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Dated: July 27, 2009.

**Eskinder Negash,**

Director, Office of Refugee Resettlement.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-N-0353]

#### Cooperative Agreement Between the Food and Drug Administration and the Dauphin Island Sea Lab

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing its intention to receive and consider a single source application for the award of a cooperative agreement in fiscal year 2009 (FY09) to the 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 24, 2009.
2. The anticipated start date is in September 2009.
3. The opening date is August 3, 2009.
4. The expiration date is August 25, 2009.

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

*Center Contact:* LaQuia Geathers, Center for Food Safety and Applied Nutrition (CFSAN) (HFS-669), Food and Drug Administration (FDA), 5100 Paint Branch, Pkwy., College Park, MD 20740, 301-436-2821, e-mail: [LaQuia.Geather@fda.hhs.gov](mailto:LaQuia.Geather@fda.hhs.gov).

#### *Scientific/Programmatic Contact:*

Julia Pryor, Division of Seafood Science and Technology, FDA, CFSAN, Office of Food Safety, Gulf Coast Seafood Laboratory, 1 Iberville Dr., Dauphin Island, AL 36528, 251-694-4479; FAX: 251-694-4477, e-mail: [Julia.Pryor@fda.hhs.gov](mailto:Julia.Pryor@fda.hhs.gov).

*Grants Management Contact:* Camille Peake, Division of Acquisition Support and Grants, FDA (HFA 500), 5630 Fishers Lane (rm. 2139), Rockville, MD 20857, 301-827-

7175, FAX: 301-827-7101, e-mail: [Camille.Peake@fda.hhs.gov](mailto:Camille.Peake@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.cfsan.fda.gov/list.html>. Click on National Food Safety Program; click [www.FoodSafety.gov](http://www.FoodSafety.gov); click search and site index; search on "CFSAN Grants."

#### SUPPLEMENTARY INFORMATION:

##### I. Funding Opportunity Description

[RFA-FD-09-017]

[Catalog of Federal Domestic Assistance Number: 93.103]

##### A. Background

This FOA issued by the Office of Food Safety is soliciting a sole source grant application from the DISL. FDA is authorized to enforce the Federal Food, Drug, and Cosmetic Act (the act) as amended (21 U.S. C. 301 *et seq.*). In fulfilling its responsibilities under the 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 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

The 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 on going 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 FY09 will be up to \$250,000 total costs (direct plus indirect costs).

### B. Length of Support

The award will provide 12 months of support contingent upon satisfactory performance in the achievement of project and program reporting.

## 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.cfsan.fda.gov/list.html>. Persons interested in applying for a grant may obtain an application from the PHS 398 application instructions available at <http://grants.nih.gov/grants/forms.htm>. The following steps are required for paper submission:

- Step 1: Obtain a Dun and Bradstreet Number (DUNS)

Applicants are now required to have a DUNS number to apply for a grant or cooperative agreement from the Federal Government. The DUNS number is a 9-digit identification number that uniquely identifies business entities. To obtain a DUNS number, call DUN and Bradstreet at 1-866-705-5711. Be certain that you identify yourself as a Federal grant applicant when you contact Dun and Bradstreet. For foreign entities the Web site <https://eupdate.DNB.com>.

- Step 2: Register With Central Contractor Registration (CCR)

Applicants must register with the CCR database. You must have a DUNS number to begin your registration. This database is a government-wide warehouse of commercial and financial information for all organizations conducting business with the Federal Government. The preferred method for

completing a registration is through the Web site at <https://www.ccr.gov>. This Web site provides a CCR handbook with detailed information on data you will need prior to beginning the online pre-registration, as well as steps to walk you through the registration process.

- 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: Camille Peake, Division of Acquisition Support and Grants, Food and Drug Administration (HFA 500), 5630 Fishers Lane, rm. 2139, Rockville, MD 20857, 301-827-7175, FAX: 301-827-7101, e-mail: [Camille.Peake@fda.hhs.gov](mailto:Camille.Peake@fda.hhs.gov).

Dated: July 28, 2009.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2008-N-0582]

#### Kim C. Hendrick: Debarment Order

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the act) permanently debaring Kim C. Hendrick, M.D., from providing services in any capacity to a person that has an approved or pending drug product application. We base this order on a finding that Dr. Hendrick was convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of a drug product, and for conduct otherwise relating to the regulation of a drug product under the act. After being given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation, Dr. Hendrick failed to request a hearing. Dr. Hendrick's failure to request a hearing constitutes a waiver of his right to a hearing concerning this action.

**DATES:** This order is effective August 4, 2009.

**ADDRESSES:** Submit applications for special termination of debarment to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

#### FOR FURTHER INFORMATION CONTACT:

Robert Hummel, Sr., Division of Compliance Policy (HFC-230), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240-632-6845.

#### SUPPLEMENTARY INFORMATION:

### I. Background

Section 306(a)(2)(A) of the act (21 U.S.C. 335a(a)(2)(A)) requires debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product. Section 306(a)(2)(B) of the act requires debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct otherwise relating to the regulation of any drug product under the act.

On September 11, 2007, the U.S. District Court for the Eastern District of Michigan accepted Dr. Hendrick's guilty plea and entered judgment against him for one count of mail fraud, a federal felony offense under 18 U.S.C. 1341. This offense was committed when Dr. Hendrick was a licensed physician practicing medicine in the State of Michigan. Dr. Hendrick agreed to participate in the clinical research trial for Augmentin XR, including its use in the treatment of adults with Acute Bacterial Sinusitis (ABS). As part of his participation in the clinical study, he agreed to conduct the study in conformity with the protocol established by GlaxoSmithKline and to comply with FDA regulations. He also agreed to take X-rays, before and after treatment, of persons he diagnosed with ABS, and to have an independent radiologist analyze these and issue reports regarding the X-rays.

Dr. Hendrick admitted that instead of having an independent radiologist review the X-rays and issue reports, he allowed certain X-rays to be sent in batch form, which was a direct violation of the protocol. Further, he did not verify the purported signatures of the independent radiologist reports and, instead, failed to disclose to GlaxoSmithKline and/or FDA that the signatures were unverified and possibly