

(CRM). It is directed by the Director of IT Services. It is also a primary resource for advising the HHS CIO on technology implementation, and for piloting HHS CIO special programs. ITS is responsible for the following:

a. Operating, maintaining, and enhancing the ITSC computer network and services, including services for participating HHS organizations.

b. Implementing and monitoring network policies and procedures, and developing plans and budgets for network support services.

c. Ensuring reliable, high-performance network services.

d. Implementing and operating electronic tools to enhance Secretarial communications with all HHS personnel.

e. Coordinating with OPDIVs and STAFFDIVs to develop ITSC, IT capital planning and budgeting processes, providing direct planning support to assure that IRM plans support agency business planning and mission accomplishment, as it applies to the infrastructure.

f. Implementing policies and guidance on information resources management within ITSC for acquisition and use of information technology, support of technical R model, and coordination of implementation procedures.

g. Maintaining and operating the inventory of automated data processing equipment for the ITSC participating agencies.

h. Operating and maintaining an information technology support service (Help Desk and Call Center) for participating HHS components.

i. Managing contracts for equipment and support services related to the provision of IT services in ITSC participating agencies.

j. Representing the Department through participation on interagency and Departmental work groups and task forces, as appropriate.

k. Responsible for ITSC compliance with and implementation of all applicable HHS policies and Federal Laws regarding IT Security.

l. Reviewing and facilitating acquisitions for activities related to ITSC.

Dated: July 28, 2003.

Ed Sontag,

Assistant Secretary for Administration and Management.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

NIOSH/NCI Joint Study Meeting

The National Institute for Occupational Safety and Health (NIOSH), and the National Institutes of Health, National Cancer Institute (NCI), announce the following meeting:

Name: Stakeholder informational meeting on the joint NIOSH/NCI study entitled, "A Cohort Mortality Study with a Nested Case-Control Study of Lung Cancer and Diesel Exhaust among Non-metal Miners."

Time and Date: 9 a.m.–12 noon, Wednesday, November 5, 2003.

Place: Room 705A, Hubert Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

Status: Open to the public, limited only by space available. The meeting room accommodates up to 50 people.

Purpose: To provide an overview of progress of the study, and to exchange information among government, stakeholders, and other interested parties.

Matters To Be Discussed: The agenda will include a short summary of the background of the NIOSH/NCI study, and reviews of progress on the different components of the study. Viewpoints and suggestions from industry, labor, academia, other government agencies, and the public are invited. Written comments will also be considered.

Contact Person for More Information: Michael Attfield, Ph.D., NIOSH Project Director, Division of Respiratory Disease Studies, M/S 234, 1095 Willowdale Road, Morgantown, West Virginia 26505-2888, telephone 304/285-5737, e-mail MDA1@CDC.GOV.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the CDC and ATSDR.

Dated: September 30, 2003.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D-0229]

Guidance for Industry on Continuous Marketing Applications: Pilot 2—Scientific Feedback and Interactions During Development of Fast Track Products Under the Prescription Drug User Fee Act of 1992

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Continuous Marketing Applications: Pilot 2—Scientific Feedback and Interactions During Development of Fast Track Products Under PDUFA." This is one in a series of guidance documents that FDA agreed to draft and implement in conjunction with the June 2002 reauthorization of the Prescription Drug User Fee Act of 1992 (PDUFA). This guidance discusses how the agency will implement a pilot program for frequent scientific feedback and interactions between FDA and applicants during the investigational phase of development for certain Fast Track drug and biological products. Applicants are being asked to apply to participate in the Pilot 2 program.

DATES: Submit written or electronic comments on agency guidances at any time. FDA will begin accepting applications for participation in Pilot 2 on October 6, 2003.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or to the Office of Communications, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self addressed adhesive label to assist either office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: