

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

[Docket No. FDA-2014-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 March 27, 2014, from 8 a.m. to 5 p.m. This meeting is a reschedule of a postponed meeting announced in the **Federal Register** of January 8, 2014 (79 FR 1384), originally scheduled for February 13, 2014.

*Location:* FDA White Oak Campus, 10903 New Hampshire Ave., Building 31, the Great Room, White Oak Conference Center (Rm. 1503), 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 for More Information:* Kristina Toliver, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, email: [CRDAC@fda.hhs.gov](mailto: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:* The committee will discuss biologics license application (BLA) 125468, serelaxin injection, submitted by Novartis Pharmaceuticals Corp., as a treatment to improve the symptoms of acute heart failure through reduction of the rate of worsening of heart 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 March 24, 2014. Oral presentations from the public will be scheduled between approximately 1 p.m. and 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 March 21, 2014. 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 March 24, 2014.

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: March 4, 2014.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

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**BILLING CODE 4160-01-P**

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Health Resources and Services Administration

## National Advisory Council on Nurse Education and Practice; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given of the following meeting:

*Name:* National Advisory Council on Nurse Education and Practice (NACNEP).

*Date and Time:* March 21, 2014, 9:30 a.m.-5:00 p.m. Eastern Standard Time.

*Place:* Webinar Format.

*Status:* This meeting will be open to the public.

*Purpose:* The purpose of this meeting is to identify the key issues facing public health nursing and population health, and to formulate policy recommendations for Congress and the Secretary to ensure the nursing workforce is ready to meet these challenges. The objectives of the meeting are: (1) To articulate the key challenges facing public health nursing and population health; (2) to develop goals and priorities for Council action to address these challenges; and (3) to develop recommendations on the activities, initiatives, and partnerships that are critical to advancing twenty-first century public health nurse education and practice models needed to promote the health of the public. This meeting will form the basis for NACNEP's mandated *Twelfth Annual Report to the Secretary of the U.S. Department of Health and Human Services and Congress*. The meeting will include presentations and discussion focused around the purpose and objectives of this meeting.

*Agenda:* A tentative agenda will be available on the NACNEP Web site 10