Families.

Attn: Desk Officer for the
outcomes with this widely used drug.
these events and improve patient
identify the components of the heparin
mixtures have the propensity to cause
component(s) of the complex heparin
mixtures have the propensity to cause
heparin and heparin-PF4 complexes
physicochemical characterization of
reagents for studies aimed at identifying
antibodies to complexes formed
clinical HIT symptoms.
length heparins are much less likely to
also been shown to cause HIT antibody
pentasaccharide (fondaparinux) have
heparins or the synthetic
addition, low molecular weight
observed in all patients with HIT. In
concomitant complications associated
with clots. PF4-heparin antibodies are
dependent immune disorder caused by
use since the 1930s. HIT is a drug-
thrombocytopenia (HIT) in order 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
(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
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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
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

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.

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• 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]

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 progressive 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 or 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/ucm11462.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]

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