government to petition for an exemption from preemption under the provisions of section 403A of the FD&C Act.

Dated: August 12, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–21041 Filed 8–17–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0012]

Direct Discovery of HLA Associated Influenza Epitopes Isolated From Human Cells for Vaccine and Therapeutic Evaluation and Development (U01)

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 sole source cooperative agreement with the University of Oklahoma Health Sciences Center. The goal of the FDA, Center for Drug Evaluation and Research, Office of Chief Scientist, is to develop technology to molecularly characterize peptide epitopes that are processed and presented on soluble HLA (human leucocyte antigen) expressed by human cells. Initial studies will examine and characterize influenza peptides isolated from several different soluble Class I HLAs produced from influenza infected human lung cell lines. There is a growing interest in developing universal vaccines for influenza by targeting conserved internal proteins to stimulate cross-protective CTLs (cytolytic T lymphocyte) to provide long-lasting immunity. It is therefore critically important to identify which viral epitopes are generated by antigen processing in influenza infected lung cells, the target cells of cell mediated immune response to respiratory viruses. FDA seeks a collaboration to develop this technology for this purpose which can then be applied to identifying and characterizing other HLA-presented epitopes in viral infections, cancer, and immune toxicities.

DATES: Important dates are as follows:

1. The application due date is September 1, 2011.

2. The anticipated start date is November 1, 2011.

3. The opening date is August 18, 2011.

4. The expiration date is November 2, 2011.

FOR FURTHER INFORMATION AND ADDITIONAL REQUIREMENTS CONTACT:

For Programmatic questions and concerns contact: Michael Norcross, Center for Drug Evaluation and Research, Food and Drug Administration, 9000 Rockville Pike, N29B, Rm. 4NN (HFD 122), Bethesda, MD 20892, *Telephone:* 301–827–0793; *E-mail: Michael.norcross@fda.hhs.gov.*

For Financial and Administrative questions and concerns contact: Gladys M. Bohler, Food and Drug Administration, Office of Acquisitions and Grant Services, 5630 Fisher's Lane, Rm. 1078 (HFA 500), Rockville, MD 20857, *Telephone:* 301–827–7175, *E-mail: gladys.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/AboutFDA/CentersOffices/CDER/ucm088761.htm.*

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

Funding Opportunity Number: RFA–FD–12–001.

Catalog of Federal Domestic Assistance Number: 93.103.

A. Background

Knowledge on how viral and self proteins are processed and presented in HLA molecules is important to understand how the body defends itself from infection and how immune responses can lead to tissue toxicities. Developing technology to allow direct identification of epitopes bound by HLA molecules is critical to vaccine and therapeutic immune strategies. FDA is interested in collaborative research to develop and implement this technology which will be valuable in evaluation and review of vaccines and therapeutics. Initial studies will address identifying epitopes from influenza that are presented by different HLA alleles in infected lung cells.

Influenza virus infection affects a significant proportion of the population and is associated with serious morbidity and mortality. Although many epitopes can be predicted by computer programs and by screening peripheral blood cells with panels of viral peptides from influenza, the peptides that are presented on the infected target cells in the tissues and the infiltrating T cells that recognize the HLA-peptide complexes are the critical elements to control and recover from infection. The technology of directly identifying viral epitopes in HLA can elucidate viral targets for T cells and provide the foundation for new approaches for rapid development of effective vaccines. More effective vaccines to prevent and control influenza infections will have broad public health benefits by reducing morbidity and mortality of this infectious disease.

B. Research Objectives

For this purpose, a direct epitope elution approach is needed to allow milligram quantities of HLA-peptide complexes to be purified from influenza infected lung cells lines that express soluble HLA. Human lung cell lines engineered to secrete soluble HLA from three supertypes (A*01, A*03, and B*27) should be infected with at least two current influenza strains and HLA collected during infection. HLA will be purified and bound peptides eluted. Influenza peptides should be systematically identified by mass spectrometry analysis and sequencing. Synthetic viral peptides can then be tested for binding to recombinant HLA to verify binding specificity and affinity. Influenza epitopes identified in this initial phase of the project can be evaluated for immunogenicity and antigenicity in follow up studies.

This project will provide the regulatory science to facilitate development and evaluation of direct discovery of HLA presented epitopes. The direct epitope methodology will be applied to current influenza strains initially, but has the flexibility to address novel pandemic strains and other pathological agents.

Goal 1: Identify virus-encoded class I HLA peptides presented during influenza infection of human lung cells.

Goal 2: In vitro validation of class I HLA-presented influenza peptides.

Goal 3: Develop HLA-epitope direct-discovery technology for use in FDA laboratories.

