Director, Division of Respiratory Disease Studies (DRDS), National Institute for Occupational Safety and Health (NIOSH), ALOSH Bldg., Rm. H–2920, MS H2900, 1095 Willowdale Road, Morgantown, WV 26505.

Director, Pittsburgh Research Laboratory, NIOSH, 626 Cochrans Mill Road, Pittsburgh, PA 15236.

Director, Spokane Research Laboratory, NIOSH, 315 E. Montgomery Avenue, Spokane, WA 99207.

Director, Office of Compensation and Support (OCAS), NIOSH, Robert A. Taft Laboratories, 4676 Columbia Parkway, Cincinnati, OH 45226.

Policy coordination is provided by: Director, National Institute for Occupational Safety and Health (NIOSH), Bldg. HHH, Rm. 715H, MS P–12, 200 Independence Avenue, SW., Washington, DC 20201.

NOTIFICATION PROCEDURE:

An individual may learn if a record exists about him or herself by contacting the system manager at the above address. Requesters in person must provide driver's license or other positive identification. Individuals who do not appear in person must either: (1) Submit a notarized request to verify their identity; or (2) certify that they are the individuals they claim to be and that they understand that the knowing and willful request for or acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Privacy Act subject to a $5,000 fine.

An individual who requests notification of or access to medical records shall, at the time the request is made, designate in writing a responsible representative who is willing to review the record and inform the subject individual of its contents at the representative's discretion. A subject individual will be granted direct access to a medical record if the system manager determines direct access is not likely to have adverse effect on the subject individual.

The following information must be provided when requesting notification: (1) Full name; (2) the approximate date and place of the study, if known; and (3) nature of the questionnaire or study in which the requester participated.

RECORD ACCESS PROCEDURES:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. An accounting of disclosures that have been made of the record, if any, may be requested.

CONTESTING RECORD PROCEDURES:

Contact the official at the address specified under System Manager above, reasonably identify the record and specify the information being contested, the corrective action sought, and the reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

RECORD SOURCE CATEGORIES:

Vital status information is obtained from Federal, State and local governments and other available sources selected from those listed in Appendix I. Information is obtained directly from the individual and employer records, whenever possible.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

Appendix I—Potential Sources for Determination of Health Status, Vital Status and/or Last Known Address

Military records
Appropriate State Motor Vehicle Registration Departments
Appropriate State Driver's License Departments
Appropriate State Government Division of: Assistance Payments (Welfare), Social Services, Medical Services, Food Stamp Program, Child Support, Board of Corrections, Aging, Indian Affairs, Worker's Compensation, Disability Insurance
Retail Credit Association follow-up
Veterans Administration files
Appropriate employee union or association records
Appropriate company pension or employment records
Company group insurance records
Appropriate State Vital Statistics Offices
Life insurance companies
Railroad Retirement Board
Area nursing homes
Area Indian Trading Posts
Mailing List Correction Cards (U.S. Postal Service)
Letters and telephone conversations with former employees of the same establishment as cohort member
Appropriate local newspaper (obituaries)
Social Security Administration
Internal Revenue Service
National Death Index
Centers for Medicare & Medicaid Services
Pension Benefit Guarantee Corporation
State Disease Registries

[FR Doc. 03–24481 Filed 9–26–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0422]

Annual Stakeholder Meeting on the Implementation of the Medical Device User Fee Modernization Act of 2002 Provisions; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public meeting: Annual Stakeholder Meeting on the Implementation of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA). The topic of discussion is the agency's progress in implementing the various MDUFMA provisions, including the guidances FDA has issued on the new law.

DATES: The meeting will be held on December 3, 2003, from 9 a.m. to 5 p.m. at the Gaithersburg Hilton Hotel, 690 Perry Pkwy., Gaithersburg, MD 20877. Registration is required by November 3, 2003. All individuals wishing to make a presentation or to speak on an issue also must indicate their intent and the topic to be addressed and provide an abstract of the topic to be presented by November 3, 2003. Time for presentations will be limited to 10 minutes.

ADDRESSES: Send written requests to make a 10-minute oral presentation to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Send electronic requests to make a 10-minute oral presentation to *http://www.fda.gov/dockets/ecomments*. Include your name, title, firm name, address, telephone, and fax number with your request. All requests and presentation materials must include the docket number found in brackets in the heading of this document. Submit all requests and presentation materials by November 3, 2003.

FOR FURTHER INFORMATION CONTACT: Sherrie Appel, Center for Devices and Radiological Health (HFZ–200), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–443–2845, FAX: 301–443–8810, e-mail: *saa@cdrh.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On October 26, 2002, MDUFMA amended the Federal Food, Drug, and

Cosmetic Act to include several new significant provisions. MDUFMA authorizes the following provisions: (1) User fees for certain premarket applications, (2) establishment inspections by FDA-accredited persons (third-parties), and (3) new requirements for reprocessed single-use devices. In addition, the new law contains several provisions that, while narrower in scope than the previously mentioned provisions, are significant changes to the device law. These include a modular review program for premarket approval applications (PMAs), electronic labeling for certain prescription devices, several provisions concerning devices for pediatric use, and a new labeling requirement that requires the manufacturer's name to appear on the device itself, with certain exceptions.

