(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.

[FR Doc. 03–25283 Filed 10–3–03; 8:45 am]

BILLING CODE 4150–04–M

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.

[FR Doc. 03–25233 Filed 10–3–03; 8:45 am]

BILLING CODE 4163–19–P

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:

John Jenkins, CDER (HFD–020), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–3937, or
Robert A. Yetter, CBER (HFM–25), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20892, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Description of the Guidance

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.'' In conjunction with the June 2002 reauthorization of PDUFA, FDA agreed to meet specific performance goals (PDUFA Goals). The PDUFA Goals include two pilot programs to explore the continuous marketing application (CMA) concept. The CMA concept builds on the current practice of interaction between FDA and applicants during drug development and application review and proposes opportunities for improvement.

In the **Federal Register** of June 17, 2003 (68 FR 35901), FDA announced the availability of a draft version of this guidance. FDA received a number of comments when it issued the draft version of this guidance. We have considered the comments on the draft guidance carefully and have made some changes to address those comments. Among other things, we have revised the guidance to clarify the eligibility requirements and selection process for Pilot 2 and provide for public availability of additional information during the program.

Under the CMA Pilot 2 program, certain drug and biologic products that have been designated as Fast Track (i.e., products intended to treat a serious and/or life-threatening disease for which there is an unmet medical need) are eligible to be considered for participation in Pilot 2. Pilot 2 is an exploratory program and FDA will evaluate its impact on the investigational phase of drug development. Under the pilot program, a maximum of one Fast Track product per review division in CDER and CBER will be selected to participate. This guidance provides information regarding the selection of applications for Pilot 2, the formation of agreements between FDA and applicants on the investigational new drug application communication process, and other procedural aspects of Pilot 2. See **DATES** for when FDA will begin accepting applications for participation in Pilot 2.

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The collection(s) of information in this guidance was approved under OMB control number 0910–0518, and will expire on March, 31, 2004. In the notice announcing the availability of the draft version of this guidance (68 FR 35901), FDA published a notice of the proposed collection of information related to the draft guidance. The **Federal Register** notice also requested comments on the burden estimated for the guidance. In the **Federal Register** of September 9, 2003 (68 FR 53174), the agency announced that it was submitting the collection of information to OMB for review and clearance under the PRA. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The time required to complete this information collection is estimated to average 80 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection.

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance at any time. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet can obtain the guidance at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/cber/guidelines.htm*.

Dated: September 29, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–25305 Filed 10–1–03; 4:09 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0228]

Guidance for Industry on Continuous Marketing Applications: Pilot 1—Reviewable Units for 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 1—Reviewable Units for 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). Pilot 1 will enable certain applicants to receive early feedback on portions of their applications. Pilot 1 will also evaluate the benefits and costs of providing early feedback to applicants.

DATES: Submit written or electronic comments on agency guidances at any time.

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 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: John Jenkins, CDER (HFD–020), Food