

TABLE 4—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>—Continued

Activity	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
Main Study .....	8,000	1	8,000	.33 (20 min.)	2,640
Total .....					3,320

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: June 28, 2011.  
**Leslie Kux**,  
*Acting Assistant Commissioner for Policy.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2011-N-0012]

**Food and Drug Administration (FDA) and Marine Environmental Sciences Consortium/Dauphin Island Sea Lab Collaboration (U19)**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of grant funds for the support of a cooperative agreement between the Center for Food Safety and Applied Nutrition (CFSAN) and the Marine Environmental Sciences Consortium/Dauphin Island Sea Lab (DISL). The goal of the DISL is marine science education, basic and applied marine science research, coastal zone management policy, and educating the general public.

- DATES:** Important dates are as follows:
1. The application due date is August 1, 2011.
  2. The anticipated start date is September, 2011.
  3. The opening date is the date the Funding Opportunity is published in the **Federal Register**.
  4. The expiration date is August 2, 2011.

**FOR FURTHER INFORMATION AND ADDITIONAL REQUIREMENTS CONTACT:**

**Scientific/Programmatic Contact**

Robert Dickey, Office of Food Safety, Gulf Coast Seafood Laboratory, One Iberville Dr., PO. D1-1, rm. 122 (HFS 400), Dauphin Island, AL 36528,. Tele.: 251-690-3368; e-mail: *Robert.Dickey@fda.hhs.gov*.

**Grants Management Contact**

Gladys Melendez-Bohler, Office of Acquisition and Grant Services (OAGS), Food and Drug Administration, 5630 Fishers Lane, rm. 1078, Rockville, MD 20857, Tele.: 301-827-7175; e-mail: *Gladys-Melendez-Bohler@fda.hhs.gov*.

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please refer to the full FOA located at <http://www.fda.gov/Food/NewsEvents/default.htm>.

**SUPPLEMENTARY INFORMATION:**

RFA-FD-11-015; 93.103.

**A. Background**

This FOA issued by the FDA/Office of Food Safety is soliciting a sole source grant application from the Dauphin Island Sea Lab (DISL). FDA is authorized to enforce the Federal Food, Drug, and Cosmetic Act (the FD&C Act) as amended (21 U.S.C. 301 *et seq.*). In fulfilling its responsibilities under the FD&C Act, FDA among other things, directs its activities toward promoting and protecting the public health by ensuring the safety and security of foods (Appendix A). To accomplish its mission, FDA must stay abreast of the latest developments in research and also communicate with stakeholders about complex scientific and public health issues. Increased development of research, education and outreach partnerships with the Marine Environmental Science Consortium-Dauphin Island Sea Lab (DISL) will greatly contribute to FDA's mission.

The DISL is one of Alabama's most valuable assets and adds immeasurably to the quality of life in the state and beyond. The DISL network of 21 institutions enrolls students worldwide in degree programs delivered in classrooms, laboratories, education centers, and online. The DISL's nationally ranked programs, leading-edge research collaborations, and innovative business partnerships provide an environment to support diverse multidisciplinary exchanges with FDA. The scientific, public health and policy expertise within FDA provide opportunities for collaborations

that support the DISL mission and strategic themes to provide access to high-quality education, research discovery, and knowledge-based services responsive to both the promises and demands of the state and the nation in the new century.

**B. Research Objectives**

FDA Gulf Coast Seafood Laboratory (GCSL) and the Marine Environmental Science Consortium of the DISL (the Parties) have a shared interest in scientific progress in the diverse disciplines that directly and indirectly affect seafood safety and human and animal health. The Parties also endorse scientific training for faculty, students and staff to foster a well-grounded foundation in interdisciplinary fields in which academia and government share mutual interest.

The cooperative agreement will establish terms of collaboration between FDA and DISL to support these shared interests that can be pursued through programs of collaborative research, public outreach, cooperative international initiatives, disciplinary training, and exchange of scientists and staff, including a program of graduate student internships.

The types of activities expected to develop from this agreement include:

- Exchanges between university faculty and staff and FDA scientists and staff;
- Educational opportunities for qualified students (graduate), staff members and faculty members in the Parties' laboratories, classroom and offices;
- Joint meetings for education and research;
- Research collaborations;
- Cooperative international activities including outreach; and
- Sharing of unique facilities and equipment for increased cost efficiencies for scientific endeavors;
- Promulgation and communication of identified collaborative efforts through appropriate means;
- Adjunct, affiliates and research facility appointments for appropriate FDA professional staff, provided that appointment of such candidates will advance specific programmatic

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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## 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.