Evaluation and Research (HFD–003), Food and Drug Administration, 10993 New Hampshire Ave., Bldg. 21, rm. 3542, Silver Spring, MD 20993–0002, 301–796–1242; or

Christopher Joneckis, Center for Biologics Evaluation and Research (HFM–20), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–435–5681.

Regarding the ICH: Michelle Limoli, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4480.

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; 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, Health Canada, and the European Free Trade Area.

In June 2006, the ICH Steering Committee agreed that a draft guidance entitled ''Q4B Regulatory Acceptance of Analytical Procedures and/or Acceptance Criteria'' should be made available for public comment. The draft guidance is the product of the Q4B Quality Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the Q4B Quality Expert Working Group.

The draft guidance provides information on a Q4B process for evaluating harmonization proposals for specific APAC topics originating principally from the three-party Pharmacopoeial Discussion Group (PDG). The PDG consists of representatives from the European Directorate for the Quality of Medicines in the Council of Europe; the Japanese Ministry of Health, Labour and Welfare, and the United States Pharmacopeial Convention, Inc. Once finalized, the Q4B guidance will describe the process for formally conveying the evaluation outcomes as topic-specific annexes to the core Q4B guidance. Each annex will be issued separately following the ICH step process, providing guidance to assist industry and regulators in the implementation of the specific topic evaluated by the ICH Q4B process.

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 this topic. 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 Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the Division of Dockets Management 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/ohrms/dockets/default.htm*, *http://www.fda.gov/cder/guidance/index.htm*, or *http://www.fda.gov/cber/publications.htm*.

Dated: July 31, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–12807 Filed 8–7–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2006–25528]

Chemical Transportation Advisory Committee

AGENCY: Coast Guard, DHS.

ACTION: Notice of meeting.

SUMMARY: The Chemical Transportation Advisory Committee (CTAC), its Subcommittee on Hazardous Cargo Transportation Security (HCTS), as well as its Working Groups on MARPOL Annex II, Barge Hazard Communication and Vapor Control Systems (VCS) will meet to discuss various issues relating to the marine transportation of hazardous materials in bulk. These meetings will be open to the public.

DATES: The Working Group on MARPOL Annex II will meet on Tuesday, August 22, 2006, from 8:30 a.m. to 12 p.m. and the HCTS Subcommittee will meet on Tuesday, August 22, 2006 from 12:30 p.m. to 5 p.m. The Working Group on VCS will meet on Wednesday, August 23, 2006 from 8:30 a.m. to 12 p.m. and the Working Group on Barge Hazard Communication will meet on Wednesday, August 23, 2006, from 12:30 p.m. to 5 p.m. CTAC will meet on Thursday, August 24, 2006, from 9 a.m. to 3:30 p.m. These meetings may close early if all business is finished. Written material and requests to make oral presentations should reach the Coast Guard on or before August 18, 2006. Requests to have a copy of your material distributed to each member of the Committee should reach the Coast Guard on or before August 18, 2006.

ADDRESSES: The HCTS Subcommittee and the Working Groups on MARPOL Annex II, VCS, and Barge Hazard Communication will be held at American Commercial Barge Lines LLC, 1701 East Market Street, Jeffersonville, IN 47130. The CTAC meeting will be held at The Ramada Inn Jeffersonville, 700 W. Riverside Drive, Jeffersonville, IN 47130. Send written material and requests to make oral presentations to Commander Richard Raksnis, Executive Director of CTAC, Commandant (G-

PSO–3), U.S. Coast Guard Headquarters, 2100 Second Street S.W., Washington, DC 20593–0001 or e-mail: *CTAC@comdt.uscg.mil.* This notice is available on the Internet at *http://dms.dot.gov.*

FOR FURTHER INFORMATION CONTACT: Commander Richard Raksnis, Executive Director of CTAC, or Ms. Sara Ju, Assistant to the Executive Director, telephone (202) 372–1425, fax (202) 372–1926.

SUPPLEMENTARY INFORMATION: Notice of these meetings is given under the Federal Advisory Committee Act, 5 U.S.C. App. 2.

Agenda of Working Group on MARPOL Annex II Meeting on Tuesday, August 22, 2006

(1) Introduce Working Group members and attendees.

(2) Finalize guidance document for the U.S. implementation of revisions to MARPOL Annex II and the International Code for the Construction and Equipment of Ships Carrying Dangerous Chemicals in Bulk (IBC Code).