The agency has been working to implement the new law since its passage in October 2002. During this time, FDA has accomplished the following milestones: Established a user fee program with payment, billing, and appeals procedures; met statutory timeframes for the release of the accreditation criteria for persons conducting third-party inspections and the identification of certain reprocessed single-use devices that will be subject to additional premarket requirements; and published several guidances, such as those related to PMA supplement definitions and bundling of multiple devices in a single application. The agency is drafting other documents to be issued in the near future.

Agenda: On December 3, 2003, FDA is providing the opportunity for all interested persons to provide information and share their views on the implementation of MDUFMA. The agenda will consist of the following panel sessions that will include panelists from FDA, industry, and other stakeholders:

- Panel 1: How is the User Fees Process Working? This panel will consider the small business determinations and the user fee process and performance goals.
- Panel 2: Electronic Labeling and Identification of the Manufacturer on the Device. This panel will address electronic labeling for prescription devices intended for use in healthcare facilities (section 206 of MUDFMA (Public Law 107–250)) and identification of the manufacturer on the device itself (section 301 of MDUFMA (Public Law 107–250)).
- Panel 3: Bundling, Modular PMA, and Expedited PMAs. This panel will discuss guidances that address various PMA issues, including definitions of supplements, modular review, bundling multiple devices/indications for use in a single application, and clinical studies of pediatric devices.
- Panel 4: Third-Party Inspection Program. This panel will discuss implementation of the program, including eligibility criteria for use of a third party by a manufacturer.
- Panel 5: Reuse. This panel will discuss FDA-identified reprocessed single-use devices that will require premarket submission of validation data and the associated guidance for submission of data.
- General Discussion Period From the Floor: At the conclusion of the panels, there will be a general discussion from the floor.

Also at this time, FDA is particularly interested in receiving comments from stakeholders on other topics for discussion. The agency is interested in receiving recommendations about other provisions yet to be implemented both in terms of their priority for implementation and specifics on the implementation itself.

FDA will place an additional copy of any material it receives on the docket for this document (2003N–0422). Comments and materials may be seen at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday (see **ADDRESSES**).

Registration: Online registration for the meeting is required by November 3, 2003. Acceptance will be on a first-come, first-served basis. There will be no onsite registration. Please register online at *http://www.fda.gov/cdrh/meetings/120303.html*. FDA is pleased to provide the opportunity for interested persons to listen from a remote location to the live proceedings of the meeting. In order to ensure that a sufficient number of call-in lines are available, please register to listen to the meeting at *http://www.fda.gov/cdrh/meetings/120303.html* by November 3, 2003. Persons without Internet access may register for the onsite meeting or to listen remotely by calling 301–443–2845 by November 3, 2003.

If you need special accommodations due to a disability, please contact Sherrie Appel at 301–443–2845 at least 7 days in advance.

Transcripts: Following the meeting, transcripts will be available for review at the Division of Dockets Management (see **ADDRESSES**).

Dated: September 22, 2003.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 03–24494 Filed 9–26–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Cooperative Agreement to the Fund for the City of New York, on Behalf of the New York City Department of Health and Mental Hygiene and the Fund for Public Health in New York, Inc.

AGENCY: Health Resources and Services Administration, DHHS.

ACTION: Notice of award.

Catalog of Federal Domestic Assistance: #93.003.

SUMMARY: Notice is hereby given that a noncompetitive cooperative agreement award is being made to the Fund for the City of New York, on behalf of the New York City Department of Health and Mental Hygiene and the Fund for Public Health in New York, Inc. The award is being made to support the efforts of the New York City Department of Health and Mental Hygiene to develop model approaches for addressing the special needs of high density metropolitan areas with high levels of risk for bioterrrorism attacks and other public health emergencies.

This eighteen month agreement at a level of $5 million is being funded non-competitively because it is expected to provide useful information and guidance to this Department and to other health departments and levels of government regarding how to deal with threats and actual events in high density areas at high risk for attacks. One area of particular interest is developing and evaluating best practice guidelines for emergency preparedness in primary care settings. This includes developing effective models of clinic training. There has been concern expressed that the Federally Qualified Health Centers have not been sufficiently involved in regional planning for, and preparing to respond to, a bioterrorist event or other public health emergency. These clinics will likely serve a role with regard to triaging victims, as well as potentially offering mass prophylaxis. This effort will be designed to develop best practice guidelines and recommendations for primary care emergency management; develop an educational curriculum to disseminate best emergency practices to primary care centers; and test, evaluate and refine the guidelines, training curriculum, and template drills to share with primary care centers citywide.

A second area of interest is preparation of terrorism preparedness exercises. It is important to identify