

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In June 2009, the ICH Steering Committee agreed that a draft guidance entitled "Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 9: Tablet Friability General Chapter" should be made available for public comment. The draft guidance is the product of the Q4B Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the Q4B Expert Working Group.

The draft guidance provides the specific evaluation results from the ICH Q4B process for the Tablet Friability General Chapter harmonization proposal originating from the three-party PDG. This draft guidance is in the form of an annex to the core ICH Q4B guidance. Once finalized, the annex will provide 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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115).

The draft guidance, when finalized, will represent the agency's current thinking on this topic.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. 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.regulations.gov>, <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm>.

Dated: July 31, 2009.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E9-19528 Filed 8-13-09; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention (CDC)

#### Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Health Promotion and Disease Prevention Research Centers, Special Interest Project Competitive Supplements (SIPS) (U48 Panels N-P), RFA-DP09-101SUPP09, Initial Review

**Cancellation:** The notice was originally published in the **Federal Register** on July 21, 2009 (Volume 74, Number 138) [page 35877]. The following panels are cancelled: N, O and P.

**Contact Person for More Information:** Brenda Colley-Gilbert, Ph.D., Director, Extramural Research Program Office, CCCH, 4770 Buford Highway, MS K-92,

Atlanta, GA 30341, Telephone (770) 488-6295.

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.

**Elaine L. Baker,**

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

[FR Doc. E9-19501 Filed 8-13-09; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

[Docket No. USCG-2008-0333]

#### Delaware River and Bay Oil Spill Advisory Committee; Meeting

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of meeting.

**SUMMARY:** The Delaware River and Bay Oil Spill Advisory Committee (DRBOSAC) will meet in Lewes, DE to discuss various issues to improve oil spill prevention and response strategies for the Delaware River and Bay. This meeting will be open to the public.

**DATES:** The Committee will meet on Wednesday, September 9, 2009, from 2 p.m. to 4 p.m. This meeting may close early if all business is finished. Written material, requests to make oral presentations, and requests to have a copy of your material distributed to each member of the committee should reach the Coast Guard on or before September 2, 2009.

**ADDRESSES:** The Committee will meet at Virden Retreat Center, University of Delaware (the Harbor Room), 700 Pilottown Road, Lewes, DE 19958. Send written material and requests to make oral presentations to Gerald Conrad, Liaison to the Designated Federal Officer (DFO) of the DRBOSAC, Coast Guard Sector Delaware Bay, 1 Washington Ave., Philadelphia, PA 19147. This notice and any documents identified in the Supplementary Information section as being available in the docket may be viewed online, at <http://www.regulations.gov>, using docket number USCG-2008-0333.

**FOR FURTHER INFORMATION CONTACT:** Gerald Conrad, Liaison to the DFO of the DRBOSAC, telephone 215-271-4824.

**SUPPLEMENTARY INFORMATION:** Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. App. (Pub. L. 92-463).

#### Agenda of the Meeting

The agenda for the September 9 meeting will be as follows:

- (1) Opening comments.
- (2) Introductions.
- (3) Administrative announcements.
- (4) Pre-approved presentations from the public.
- (5) Debriefs from each DRBOSAC Subcommittee.
- (6) Public comments.
- (7) Future Committee business.
- (8) Closing.

More information and detail on the meeting will be available at the committee Web site, located at <https://homeport.uscg.mil/drbosac>. Additional detail may be added to the agenda up to September 2, 2009.

#### Procedural

This meeting is open to the public. All persons entering the Harbor Room will need to sign in at the door. Please note that the meeting may close early if all business is finished.

The public will be able to make oral presentations during the meeting when given the opportunity to do so. Members of the public may seek pre-approval for their oral presentations by contacting the Coast Guard no later than September 2, 2009. The public may file written statements with the committee; written material should reach the Coast Guard no later than September 2, 2009. If you would like a copy of your material distributed to each member of the committee in advance of the meeting, please submit 35 copies to the Liaison to the DFO no later than September 2, 2009, and indicate that the material is to be distributed to committee members in advance of the September 9 meeting.

Please register your attendance with the Liaison to the DFO no later than September 2, 2009.

#### 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, contact the Liaison to the DFO as soon as possible.

Dated: August 6, 2009.

