Dated: April 18, 2001.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC)

[FR Doc. 01–10055 Filed 4–23–01; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): NORA: RFA OH–01–007: Community-Based Interventions to Prevent Childhood Agricultural Injury and Disease

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: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP) NORA: RFA OH–01–007: Community-Based Interventions to Prevent Childhood Agricultural Injury and Disease.

Times and Dates: 5 p.m.–5:30 p.m., May 15, 2001. (Open); 5:30 p.m.–9 p.m., May 15, 2001. (Closed); 8 a.m.–5 p.m., May 16, 2001. (Closed).

Place: State Plaza Hotel, 2117 E. State Street, NW, Washington, DC 20037.

Status: Portions of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Deputy Director for Program Management, CDC, pursuant to Public Law 92–463.

Matters to be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to Program Announcement NORA: RFA OH–01–007.

Contact Person for More Information: Gwendolyn H. Cattledge, Ph.D., Office of Extramural Programs, National Institute for Occupational Safety and Health, CDC, 1600 Clifton Rd, NE, M/S D28, Atlanta, Georgia 30333, telephone 404–639–2378.

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: April 12, 2001.

Carolyn J. Russell,

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

[FR Doc. 01–10057 Filed 4–23–01; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Meeting

National Center for Health Statistics (NCHS), Data Policy and Standards Staff, announces the following meeting.

Name: ICD–9–CM Coordination and Maintenance Committee meeting.

Time and Date: 9 a.m.–5 p.m., May 17–18, 2001.

Place: The Health Care Financing Administration, Auditorium, 7500 Security Boulevard, Baltimore, Maryland. In the interest of security, the H.C.F.A. has instituted stringent procedures for entrance into the building by non-government employees. Persons without a government I.D. will need to show a photo I.D. and sign-in at the security desk upon entering the building.

Status: Open to the public, as limited by the capacity of the meeting room, which is 75 people.

Purpose: The ICD–9–CM Coordination and Maintenance (C&M) Committee will hold its first meeting of the 2001 calendar year cycle on Thursday and Friday May 17–18, 2001. The C&M meeting is a public forum for the presentation of proposed modifications to the International Classification of Diseases, Ninth-Revision, Clinical Modification.

Matters to be Discussed: Agenda items include:

Critical illness neuropathy
Ocular torticollis
Personal history of pre-term labor
Fussy infant/excessive crying of infant
Perinatal conditions
Aqueous misdirection
Disruption of operation wound
Dieulafoy lesion
Aftercare codes
Supplemental oxygen dependency
Scooter external cause code

Implementation issues on the ICD–10–Procedure Classification System (PCS) coding system. Presenters will include:

The American Health Information Management Association (AHIMA)
The American Hospital Association (AHA)
The American Medical Association (AMA)
McKesson HBOC
DRG Review, Inc.
AdvaMed
Ingenix Syndicated Content Group
Princeton Provider Group

ICD–9–CM procedure topics to be covered:

High-Dose Interleukin-2
Spinal Fusion Devices
Addenda

Contact Person for Additional Information: Amy Blum, Medical Classification Specialist, Data Policy and Standards Staff, NCHS, 6526 Belcrest Road, Room 1100, Hyattsville, Maryland 20782, telephone 301/458–4106 (diagnosis), Amy Gruber, Health Insurance Specialist, Division of Acute Care, HCFA, 7500 Security Blvd., Room C4–07–07, Baltimore, Maryland, 21244 telephone 410–786–1542 (procedures).

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 CDC and the Agency for Toxic Substances and Disease Registry.

Dated: April 18, 2001.

Carolyn J. Russell,

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

[FR Doc. 01–10056 Filed 4–23–01; 8:45 am]

BILLING CODE 4160–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0167]

Preparation for ICH Meetings in Tokyo, Japan, Including Progress on the Common Technical Document and Possibilities for New Topics; Notice of Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting entitled ''Preparation for ICH Meetings in Tokyo, Japan, Including Progress on the Common Technical Document and Possibilities for New Topics,'' to solicit information and receive comments on the future of the International Conference on Harmonisation (ICH) as well as the upcoming meetings in Tokyo, Japan. The topic to be discussed is the

Common Technical Document (CTD) and possibilities for new topics. The purpose of the meeting is to solicit public input prior to the next Steering Committee and Expert Working Group meetings in Tokyo, Japan, May 21 to 24, 2001, at which discussion of the CTD and possible new topics will be continued.

Date and Time: The public meeting will be held on May 8, 2001, 10:30 a.m. to 2 p.m.

Location: The public meeting will be held at 5630 Fishers Lane, rm. 1066, Rockville, MD 20852.

Contact: Kimberly Topper, Center for Drug Evaluation and Research, Food and Drug Administration, 5630 Fishers Lane, Rockville, MD 20852, 301–827–7001, FAX 301–827–6801, or email: Topperk@cder.fda.gov.

Registration and Requests for Oral Presentations: Send registration information (including name, title, firm name, address, telephone, and fax number), and written material and requests to make oral presentations to the contact person by May 1, 2001.

If you need special accommodations due to a disability, please contact Kimberly Topper at least 7 days in advance.

SUPPLEMENTARY INFORMATION:

I. Background

The International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH) was established in 1990 as a joint regulatory/industry project to improve, through harmonization, the efficiency of the process for developing and registering new medicinal products in Europe, Japan, and the United States without compromising the regulatory obligations of safety and effectiveness.

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for medical product development among regulatory agencies. The ICH was organized to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. The ICH is concerned with harmonization among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labor, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations. The ICH Steering Committee includes representatives from each of the ICH sponsors and Canadian Therapeutics Programme, and the European Free Trade Area. The ICH process has achieved significant harmonization of the technical requirements for the approval of pharmaceuticals for human use in the three ICH regions. The current ICH process and structure can be found on the Internet at http://www.ifpma.org/ich1.html.

II. Issues To Be Discussed at the Public Meeting

The issues to be discussed include the following: (1) ICH overview and procedures, (2) CTD, and (3) possibilities for new topics (e.g., biotech and postmarketing surveillance).

Interested persons may present data, information, or views orally or in writing, on issues pending at the public meeting. Oral presentations from the public will be scheduled between approximately 10:30 a.m. and 2 p.m. Time allotted for oral presentations may be limited to 10 minutes. Those desiring to make oral presentations should notify the contact person by May 1, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses, phone number, fax, and e-mail of proposed participants, and an indication of the approximate time requested to make their presentation.

The agenda for the public meeting will be available on May 2, 2001, at the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, under Docket Number 01N-0167.

Transcripts: Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

Dated: April 18, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01–10068 Filed 4–23–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Exchange of Letters Between the Food and Drug Administration and Japan Concerning the Exchange of Certain Information on Pharmaceutical Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of an exchange of letters between FDA, Department of Health and Human Services, United States of America and the Inspection and Guidance Division, Pharmaceutical and Medical Safety Bureau, Ministry of Health and Welfare, Japan. The parties concluded this exchange of letters on December 27, 2000. These letters express the intentions of the United States and Japan to exchange information on matters useful to preserving the safety, quality, and efficacy of pharmaceutical products in the markets of the United States and Japan.

DATES: Cooperation under the exchange of letters began December 27, 2000.

FOR FURTHER INFORMATION CONTACT: Joseph Famulare, Division of Manufacturing and Product Quality (HFD–320), Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301–827–0590.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and memoranda of understanding between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this exchange of letters.

Dated: April 11, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

BILLING CODE 4160–01–S