if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following:

Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–7285, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2013–14589 Filed 6–18–13; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0012]

Linking Marketplace Heparin Product Attributes and Manufacturing Processes to Bioactivity and Immunogenicity

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 award to the University of North Carolina. The goal of the award is to identify what component(s) of the complex heparin mixtures have the propensity to cause heparin induced thrombocytopenia (HIT) to improve the safety of heparin drug products. The FDA seeks to identify the components of the heparin mixture that are associated with HIT so that actions may be taken to reduce these events and improve patient outcomes with this widely used drug.

DATES: Important dates are as follows:

1. The application due date is July 15, 2013.

2. The anticipated start date is August, 2013.

3. The opening date is the date this announcement is published in the **Federal Register**.

4. The expiration date is July 16, 2013.

ADDRESSES: Submit the paper application to: Gladys Melendez at the Food and Drug Administration, Grants Management (HFA–500), 5630 Fishers Lane, Rockville, MD 20857. For more information, see section III of the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: David Keire, Center for Drug Evaluation and Research, Food and Drug Administration, 1114 Market St., rm. 1002, St Louis, MO, 63130, 314–539–3850; or Gladys Melendez, Office of Acquisition Support and Grant Services, Food and Drug Administration, 5630 Fishers Lane, Rockville, MD 20857, 301–827–7175, email: *Gladys.bohler@fda.hhs.gov.*

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please contact *Gladys.bohler @fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

Request for Application: FDA RFA–13–007

[Catalog of Federal Domestic Assistance: 93.103]

A. Background

The goal of this Research Project is to identify which components of heparin drug mixtures have the propensity to cause heparin induced thrombocytopenia (HIT) in order to improve the safety profile of this widely used anticoagulant. Heparin is a heterogeneous mixture of polysaccharides of varying length, sulfation pattern, acylation and conformation that has been in clinical use since the 1930s. HIT is a drug-dependent immune disorder caused by antibodies to complexes formed between platelet factor 4 (PF4) and heparin which can occur in patients who undergo major trauma (e.g. broken bones and cardiovascular surgery) and receive heparin. The condition leads to formation of abnormal blood clots and concomitant complications associated with clots. PF4-heparin antibodies are observed in all patients with HIT. In addition, low molecular weight heparins or the synthetic pentasaccharide (fondaparinux) have also been shown to cause HIT antibody formation although these smaller chain length heparins are much less likely to lead to clinical HIT symptoms.

The major limitation in the available reagents for studies aimed at identifying the components of heparin that lead to the pathogenesis of HIT is the lack of pure component heparin standards. Therefore, this collaboration brings together the following capabilities and laboratories: (1) Synthesis of heparin chains of the same length, sulfation pattern and conformation (Dr. Liu at the University of North Carolina and Dr. Linhardt at Rensselaer Polytechnical Institute), (2) synthesis and physicochemical characterization of heparin and heparin-PF4 complexes (Keire FDA/DPA St Louis) and (3) a HIT-immunogenicity animal model (Dr. Arepally at Duke University). FDA believes that this combination of skills and expertise has the potential to make pure standards, fully characterize the standards, create and characterize PF4-heparin standard aggregates and assess their propensity to elicit an immune response in an animal model. This research is unique and not otherwise available. The ability to make pure heparin standards in gram quantities and fully characterize their properties is only available from the Liu and Linhardt laboratories. Furthermore, Dr. Arepally's mouse model of HIT immunogenicity is not available in any other laboratory. When completed the study will identify heparin components that enhance HIT propensity and which could potentially be minimized in heparin manufacturing, leading to safer heparin drugs with better patient outcomes.

B. Research Objectives

The research objective is to identify the components of the heparin mixture that have the propensity to lead to HIT pathogenesis.

C. Eligibility Information

This is a sole source RFA because the investigators identified in this document have unique skills and expertise necessary to perform the proposed work.

II. Award Information/Funds Available

A. Award Amount

Only one award will be available to the University of North Carolina in the amount of $250,000 (Total Cost) in the first year.

B. Length of Support

Depending on research progress and subject to the availability of funds additional funds may be awarded under this grant for up to a five year project period reflecting $250,000 Total Cost per year.

III. Paper Application, Registration, and Submission Information

To submit a paper application in response to this FOA, applicants should first review the full announcement. Persons interested in applying for a grant may obtain an application at *http://grants.nih.gov/grants/forms.htm.*

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 Melendez; Grants Management, Food and Drug Administration, 5630 Fishers Lane, rm. 2032; HFA–500; Rockville, MD 20857.

Dated: June 12, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–14579 Filed 6–18–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Cardiovascular and Renal Drugs 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: Cardiovascular and Renal Drugs 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 5, 2013, from 8 a.m. to 5:30 p.m.

Location: FDA White Oak Campus, Building 31, the Great Room, White Oak Conference Center (Rm. 1503), 10903 New Hampshire Ave., 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: Kristina Toliver, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., WO31–2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: *CRDAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). 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 at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On August 5, 2013, the committee will discuss new drug application (NDA) 204441, tolvaptan tablets, submitted by Otsuka Pharmaceutical Company, Ltd., for the proposed indication of slowing kidney disease in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease (autosomal dominant polycystic kidney disease is a genetic disease that affects the kidney and can lead to kidney failure).

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 meeting 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 22, 2013. Oral presentations from the public will be scheduled between approximately 1 p.m. to 2 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, 2013. 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 15, 2013.

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 Kristina Toliver 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 14, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013–14632 Filed 6–18–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Rechanneling the Current Cardiac Risk Paradigm: Arrhythmia Risk Assessment During Drug Development Without the Thorough QT Study; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA), the Cardiac Safety Research Consortium, and the International Life Sciences Institute's Health and Environmental Sciences Institute (HESI) will cosponsor a public workshop entitled ''Rechanneling the Current Cardiac Risk Paradigm: Arrhythmia Risk Assessment During Drug Development Without the Thorough QT Study.'' The workshop will introduce for discussion a new