

objectives of the parties as appropriate, and provided that such appointments comply with university policies on appointment of facility/affiliates;

- In an effort to enhance collaborative interactions and communication between both institutions, FDA and DISL will collaborate in the development of regular workshops where faculty from all the institutions within the DISL and FDA scientists and staff share information about ongoing research, education and outreach efforts of mutual interest.

### C. Eligibility Information

Competition is limited to the DISL. There are no other sources that can provide the required proximity to the FDA/GCSL and independent marine fieldwork capability required. The DISL is a diverse institutional consortium of undergraduate and graduate education and research. University programs faculty at the DISL are actively involved in both basic and applied research in coastal waters of the northern Gulf of Mexico. The DISL operates marine research vessels (boats) crewed by faculty and students for field studies and sample collections. DISL possesses extensive laboratory and wet-laboratory resources relevant to the mission of the FDA/GCSL. The DISL is located within 1 mile of the FDA/GCSL which will engage the proposed program of collaboration and internships. This unique circumstance of capability, capacity and proximity is irreplaceable without extended and costly concessions.

## II. Award Information/Funds Available

### A. Award Amount

The estimated amount of support in FY12 will be up to \$125,000. (direct plus indirect costs) with the possibility of 4 additional years of support for up to \$125,000.00 per year, subject to the availability of funds. Future year amounts will depend on annual appropriations and successful contract performance.

### B. Length of Support

The award will provide 1 year of support and include future recommended support for 4 additional years, contingent upon satisfactory performance in the achievement of project and program reporting objectives during the preceding year and the availability of Federal fiscal year appropriations.

## III. Paper Application, Registration, and Submission Information

To submit a paper application in response to this FOA, applicants should

first review the full announcement located at <http://www.fda.gov/Food/NewsEvents/default.htm>. (FDA has verified the Web site addresses throughout this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.) Persons interested in applying for a grant may obtain an application at <http://grants2.nih.gov/grants/funding/phs398/phs398.html>. For all paper application submissions, the following steps are required:

- Step 1: Obtain a Dun and Bradstreet Data Universal Numbering System (DUNS) Number.
- Step 2: Register With Central Contractor Registration.
- Step 3: Register With Electronic Research Administration (eRA) Commons.

Steps 1 and 2, in detail, can be found at [http://www07.grants.gov/applicants/organization\\_registration.jsp](http://www07.grants.gov/applicants/organization_registration.jsp). Step 3, in detail, can be found at <https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp>. After you have followed these steps, submit paper applications to:

Gladys Melendez-Bohler, Office of Acquisition and Grant Services (OAGS), Food and Drug Administration, 5630 Fishers Lane, rm. 1078, Rockville, MD 20857.

Dated: June 28, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0002]

### Transmissible Spongiform Encephalopathies Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Transmissible Spongiform Encephalopathies Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the Agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on August 1, 2011, from 9 a.m. to approximately 4:30 p.m.

*Location:* Hilton Hotel, Washington DC North Gaithersburg, 620 Perry Pkwy., Gaithersburg, MD 20877. For those unable to attend in person, the meeting will also be Web cast. The Web cast will be available at the following link. Transmissible Spongiform Encephalopathies Advisory Committee <http://fda.yorkcast.com/webcast/Viewer/?peid=8477143b2da5442a8192731eccde3b7a1d>.

**CONTACT PERSON:** Bryan Emery or Rosanna Harvey, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

*Agenda:* The committee will discuss donor deferral for time spent in Saudi Arabia to reduce the risk of variant Creutzfeldt-Jakob disease (vCJD) by blood and blood products and human cells, tissues and cellular and tissue-based products.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before July 25, 2011. Oral presentations from the public will be scheduled on August 1, 2011, between approximately 2:15 p.m. and 2:45 p.m.

Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before July 15, 2011. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by July 18, 2011.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Bryan Emery or Rosanna Harvey at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: June 28, 2011.

**Jill Hartzler Warner,**  
*Acting Associate Commissioner for Special Medical Programs.*

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**BILLING CODE 4160-01-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

**[Docket No. FDA-2011-N-0002]**

#### **Advisory Committee for Pharmaceutical Science and Clinical Pharmacology; Notice of Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration

(FDA). The meeting will be open to the public.

*Name of Committee:* Advisory Committee for Pharmaceutical Science and Clinical Pharmacology.

*General Function of the Committee:* To provide advice and recommendations to the Agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on July 26, 2011, from 8 a.m. to 5:30 p.m.

*Location:* FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. Information regarding special accommodations due to a disability, visitor parking and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You", click on "Public Meetings at the FDA White Oak Campus". Please note that visitors to the White Oak Campus must enter through Building 1.

*Contact Person:* Yvette Waples, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, e-mail: [ACPS-CP@fda.hhs.gov](mailto:ACPS-CP@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

*Agenda:* On July 26, 2011, the committee will discuss presentations by the Office of Generic Drugs (OGD) on bioequivalence issues and quality standards relative to narrow therapeutic index (NTI) drug products as a class. In response to feedback during the April 13, 2010, Advisory Committee for Pharmaceutical Science and Clinical Pharmacology (ACPS-CP) meeting, the committee will further discuss the definition and list of NTI drugs, as well as proposed bioequivalence standards for these products. The committee will also receive awareness presentations relevant to OGD's ongoing focus on quality and safety of generic drug products. Presentations will outline current activities seeking to better

understand the impact of formulation and quality on the performance of generic drug products and current thinking related to potential regulatory pathways for these issues.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before July 19, 2011. Oral presentations from the public will be scheduled between approximately 11 a.m. to 12 noon, and 4:30 p.m. to 5 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before July 12, 2011. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by July 13, 2011.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Yvette Waples at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on