Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Michele L. Pearson, M.D., Executive Secretary, HICPAC, Division of Healthcare Quality Promotion, NCID, CDC, 1600 Clifton Road, NE, M/S A–07, Atlanta, Georgia 30333, telephone 404/498–1182.

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 Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: January 22, 2003.

Alvin Hall,

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

[FR Doc. 03–1825 Filed 1–27–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Interagency Committee on Smoking and Health: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting:

Name: Interagency Committee on Smoking and Health (ICSH).

Date and Time: February 11, 2003, 1 p.m.—4 p.m.

Place: Department of Health and Human Services, Hubert H. Humphrey Building, Auditorium, Room 800, 200 Independence Avenue, SW, Washington, DC 20201.

Status: Open to the public, limited only by the space available. Those who wish to attend are encouraged to register with the contact person listed below. If you will require a sign language interpretator, or have other special needs, please notify the contact person by 4:30 E.S.T. on February 5, 2003.

Purpose: The Interagency Committee on Smoking and Health advises the Secretary, Health and Human Services, and the Assistant Secretary for Health in the (a) coordination of all research and education programs and other activities within the Department and with other federal, state, local and private agencies and (b) establishment and maintenance of liaison with appropriate private entities, federal agencies, and state and local public health agencies with respect to smoking and health activities.

Matters to be Discussed: The agenda will focus on the National Action Plan for Tobacco Cessation drafted by the Cessation Subcommittee. During the meeting, the action plan will be presented, debated and voted on by the ICSH. At a future date the Plan will be presented to the Secretary of Health and Human Services.

Contact Person for More Information: Substantive program information as well as summaries of the meeting and roster of committee members may be obtained from the Internet at *http://www.cdc.gov/tobacco* in mid-March or from Ms. Monica L. Swann, Program Specialist, Office on Smoking and Health, 200 Independence Avenue, SW, Suite 317B, Washington, DC 20201, (202) 205–8500.

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 Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: January 22, 2003.

Alvin Hall,

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

[FR Doc. 03–1823 Filed 1–27–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0526]

Draft Guidance for Industry on Drug Product: Chemistry, Manufacturing, and Controls Information; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Drug Product: Chemistry, Manufacturing, and Controls Information.'' This draft guidance provides recommendations on the chemistry, manufacturing, and controls (CMC) information for drug products that should be submitted in original new drug applications (NDAs) and abbreviated new drug applications (ANDAs). The draft guidance is structured to facilitate the preparation of applications submitted in Common Technical Document (CTD) format.

DATES: Submit written or electronic comments on the draft guidance by June 27, 2003. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (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 draft guidance document.

FOR FURTHER INFORMATION CONTACT: Upinder Atwal, Center for Drug Evaluation and Research (HFD–623), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20852, 301–827–5848, or Christopher Joneckis, Center for Biologics Evaluation and Research (HFM–1), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20892, 301–435–5681.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Drug Product: Chemistry, Manufacturing, and Controls Information.'' This draft guidance addresses the information to be submitted in NDAs and ANDAs for drug products to ensure continued product quality (i.e., identity, strength, quality, purity, and potency). Recommendations are provided on the information that should be included for: (1) Description and composition of the drug product, (2) manufacture, (3) control of excipients, (4) control of drug products, (5) reference standards or materials, (6) container closure systems, and (7) stability. Information is also provided on the type of pharmaceutical development information that should be included in an NDA or ANDA. The draft guidance is structured to facilitate the preparation of applications submitted in CTD format. The draft guidance, when finalized, will replace the guidance entitled ''Submitting Documentation for the Manufacture and Controls for Drug Products'' (February 1987).

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 (44 U.S.C. 3501–3520). The collection of information in this guidance was approved under OMB control number 0910–0001.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on CMC information for drug products.

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 Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments to *http://www.fda.gov/dockets/ecomments* or two hard copies of any written comments, except that individuals may submit one hard copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/cder/guidance/index.htm*, *http://www.fda.gov/cber/guidelines.htm*, or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: January 27, 2003.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 03–1919 Filed 1–27–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE INTERIOR

Office of the Secretary

Privacy Act of 1974: As Amended; Revision to an Existing System of Records

AGENCY: Office of the Secretary, Department of the Interior.