**Nakeisha B. Hills,**

*Lieutenant Commander, U.S. Coast Guard, Preparedness Officer, Sector Delaware Bay Acting Designated Federal Officer.*

[FR Doc. E9-19550 Filed 8-13-09; 8:45 am]

**BILLING CODE 4910-15-P**

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-5337-N-01]

### Additional Allocations and Waivers Granted to and Alternative Requirements for 2008 Community Development Block Grant (CDBG) Disaster Recovery Grantees

**AGENCY:** Office of the Secretary, HUD.

**ACTION:** Notice of allocations, waivers, and alternative requirements.

**SUMMARY:** This Notice advises the public of the second allocation for grant funds for CDBG disaster recovery grants for the purpose of assisting in the recovery in areas covered by a declaration of major disaster under title IV of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 *et seq.*) as a result of recent natural disasters. As described in the **SUPPLEMENTARY INFORMATION** section of this Notice, HUD is authorized by statute and regulations to waive statutory and regulatory requirements and specify alternative requirements for this purpose, upon the request of the state grantees. This Notice also describes: (1) How the allocatees may implement the common application, eligibility, and administrative waivers and the common alternative and statutory requirements for the grants; and (2) additional waivers and alternative requirements for certain earlier grants.

**DATES:** *Effective Date:* August 19, 2009.

#### FOR FURTHER INFORMATION CONTACT:

Scott Davis, Director, Disaster Recovery and Special Issues Division, Office of Block Grant Assistance, Department of Housing and Urban Development, 451 7th Street, SW., Room 7286, Washington, DC 20410, telephone number 202-708-3587. Persons with hearing or speech impairments may access this number via TTY by calling the Federal Information Relay Service at telephone number 800-877-8339. Facsimile inquiries may be sent to Mr. Davis at facsimile number 202-401-2044. (Except for the "800" number, these telephone numbers are not toll free.)

#### SUPPLEMENTARY INFORMATION:

##### Authority To Grant Waivers

The Consolidated Security, Disaster Assistance, and Continuing Appropriations Act, 2009 (Pub. L. 110-329, approved September 30, 2008) (hereinafter, "Second 2008 Act") to differentiate it from the earlier 2008 Supplemental Appropriations Act) (Pub. L. 110-252 approved June 30, 2008)

(hereinafter "First 2008 Act"), appropriated \$6.5 billion, to remain available until expended, in CDBG funds for necessary expenses related to disaster relief, long-term recovery, and restoration of infrastructure, housing, and economic revitalization in areas affected by hurricanes, floods, and other natural disasters occurring during 2008, for which the President declared a major disaster under title IV of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 *et seq.*). To date, \$377,139,920 has been rescinded, \$6,500,000 was set-aside for HUD administrative costs, and \$2,145,000,000 was allocated by HUD in November 2008. This Notice allocates the remaining \$3,971,360,080.

The First 2008 Act also appropriated funds for 2008 disaster recovery grantees, although it only provided funds for disasters occurring in May and June 2008. Both the First 2008 Act and the Second 2008 Act authorize the Secretary to waive, or specify alternative requirements for, any provision of any statute or regulation that the Secretary administers in connection with the obligation by the Secretary or use of these funds and guarantees by the recipient, except for requirements related to fair housing, nondiscrimination, labor standards, and the environment (including requirements concerning lead-based paint), upon a request by the state explaining why such waiver is required to facilitate the use of such funds or guarantees, and a finding by the Secretary that such a waiver would not be inconsistent with the overall purpose of title I of the Housing and Community Development Act of 1974 (HCD Act). Additionally, regulatory waiver authority is provided by 24 CFR 5.110, 91.600, and 570.5. The following application and reporting waivers and alternative requirements are in response to requests from the states receiving an allocation under today's **Federal Register** Notice.

The Secretary finds that the following waivers and alternative requirements, as described below, are necessary to facilitate use of the funds for the statutory purposes and are not inconsistent with the overall purpose of title I of the HCD Act or the Cranston-Gonzalez National Affordable Housing Act, as amended.

Under the requirements of the First 2008 Act and the Second 2008 Act, statutory and regulatory waivers must be published in the **Federal Register**. Except as described in this Notice, statutory and regulatory provisions governing the CDBG program for states, including those at 24 CFR part 570,