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]

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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.

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Dated: January 22, 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. 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.