C Graboske Jr.

Dr. Harold Graboske, Jr
Deputy Director, Science and Technology
Lawrence Livermore National Laboratory

23 Feb 04
Date

[FR Doc. 04–17511 Filed 7–30–04; 8:45 am]
BILLING CODE 4160–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Establishment of Prescription Drug User Fee Rates for Fiscal Year 2005

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rates for prescription drug user fees for fiscal year (FY) 2005. The Federal Food, Drug, and Cosmetic Act (the Act), as amended by the Prescription Drug User Fee Amendments of 2002 (PDUFA III), authorizes FDA to collect user fees for certain applications for approval of drug and biological products, on establishments where the products are made, and on such products. Base revenue amounts for application fees, establishment fees, and product fees for FY 2005 were established by PDUFA III. Fees for applications, establishments, and products are to be established each year by FDA so that revenues from each category will approximate the levels established in the statute, after those amounts have been first adjusted for inflation and workload. This notice establishes fee rates for FY 2005 for application fees ($672,000 for an application requiring clinical data, and $336,000 for an application not requiring clinical data or a supplement requiring clinical data), establishment fees ($262,200), and product fees ($41,710). These fees are effective on October 1, 2004, and will remain in effect through September 30, 2005. For applications and supplements that are submitted on or after October 1, 2004, the new fee schedule must be used. Invoices for establishment and product fees for FY 2005 will be issued in August 2004, using the new fee schedule.

FOR FURTHER INFORMATION CONTACT: Frank Claunts, Office of Management (HFA–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4427.

SUPPLEMENTARY INFORMATION:

I. Background

Sections 735 and 736 of the act (21 U.S.C. 379g and h), establish three different kinds of user fees. Fees are assessed on: (1) Certain types of applications and supplements for approval of drug and biological products, (2) certain establishments where such products are made, and (3) certain products (21 U.S.C. 379h(a)). When certain conditions are met, FDA may waive or reduce fees (21 U.S.C. 379h(d)).

For FY 2003 through 2007 base revenue amounts for application fees, establishment fees, and product fees are established by PDUFA III (title 5 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002). Base revenue amounts established for years after FY 2003 are subject to adjustment for inflation and workload. Fees for applications, establishments, and products are to be established each year by FDA so that revenues from each category will approximate the levels established in the statute, after those amounts have been first adjusted for inflation and workload. The revenue levels established by PDUFA III continue the arrangement under which one-third of the total user fee revenue is projected to come from each of the three types of fees: Application fees, establishment fees, and product fees.

This notice establishes fee rates for FY 2005 for application, establishment, and product fees. These fees are effective on October 1, 2004, and will remain in effect through September 30, 2005.

II. Revenue Amount for FY 2005, and Adjustments for Inflation and Workload

A. Statutory Fee Revenue Amounts

PDUFA III specifies that the fee revenue amount for fiscal year 2005 for each category of fees (application, product, and establishment) is $84,000,000, for a total of $252,000,000 from all three categories of fees (21 U.S.C. 379h(b), before any adjustments are made.

B. Inflation Adjustment to Fee Revenue Amount

PDUFA III provides that fee revenue amounts for each fiscal year after 2003 shall be adjusted for inflation. The adjustment must reflect the greater of: (1) The total percentage change that occurred in the consumer price index (CPI) (all items; U.S. city average) during the 12-month period ending June 30 preceding the fiscal year for which fees are being set, or (2) the total percentage pay change for the previous fiscal year for Federal employees stationed in the Washington, DC, metropolitan area. PDUFA III provides for this annual adjustment to be cumulative and compounded annually after FY 2003 (see 21 U.S.C. 379h(c)(1)).

The inflation increase for FY 2004 was 4.27 percent. This was the greater of the CPI increase during the 12-month period ending June 30 preceding the fiscal year for which fees are being set (June 30, 2003—which was 2.11 percent) or the increase in pay for the previous fiscal year (2003 in this case) for Federal employees stationed in the Washington, DC, metropolitan area (4.27 percent).

The inflation increase for FY 2005 is 4.42 percent. This is the greater of the CPI increase during the 12-month period ending June 30 preceding the fiscal year for which fees are being set (June 30, 2004—which was 3.27 percent) or the increase in pay for the previous fiscal year (2004 in this case) for Federal employees stationed in the Washington, DC, metropolitan area (4.42 percent).

Compounding these amounts (1.0427 times 1.0442) yields a total compounded inflation adjustment of 8.88 percent for FY 2005.

The inflation adjustment for each category of fees for FY 2005 is the statutory fee amount ($84,000,000) increased by 8.88 percent, the inflation adjuster for FY 2005. The FY 2005 inflation-adjusted revenue amount is $91,459,200 for each category of fee, for a total inflation-adjusted fee revenue amount of $274,377,600 in FY 2005.

C. Workload Adjustment to Inflation Adjusted Fee Revenue Amount

For each fiscal year beginning in FY 2004, PDUFA III provides that fee revenue amounts, after they have been adjusted for inflation, shall be further adjusted to reflect changes in workload for the process for the review of human drug applications (see 21 U.S.C. 379h(c)(2)).

The conference report accompanying PDUFA III, House of Representatives report number 107–481, provides additional instructions on how the workload adjustment provision of PDUFA III is to be implemented. Following that guidance, FDA calculated the average number each of the four types of applications specified in the workload adjustment provision (human drug applications, commercial investigational new drug applications (INDs), efficacy supplements, and manufacturing supplements) received over the 5-year period that ended on June 30, 2002 (base years), and the average number of each of these types of applications over the most recent 5-year period that ended June 30, 2004.

The results of these calculations are presented in the first 2 columns of table 1 of this document. Table 1, column 3 of this document, reflects the percent