ACTION: Proposed revisions to an existing system of records.

SUMMARY: Under the Privacy Act of 1974, as amended (5 U.S.C. 552a), the Department of the Interior is issuing public notice of its intent to modify an existing Privacy Act system of records notice managed by the Office of the Secretary entitled the ''Electronic Email Archive System (EEAS)'', Interior—OS–10 (67 FR 46202–46203, dated July 12, 2002). The revisions will update the ''Categories of individuals covered by the system'' section.

EFFECTIVE DATE: These actions will be effective January 28, 2003.

FOR FURTHER INFORMATION CONTACT: For more information on the EEAS system and its requirements, please contact Regina Lawrence, Office of the Chief Information Officer, Department of the Interior at 202–208–5413, or mail at MS–5312–MIB, 1849 C St. NW., Washington, DC 20240.

SUPPLEMENTARY INFORMATION: In this notice, the Department of the Interior is proposing to add additional Departmental bureaus/offices that will be participating in the EEAS to the ''Categories of individuals covered by the system'' section. These additional bureaus/offices are the Office of Surface Mining, the Bureau of Reclamation, and the National Business Center. These bureaus/offices are being added because they may also send or receive email with information related to Indian Trust programs. The EEAS was developed as a way to respond to information requests from the Court in the *Cobell et al.* v. *Norton, et al.*, Federal District Court Case No. 1:96CV01285 litigation.

Thus, the Department of the Interior proposes to amend EEAS, Interior—OS–10 to read as follows:

Dated: January 23, 2003.

Marilyn A. Legnini,

Departmental Privacy Act Officer.

INTERIOR/OS–10

SYSTEM NAME:

Electronic Email Archive System (EEAS).

SECURITY CLASSIFICATION:

Sensitive, but unclassified.

SYSTEM LOCATION:

The records of this system are located at a digital safe site at a location managed by the contractor for the Department of the Interior. Only information maintained at this site by the contractor is considered a Privacy Act system of records covered by this notice.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The system contains information on individuals who send and receive electronic messages using Internet email and interoffice email from and to those Departmental bureaus/offices involved with Indian Trust programs, and those individuals who are referred to in the electronic messages. These bureaus/offices are as follows: Office of the Solicitor; Bureau of Indian Affairs; Office of the Special Trustee for American Indians; Office of the Assistant Secretary—Indian Affairs; Bureau of Land Management; Office of the Assistant Secretary—Policy, Management, and Budget; Office of Hearings and Appeals; Office of Historical Trust Accounting; Office of the Secretary; the Minerals Management Service; the United States Geological Survey; the National Park Service; and the U.S. Fish and Wildlife Service. The following bureau/offices are being added to the EEAS because the Court is concerned that they may send or receive email containing individual Indian Trust related information: the Office of Surface Mining; the Bureau of Reclamation; and the National Business Center.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records include information from Internet email and interoffice email, including address of sender and receiver(s), subject, date sent or received, text of the message, name of attachment, attachment text, and certification status. The name and email address of the sender and receiver are captured along with the bcc, cc, subject line, and text of the message.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, 43 CFR part 1455, and 40 CFR part 1441.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

The system's main purpose is to respond to requests from the federal district court in *Cobell* v. *Norton* regarding information about individual Indian Trust programs that is embodied in email communication.

Disclosures outside the Department of the Interior can be made to:

(a) Contractors who service and maintain the system for the Department, ensuring that all provisions of the Privacy Act, and all other applicable laws, regulations, and policies relating to contracting and record security are met.

(b) Another Federal agency to enable that agency to respond to an inquiry by the individual to whom the record pertains.

(c)(1) To any of the following entities or individuals.

(A) The Department of Justice (DOJ), or

(B) To a court, adjudicative or other administrative body, or

(C) To a party in litigation before a court or adjudicative or administrative body, or

(D) The Department or any component of the Department, or

(E) Any Department employee acting in his or her official capacity, or

(F) Any Departmental employee acting in his or her individual capacity if the Department or the DOJ has agreed to represent that employee or pay for private representation of the employee,