associated with border crossing activities.

Alternatives Under Consideration

A preliminary group of alternatives for the proposed action that would be evaluated in the SEIS has been developed by GSA, pending comment received during scoping.

Alternative 1 (No Action Alternative). Under this alternative the Del Rio POE would be expanded per the 1992 EIS finding allowing for pedestrian access along Rio Grande Loop Road.

Alternative 2. Under this alternative the Del Rio POE would be expanded per the 1992 EIS with pedestrian access to the east of the POE along Rio Grande Loop Road provided by an elevated walkway.

Alternative 3. Under this alternative the Del Rio POE would be expanded per the 1992 EIS with pedestrian access to the east of the POE along Rio Grande Loop Road provided by a tunnel walkway.

Alternative 4. Under this alternative the Del Rio POE would be expanded per the 1992 EIS with complete closure of Rio Grande Loop Road, which traverses the POE. GSA anticipates that the following categories of impacts will be addressed in the SEIS: Land use, economic, community, environmental justice, transportation system, air quality, noise, hazardous materials and substances, cultural resources, and natural systems. The SEIS will also address methods to mitigate any significant impacts. GSA will comply with its obligations under Section 106 of the National Historic Preservation Act to identify potential impacts to cultural resources. Comments received during scoping may result in consideration of additional issues.

Scoping Process

In accordance with NEPA, a scoping process will be conducted to aid in determining the scope of issues to be addressed and for identifying the significant issues related to the proposed action. Scoping will be accomplished through a public scoping meeting, direct mail correspondence to potentially interested persons, agencies, and organizations, and meetings with persons or agencies of special concern with an interest in the proposed actions. It is important that Federal, regional, state, and local agencies, and interested individuals and groups take this opportunity to identify environmental concerns that should be addressed during the preparation of the Draft SEIS.

Public Scoping Meeting

The public scoping meeting will be held at Del Rio Civic Center, 1915 Veterans Blvd., Del Rio, TX on 19 November 2003, from 7 p.m. to 9 p.m. The meeting will be an information open house, where visitors may come, receive information, discuss the proposal with study team members, give their comments, and leave anytime during the meeting period. GSA will publish notices announcing this meeting approximately one week prior to the meeting in the *Del Rio News-Herald*, the *San Antonio Express News*, and the *Austin American-Statesman*. GSA will prepare a scoping report, available to the public, that will summarize the comments received and facilitate their incorporation into the SEIS process.

Written Comments: Agencies and the public are encouraged to provide written comments on the scoping issues in addition to or in lieu of giving their comments at the public scoping meeting. Written comments regarding the environmental analysis for the proposed action must be postmarked no later than 28 November 2003, and sent to the following address: U.S. General Services Administration, Public Building Services, Greater Southwest Region, Attention: Lisa Schaub, Environmental Advisor, 819 Taylor Street, 7PM, Fort Worth, TX 76102.

Scoping Meeting Place

The meeting will be held at the following address: Del Rio Civic Center, 1915 Veterans Blvd., Del Rio, TX, Data: 19 November 2003, Time: 7 p.m. to 9 p.m.

Dated: November 7, 2003

Lisa Schaub,

Environmental Advisor, Greater Southwest Region, General Services Administration.

[FR Doc. 03–28491 Filed 11–13–03; 8:45 am]

BILLING CODE 6820–14–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Chronic Fatigue Syndrome Advisory Committee

AGENCY: Office of the Secretary, HHS.

ACTION: Notice of meeting.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (DHHS) is hereby giving notice that the Chronic Fatigue Syndrome Advisory Committee (CFSAC) will hold a meeting. The meeting will be open to the public.

DATES: The meeting will be held on Monday, December 8, 2003, from 9 a.m. to 5 p.m.

ADDRESSES: Department of Health and Human Services, Hubert H. Humphrey Building, Room 800, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Dr. Larry E. Fields, Executive Secretary, Chronic Fatigue Syndrome Advisory Committee, U.S. Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Room 719H, Washington, DC 20201; (202) 690–7694.

