• 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

nonclinical paradigm for assessing Torsade de Pointes (TdP) risk and explore the parameters for an appropriate, strong, nonclinical proarrthymia screening method as an alternative to clinical Thorough QT studies. The workshop, which will seek input from all attendees, is intended to provide a forum for stakeholders, including experts and opinion leaders from academia, industry, and regulatory agencies in the United States, the European Union, Canada, and Asian countries, to discuss what a new framework might look like, the benefits and limitations of the current guidelines, and the importance of a uniform assay schema.

Date and Time: The public workshop will be held on July 23, 2013, from 8 a.m. to 6 p.m.

Location: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993.

Contact Person: Devi Kozeli, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4183, Silver Spring, MD 20993, 301–796–1128, email: *devi.kozeli@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

This workshop will introduce for discussion a new nonclinical paradigm for assessing TdP risk and explore the parameters for an appropriate, strong, nonclinical proarrthymia screening method as an alternative to clinical Thorough QT studies. The workshop, which will seek input from all attendees, is intended to provide a forum for stakeholders, including experts and opinion leaders from academia, industry, and regulatory agencies in the United States, the European Union, Canada, and Asian countries, to discuss what a new framework might look like, the benefits and limitations of the current guidelines, and the importance of a uniform assay schema.

A description of the planned activities for the workshop can be found at: *http://www.hesiglobal.org/i4a/pages/index.cfm?pageID=3620* (FDA has verified this online address but is not responsible for subsequent changes to the Web site where it is located after this document publishes in the **Federal Register**.)

Registration and Accommodations: Registration for non-FDA attendees should be performed online at the following address: *https://evm.auxserv.duke.edu/iebms/reg/reg_p1_form.aspx?oc=10&ct=DCRIHBD09&eventid=50715.* (FDA has verified this online address but is not responsible for subsequent changes to the Web site where it is located after this document publishes in the **Federal Register**.)

Registration for FDA attendees is also online, at the following address: *https://duke.qualtrics.com/SE/?SID=SV_bmv7T8GPm4IAPd3.*

The registration deadline for paying attendees is July 15, 2013. With the exception of FDA employees and a limited number of speakers or organizers, registrants must pay a registration fee covering the cost of facilities, materials, and food. The registration fees for different categories of attendee are as follows:

Category	*Cost*
Commercial Entity or Industry, Not Members of HESI	$950
Commercial Entity or Industry, HESI Members	600
Academia, Professional Society, or Nonprofit Organization	250
Government (non-FDA)	150

Seats are limited, and conference space will be filled in the order in which registrations are received. Attendees are responsible for their own accommodations.

If you need special accommodations due to a disability, please contact Devi Kozeli (see *Contact Person*) at least 7 days in advance.

Dated: June 12, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–14580 Filed 6–18–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Awareness and Beliefs About Cancer Survey, National Cancer Institute (NCI)

Summary: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

To Submit Comments and for Further Information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Sarah Kobrin, Division of Cancer Control and Population Sciences, 9609 Medical Center Dr., MSC 9761, Rockville, MD 20852, or call non-toll-free number 240–276–6931 or Email your request, including your address to: *kobrins@mail.nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Proposed Collection: Awareness and Beliefs about Cancer Survey, 0925–NEW, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The objective of the study is gather data about American adults' awareness and beliefs about cancer. The ultimate goal is to determine how individuals' perceptions of cancer may influence their decisions to report signs and symptoms to health care providers, perhaps affecting the disease stage of diagnosis and the effectiveness of treatment. Data will be collected from approximately 2,000 adults aged 50 years or older across the United States for the NCI Awareness and Beliefs about Cancer survey over a one-year period.

OMB approval is requested for one year. There are no costs to respondents other than their time. The total estimated annualized burden hours are 1,334.