b. The relationship between activities and objectives.

c. Description of the management and analysis of data collected for meeting objectives.

2. Ability to Carry Out the Project (30 Points)

The extent to which the applicant provides evidence of their ability to carry out the proposed activity or project and the extent to which the applicant documents the demonstrated capability to achieve the purpose of this project.

3. Understanding of the Need or Problem (20 Points)

The extent to which the applicant demonstrates a clear, concise understanding of the need or problem to be addressed.

a. Extent to which the applicant specifically includes a description of the public health importance of the planned activities to be undertaken.

b. Extent to which the applicant provides a realistic presentation of the proposed project.

4. Personnel (10 Points)

The extent to which professional personnel involved in this activity or project are qualified, including evidence of prior experience similar to this activity or project. (Complete C.V. should be provided for professional and senior administrative staff; relevant training and experience should be highlighted). If a position is vacant, a position description and complete description of required qualifications for that position are to be included in the application along with a specific plan (including time line) for hiring.

5. Management Plan (10 Points)

The extent to which the applicant provides a description of the systems and the procedures that will be used to manage the progress, budget and operations of the activity or project.

6. Budget (Not Scored)

Extent to which the budget is reasonable, clearly justified, and consistent with the intended use of cooperative agreement funds.

I. Other Requirements

Technical Reporting Requirements

Provide CDC with the original plus two copies of:

1. Interim progress report, no less than 90 days before the end of the budget period. The progress report will serve as your non-competing continuation application, and must contain the following elements:

a. Current Budget Period Activities Objectives. Describe quantified progress in achieving objectives, as well as relevant evaluation findings, changes or adjustments in objectives resulting from evaluation findings, and reasons for not attaining an objective.

b. Current Budget Period Financial Progress.

c. New Budget Period Program Proposed Activity Objectives.

d. Detailed Line-Item Budget and Justification.

e. Additional Requested Information.

2. Financial status report, no more than 90 days after the end of the budget period.

3. Final financial and performance reports, no more than 90 days after the end of the project period. Send all reports to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

Additional Requirements

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I of the program announcement as posted on the CDC Web site.

AR–1 Human Subjects Requirements
AR–7 Executive Order 12372 Review
AR–8 Public Health System Reporting Requirements
AR–9 Paperwork Reduction Act Requirements
AR–10 Smoke-Free Workplace Requirements
AR–11 Healthy People 2010
AR–12 Lobbying Restrictions
AR–13 Prohibition on Use of CDC Funds for Certain Gun Control Activities
AR–14 Accounting System Requirements
AR–15 Proof of Non-Profit Status

J. Where To Obtain Additional Information

This and other CDC announcements, the necessary applications, and associated forms can be found on the CDC Web site, Internet address: *http://www.cdc.gov.* Click on ''Funding'' then ''Grants and Cooperative Agreements''.

For general questions about this announcement, contact: Technical Information Management, CDC Procurement and Grants Office, 2920 Brandywine Rd, Room 3000, Atlanta, GA 30341–4146, Telephone: 770–488–2700.

For business management and budget assistance, contact: Sharon Robertson, Grants Management Specialist, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341–4146, Telephone: 770–488–2748, E-mail: *sqr2@cdc.gov.*

For program technical assistance, contact: Amy Loy, Office of Terrorism Preparedness and Response, Centers for Disease Control and Prevention, 1600 Clifton Road, Atlanta, GA 30333, Telephone: 404–639–7855, E-mail: *anl6@cdc.gov.*

Dated: January 22, 2003.

Sandra R. Manning,

CGFM Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 03–1824 Filed 1–27–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Healthcare Infection Control Practices Advisory Committee (HICPAC): 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 meeting.

Name: Healthcare Infection Control Practices Advisory Committee.

Times and Dates: 8:30 a.m.–5 p.m., February 24, 2003; 8:30 a.m.–4 p.m., February 25, 2003.

Place: Swissotel, 3391 Peachtree Road, NE, Atlanta, Georgia 30333.

Status: Open to the public, limited only by the space available.

Purpose: The Committee is charged with providing advice and guidance to the Secretary, HHS, the Director, CDC, the Director, National Center for Infectious Diseases (NCID), and the Director, Division of Healthcare Quality Promotion; NCID, regarding (1) the practice of hospital infection strategies for surveillance, prevention, and control of healthcare-associated infections (*e.g.*, nosocomial infections), antimicrobial resistance, and related events in settings where healthcare is provided; and (2) periodic updating of guidelines and other policy statements regarding prevention of healthcare-associated infections and healthcare-related conditions.

Matters To Be Discussed: Agenda items will include a review of the Draft Guideline for Preventing Transmission of Infectious Agents in Healthcare Settings (formerly Guideline for Isolation Precautions in Hospitals); the Draft Guideline for Disinfection and Sterilization in Healthcare Settings; the Draft Guideline for Prevention of Healthcare-associated Pneumonia; infection control issues related to smallpox and vaccinia; injection safety in ambulatory healthcare settings; and updates on CDC activities of interest to the committee.

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.