SUPPLEMENTARY INFORMATION: CFSAC was established on September 5, 2002, to replace the Chronic Fatigue Syndrome Coordinating Committee. CFSAC was established to advise, consult with, and make recommendations to the Secretary, through the Assistant Secretary for Health, on a broad range of topics including (1) the current state of knowledge and research about the epidemiology and risk factors relating to chronic fatigue syndrome, and identifying potential opportunities in these areas; (2) current and proposed diagnosis and treatment methods for chronic fatigue syndrome; and (3) development and implementation of programs to inform the public, health care professionals, and the biomedical, academic, and research community about chronic fatigue syndrome advances.

The tentative agenda for this meeting is as follows:

9 a.m.—Call to Order, Roll Call, Introductions, Minutes of the September 29th meeting.

9:30 a.m.—Presentations, Executive Secretary, Organizational Matters, Communications (Web site, listserv), Ex Officio Members, Status of Departmental CFS-directed efforts, Requested follow-ups, Q & A.

12 noon—Lunch Break.

1 p.m.—Further Discussions, Carry-over Issues, CFSAC Mission Statement, CFSAC Goals and Priorities, Name change, New Issues.

3:30 p.m.—Public Comments.

4:30 p.m.—Wrap Up, Action Steps, Timelines, Next Meeting.

5 p.m.—Adjournment.

Public attendance at the meeting is limited to space available. Individuals must provide a photo ID for entry into the meeting. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the designated contact person. Members of the public will have the opportunity to provide comments at the

meeting. Preregistration is required for public comment. Any individual who wishes to participate in the public comment session should call the telephone number listed in the contact information to register. Public comment will be limited to five minutes per speaker. Any members of the public who wish to have printed material distributed to CFSAC members should submit materials to the Executive Secretary, CFSAC, whose contact information is listed above prior to close of business December 1, 2003.

Dated: November 7, 2003.

Larry E. Fields,

Executive Secretary, Chronic Fatigue Syndrome Advisory Committee.

[FR Doc. 03–28579 Filed 11–13–03; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1996D–0009]

International Conference on Harmonisation; Revised Guidance on Q3B(R) Impurities in New Drug Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised guidance entitled ''Q3B(R) Impurities in New Drug Products.'' The revised guidance, which updates a guidance on the same topic published in the **Federal Register** of May 19, 1997 (the 1997 guidance), was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The revised guidance is intended to provide guidance to applicants for drug marketing registration on the content and qualification of impurities in new drug products produced by chemically synthesized new drug substances not previously registered in a country, region, or member State. The revised guidance clarifies the 1997 guidance, adds information, and provides consistency with more recently published ICH guidances. The revised guidance complements the ICH guidance entitled ''Q3A(R) Impurities in New Drug Substances.''

DATES: The guidance is effective November 14, 2003. Submit written or electronic comments at any time.

ADDRESSES: 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*. Submit written requests for single copies of the 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, or the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3844, FAX: 888–CBERFAX. Send two self-addressed adhesive labels to assist the office in processing your request. Requests and comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Charles P. Hoiberg, Center for Drug Evaluation and Research (HFD–800), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5918; or

Andrew Shrake, Center for Biologics Evaluation and Research (HFM–345), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20052–1148, 301–402–4635.

Regarding the ICH: Michelle Limoli, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0864.

SUPPLEMENTARY INFORMATION:

I. Background

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 drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products 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, Labour, and Welfare, and the Japanese Pharmaceutical Manufacturers Association, the Centers for Drug Evaluation and Research and 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 (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, the Health Canada's Health Products and Food Branch, and the European Free Trade Area.

In the **Federal Register** of February 11, 2003 (68 FR 6924), the agency published an ICH guidance entitled ''Q3A(R) Impurities in New Drug Substances,'' which revised Q3A. The guidance Q3A(R) provides recommendations to applicants for drug marketing registration on the content and qualification of impurities in new drug substances produced by chemical synthesis and not previously registered in a country, region, or member state.

In the **Federal Register** of July 19, 2000 (65 FR 44791), FDA published a draft tripartite guidance entitled ''Q3B(R) Impurities in New Drug Products.'' The notice gave interested persons an opportunity to submit comments by September 18, 2000.

After consideration of the comments received and revisions to the guidance, a final draft of the guidance was submitted to the ICH Steering Committee; the three participating regulatory agencies endorsed it in February 2003.

This revised guidance complements the ICH Q3A(R) guidance and provides recommendations for registration or marketing applications on the content and qualification of impurities in new drug products produced from chemically synthesized new drug substances not previously registered in a region or member state. The revised guidance addresses only those impurities in new drug products