DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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 September 13, 2012, from 8 a.m. to 5 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/Calendar/default.htm. Scroll down to the appropriate advisory committee link.

The meeting will be open to the public. Written submissions may be made to the contact person on or before August 29, 2012. Oral presentations from the public will be scheduled between approximately 10:30 a.m. to 11 a.m., and 3:30 p.m. to 4 p.m. Those individuals interested in making formal oral presentations should notify the contact person on or before August 29, 2012. Oral presentations from the public will be scheduled between approximately 10:30 a.m. to 11 a.m., and 3:30 p.m. to 4 p.m.

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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 August 22, 2012.

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 Kalyani Bhatt 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).


Jill Hartzler Warner,
Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2012–18095 Filed 7–24–12; 8:45 am]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Risks and Benefits of Hydroxyethyl Starch Solutions; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled: “Risks and Benefits of Hydroxyethyl Starch Solutions.” The purpose of this public workshop is to discuss new information on the risks and benefits of FDA-approved hydroxyethyl starch (HES) solutions.

The public workshop has been planned in partnership with the Department of Defense and the National Heart, Lung and Blood Institute, National Institutes of Health, and will include presentations and panel discussions with experts from academia, regulated industry, government, and other stakeholders.

Date and Time: The public workshop will be held on September 6, 2012, from 8:00 a.m. to 5:30 p.m., and September 7, 2012, from 8:30 a.m. to 1:00 p.m.

Location: The public workshop will be held at the Masur Auditorium, National Institutes of Health, 10 Center Dr., Bldg. 10, Clinical Center, Bethesda, MD 20892.


Registration: Mail, fax, or email your registration information (including name, title, firm or organization name, address, telephone and fax numbers, and email address) to Jennifer Scharpf (see Contact Person) by August 15, 2012. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be on a space available basis beginning at 7:00 a.m. If you need special accommodations due to a disability, please contact Jennifer Scharpf (see Contact Person) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: HES solutions are synthetic colloids administered intravenously to patients to maintain or expand plasma volume when clinically indicated. Currently, three such products are approved by FDA. HES solutions are indicated for the treatment of hypovolemia (low blood volume) that may result from trauma, sepsis, burns, or anaphylaxis. These products are used in the prehospital and hospital environment in both military and civilian settings. This public workshop will serve as a forum for discussing new information on the potential effects of HES solutions on hemostasis and on the renal system.

The first day of the public workshop will include presentations and panel discussions on the following topics: (1) The risks and benefits associated with HES solutions in different clinical settings and (2) the findings of two recent major clinical studies conducted on HES solutions.

The second day of the public workshop will include a summary discussion and presentations concerning the overall safety profile of HES solutions and a discussion of future clinical research for the evaluation of HES solutions.

Transcripts: Please be advised that as soon as possible after a transcript of the public workshop is available, it will be accessible at: http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/TranscriptsMinutes/default.htm. Transcripts of the public workshop may also be requested in writing from the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857.

Dated: July 17, 2012.

Leslie Kux,
Assistant Commissioner for Policy.

[FR Doc. 2012–18110 Filed 7–24–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301–496–7057; fax: 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Novel Analogues of the Asthma Drug

Therapeutic Agents

Description of Technology: Available for licensing are specific fenoterol analogues, such as MNF, that inhibit the growth of various types of cancers, including brain, liver, colon, and lung tumors. MNF acts as an agonist of the