Agenda of HCTS Subcommittee Meeting on Tuesday, August 22, 2006

(1) Introduce Subcommittee members and attendees.

(2) Finalize document on recommendations to change definition of certain dangerous cargo (CDC) residues.

(3) Continue Notice of Arrival regulation discussions.

Agenda of Working Group on VCS Meeting on Wednesday, August 23, 2006

(1) Introduce Working Group members and attendees.

(2) Develop recommendations for revising the Coast Guard VCS regulations on vapor balancing operations during cargo unloading.

Agenda of Working Group on Barge Hazard Communication Meeting on Wednesday, August 23, 2006

(1) Introduce Working Group members and attendees.

(2) Continue discussion on assisting first responders to identify cargoes on inland barges.

(3) Develop guidance document to implement emergency phone numbers on inland barges.

Agenda of CTAC Meeting on Thursday, August 24, 2006

(1) Introduce Committee members and attendees.

(2) Status report presentation from the CTAC HCTS Subcommittee to include discussion and vote on recommendations to the Coast Guard to change the definition of certain dangerous cargo (CDC) residues.

(3) Status report presentation from the CTAC Outreach Subcommittee.

(4) Status report presentation from the CTAC MARPOL Annex II Working Group to include discussion and vote on guidance document to be submitted to the Coast Guard on proposed implementation of revisions to MARPOL Annex II and the IBC Code in the U.S.

(5) Status report presentation from the CTAC Barge Emission and Barge Hazard Communication Working Group.

(6) Status report presentation from the VCS Working Group to include discussion and vote on recommendations to the Coast Guard for revising the Coast Guard VCS regulations on vapor balancing operations while unloading cargo.

(7) Update on Coast Guard regulatory projects.

Procedural

These meetings are open to the public. Please note that the meetings may close early if all business is finished. At the discretion of the Chair, members of the public may make oral presentations during the meetings generally limited to 5 minutes. If you would like to make an oral presentation at a meeting, please notify the Executive Director and submit written material on or before August 18, 2006. If you would like a copy of your material distributed to each member of the Committee in advance of a meeting, please submit 25 copies to the Executive Director (see **ADDRESSES**) no later than August 18, 2006.

Information on Services for Individuals With Disabilities

For information on facilities or services for individuals with disabilities, or to request special assistance at the meeting, telephone the Executive Director as soon as possible.

Dated: August 2, 2006.

J.G. Lantz,

Director of National and International Standards, Assistant Commandant for Prevention.

[FR Doc. E6–12791 Filed 8–7–06; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Bureau of Customs and Border Protection

Updated List of the Ports-of-Entry Designated for Departure of Nonimmigrant Aliens Who Are Subject to Special Registration

AGENCY: Bureau of Customs and Border Protection, Department of Homeland Security.

ACTION: Notice.

SUMMARY: This notice provides the public with an updated list of ports through which nonimmigrant aliens who have been specially registered may depart from the United States. Special registration is required of nonimmigrant aliens whose presence in the United States requires closer monitoring.

EFFECTIVE DATE: This Notice is effective August 18, 2006.

FOR FURTHER INFORMATION CONTACT: Sophie Galvan, Program Manager, Traveler Security and Facilitation Division, Office of Field Operations, Bureau of Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Room 5.4.D, Washington DC 20229.

SUPPLEMENTARY INFORMATION:

Nonimmigrant Aliens Subject To Special Registration Requirements

On August 12, 2002, the Attorney General published a final rule in the **Federal Register** at 67 FR 52584 to revise the special registration requirements for nonimmigrant aliens whose presence in the United States requires closer monitoring. The final rule requires that when a nonimmigrant alien subject to special registration departs from the United States, that immigrant must report to an Immigration and Naturalization Service (INS) inspecting officer at any port-of-entry (POE), unless INS has, by publication in the **Federal Register**, specified that POE as a port from which nonimmigrant aliens subject to special registration may not depart. This rule became effective on October 1, 2002.

On September 30, 2002, the INS published a notice in the **Federal Register** at 67 FR 61352 listing POEs through which nonimmigrant aliens who have been specially registered may depart from the United States. The notice set forth an affirmative list of POEs that could be used by specially registered nonimmigrant aliens rather than specifying ports that could not be used.