

G. CDC and the appropriate state and/or local public health authority(ies) are also authorized to make available additional information relating to the emergency use of authorized oseltamivir phosphate products that is consistent with, and does not exceed, the terms of this letter of authorization.

The emergency use of authorized oseltamivir phosphate products as described in this letter of authorization must comply with the conditions above and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration of emergency is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Joshua M. Sharfstein, M.D.
Principal Deputy Commissioner
Acting Commissioner of Food and Drugs

¹ FDA is authorizing the emergency use of Tamiflu (oseltamivir phosphate) (30 mg, 45 mg, and 75 mg) capsules and oral suspension for treatment and prophylaxis of influenza as described in the scope section of this letter (Section II). For ease of reference, this letter of authorization will use the terms "certain oseltamivir phosphate product(s)" and "authorized oseltamivir phosphate product(s)."

² No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

² No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

³ The following points should be considered before initiating treatment or prophylaxis with oseltamivir phosphate products. Oseltamivir phosphate products are not a substitute for early vaccination on an annual basis as recommended by the Centers for Disease Control and Prevention Advisory Committee on Immunization Practices. Influenza viruses change over time. Emergence of resistance mutations could decrease drug effectiveness. Other factors (for example, changes in viral virulence) might also diminish clinical benefit of antiviral drugs. Prescribers should consider available information on influenza drug susceptibility patterns and treatment effects when deciding whether to use oseltamivir phosphate products.

⁴ It is possible that public health officials or other volunteers might distribute authorized oseltamivir phosphate products to recipients, if permitted, in accordance with applicable state and local law and/or in accordance with the public health and medical emergency response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute, or dispense the covered countermeasures, and their officials, agents, employees, contractors, or volunteers following a declaration of an emergency. For ease of reference, this letter will use the term "health care provider(s)" to refer collectively to these individuals.

⁵ Please note that with respect to authorized oseltamivir phosphate products for use in patients less than 1 year old, the conclusions above are based on limited data available for review under the limited timeframe given the circumstances of the emergency. The conclusions above may evolve as the emergency circumstances evolve and as more information becomes available.

(Please note that certain written emergency use information was also amended).

Dated: June 30, 2009.

Randall W. Lutter,

Deputy Commissioner for Policy.

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CFDA Number: 93.583.

Legislative Authority: The Refugee Act of 1980 as amended, Wilson-Fish Amendment, 8 U.S.C. 1522(e)(7); section 412(e)(7)(A) of the Immigration and Nationality Act.

Amount of Award: \$1,744,533.

Period Of Support: 09/30/2009-09/29/2010.

SUMMARY: The Office of Refugee Resettlement (ORR) announces the award of program expansion supplements to five Wilson-Fish Program grantees. The Wilson-Fish Program is an alternative to traditional State-administered refugee assistance programs and provides integrated assistance and services to refugees, asylees, Amerasian Immigrants, Cuban and Haitian Entrants, Trafficking Victims and Iraqi/Afghani Special Immigrant Visas (SIVs). The five

supplemental awards will allow the grantees to provide cash and medical assistance to arriving refugees and to others who are also eligible for refugee benefits through the remainder of Fiscal Year (FY) 2009. The expansion supplement awards will enable the grantees to provide services needed to a higher number of arrivals than originally planned. The Refugee Act of 1980 mandates that the ORR reimburse State agencies and Wilson-Fish projects for the costs of cash and medical assistance for newly arriving refugees. Since 1991, ORR has reimbursed State agencies and Wilson-Fish agencies for providing cash and medical assistance to eligible individuals during their first eight months in the United States. The following Wilson-Fish Program grantees are awarded program expansion supplemental funding:

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families; Office of Refugee Resettlement

AGENCY: Office of Refugee Resettlement, ACF, HHS.

ACTION: Notice to Award Five Program Expansion Supplements to Wilson-Fish Projects.

Grantee organization	Location	Amount of award
Catholic Social Services	Anchorage, AK	\$86,931
Colorado Department of Human Services	Denver, CO	798,411
Catholic Charities of Louisville	Louisville, KY	575,000
Catholic Charities Diocese of Baton Rouge	Baton Rouge, LA	94,368
Massachusetts Office of Refugees and Immigrants	Boston, MA	189,823

FOR FURTHER INFORMATION CONTACT: Carl Rubenstein, Wilson-Fish Program

Manager, Office of Refugee Resettlement, Aerospace Building, 8th

Floor West, 901 D Street SW., Washington, DC 20447. Telephone:

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Dated: July 27, 2009.

Eskinder Negash,

Director, Office of Refugee Resettlement.

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BILLING CODE 4184-01-P

**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-
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Scientific/Programmatic Contact:

Julia Pryor, Division of Seafood
 Science and Technology, FDA,
 CFSAN, Office of Food Safety, Gulf
 Coast Seafood Laboratory, 1
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 36528, 251-694-4479; FAX: 251-
 694-4477, e-mail:
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Grants Management Contact: Camille
 Peake, Division of Acquisition
 Support and Grants, FDA (HFA
 500), 5630 Fishers Lane (rm. 2139),
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7175, FAX: 301-827-7101, e-mail:
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; 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