C. Eligibility Information

The technology requires extensive infrastructure for growing cells, purifying HLA from culture supernatants, and for mass spectrometry analysis. Staff at the University of Oklahoma Health Sciences Center are leaders in this technology and have published the first reports on applying this method to influenza. Support of this project will allow the extension of the methodology to examine other HLA types. FDA believes this is a novel and valuable methodology that should be implemented at FDA. Funding this collaborative initiative will allow FDA to acquire the proteomic expertise, training, and tissue culture support to establish a laboratory in the field of immunoproteomics. The direct

identification of viral epitopes is critically important to understanding immune responses to infection and vaccination, and there are currently no comparable methods besides the classic screening of vast arrays of overlapping viral peptides on blood lymphocytes. Peptide screening methods only identify possible target epitopes, but do not define which epitopes are expressed in lung tissue. The technology will be valuable for vaccine development and evaluation, and has the flexibility to allow rapid analysis of novel pandemic strains for immunogenic epitopes. The technology can be applied to other infectious diseases, cancer, and immunotoxicities.

II. Award Information/Funds Available

A. Award Amount

Only one grant award will be made in fiscal year (FY) 2012. The application budget is not limited, but it needs to reflect the actual needs of the proposed project. However, presently for FY 2012, the funds are available in the amount of $400,000 (total cost), and are subject to change based on the availability of funds.

B. Length of Support

The maximum period is 1 year with the option of 4 more years of budget support depending on the availability of funds.

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/AboutFDA/CentersOffices/CDER/ucm088761.htm.* 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 (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.* 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 Bohler, Grants Management Specialist (see **FOR FURTHER INFORMATION CONTACT** section of this document).

Dated: August 9, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–21043 Filed 8–17–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Dialogues in Diversifying Clinical Trials: Successful Strategies for Engaging Women and Minorities in Clinical Trials

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA) is announcing the following Office of Women's Health and Society for Women's Health Research jointly sponsored meeting: Dialogues in Diversifying Clinical Trials: Successful Strategies for Engaging Women and Minorities in Clinical Trials. The purpose of this symposium is to facilitate the broader discussion and dissemination of innovative strategies for increasing the recruitment and retention of women and minority subpopulations into clinical trials. The overarching goal of this symposium is to use a best practices learning exchange to share information and encourage successful methods and/or model implementation within a broad research community—industry, academia, and government.

Date and Time: The meeting will be held on September 22, 2011, from 8 a.m. to 9 a.m. (registration); 9 a.m. to 5:30 p.m. (program); 5:30 p.m. to 6:30 p.m. (reception); and September 23, from 8 a.m. to 1:30 p.m.

Location: The meeting will be held at L'Enfant Plaza Hotel, 480 L'Enfant Plaza, SW., Washington, DC 20024.

Contact: Deborah Kallgren, FDA Office of Women's Health, 10903 New Hampshire Ave., Bldg. 32, Rm. 2314, Silver Spring, MD 20993–0002, 301–796–9442, *Fax:* 301–847–8604, *e-mail: deborah.kallgren@fda.hhs.gov.*

Registration: Registration is free, but seating is limited to 200. Registration will be accepted online and is available at *http://www.swhr.org* through September 16, 2011. For information regarding registration contact: Rachel Griffith, Society for Women's Health Research (SWHR), 1025 Connecticut Ave., NW., Suite 701, Washington, DC 20036, 202–496–5001, *Fax:* 202–833–3472, *e-mail: rachel@swhr.org.*

If you need special accommodations due to a disability, please contact Rachel Griffith at least 7 days in advance.

Dated: August 12, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–21042 Filed 8–17–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Secretary's Advisory Committee on Heritable Disorders in Newborns and Children; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, codified at 5 U.S.C. App. 2), notice is hereby given of the following meeting:

Name: Secretary's Advisory Committee on Heritable Disorders in Newborns and Children.

Dates and Times: September 22, 2011, 8:30 a.m. to 5 p.m.; September 23, 2011, 8:30 a.m. to 3:30 p.m.

Place: Renaissance Washington, DC DuPont Circle Hotel, 1143 New Hampshire Avenue, NW., Washington, DC 20037.

Status: The meeting will be open to the public with attendance limited due to space availability. Participants are asked to register for the meeting by going to the registration Web site at *http://altarum.cvent.com/event/SACHDNC092011.* The registration deadline is Tuesday, September 20, 2011. Individuals who need special assistance, such as sign language interpretation or other reasonable accommodations, should indicate their needs on the registration website. The deadline for special accommodation requests is Friday, September 19, 2011. If there are technical problems gaining access to the Web site, please contact Maureen Ball, Meetings Coordinator, at *conferences@altarum.org.*

Purpose: The Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (Advisory Committee) was established by Congress to advise and guide the Secretary regarding the most appropriate application of universal newborn screening tests, technologies, policies, guidelines and programs for effectively reducing morbidity and mortality in newborns and children having (or at risk) for heritable disorders. The Advisory Committee, as authorized by Public Law 106–310, which added