

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 Cochran's 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
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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