

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 Cindy Hong 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: August 10, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2012-20103 Filed 8-15-12; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0001]

#### Endocrinologic and Metabolic 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:* Endocrinologic and Metabolic Drugs Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the Agency on FDA's regulatory issues.

**DATES:** *Date and Time:* The meeting will be held on October 18, 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/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:* Paul Tran, 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: [EMDAC@fda.hhs.gov](mailto:EMDAC@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), to find out further information regarding FDA advisory committee information. 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/Calendar/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 new drug application (NDA) 203568, mipomersen injection, by Genzyme Corporation. The proposed indication (use) is as an adjunct to maximally tolerated lipid-lowering medications and diet to reduce low-density lipoprotein (LDL) cholesterol, apolipoprotein B, total cholesterol, non-high density lipoprotein-cholesterol and lipoprotein (a) in patients with homozygous familial hypercholesterolemia.

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 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 October 2, 2012. 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 September 24, 2012. 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 September 25, 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 Paul Tran at least 7 days in advance of the meeting.

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Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 10, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0001]

#### Endpoints for Clinical Trials in Kidney Transplantation; Public Workshop

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop to discuss the endpoints for clinical trials of drugs and therapeutic biologics in kidney transplantation. This public workshop is intended to provide information and gain perspective from health care providers, academia, and industry on the role of various clinical, laboratory, histologic, genomic/proteomic, safety, and other endpoints

used to evaluate patient and allograft outcome in clinical trials of kidney transplantation. The meeting will include a discussion of measure of patient and graft survival, evaluation of the allograft by histology and biomarkers, glomerular filtration rate or other measures of renal function, evaluation of safety, and other topics. The input from this public workshop will help in developing topics for further discussion and may serve to inform recommendations on potential endpoints in clinical trials of kidney transplantation.

**Date and Time:** The public workshop will be held on September 10, 2012, from 9 a.m. to 6 p.m., and on September 11, 2012, from 8 a.m. to 3 p.m.

**Location:** The public workshop will be held at the Sheraton Silver Spring Hotel, 8777 Georgia Ave., Silver Spring, MD 20910, 301-589-0800. Seating is limited and available only on a first-come, first-served basis.

**CONTACT PERSON FOR MORE INFORMATION:** Christine Moser or Ramou Mauer, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6209, Silver Spring, MD 20993-0002, 301-796-1300 or 301-796-1600.

**Registration:** Registration is free for the public workshop. Interested parties are encouraged to register early because space is limited. Seating will be available on a first-come, first-served basis. To register electronically, email registration information (including name, title, firm name, address, telephone, and fax number) to [endpoints@fda.hhs.gov](mailto:endpoints@fda.hhs.gov). Persons without access to the Internet can call Christine Moser, 301-796-1300, or Ramou Mauer, 301-796-1600, to register.

Persons needing a sign language interpreter or other special accommodations should notify Christine Moser or Ramou Mauer (see **CONTACT PERSON FOR MORE INFORMATION**) at least 7 days in advance.

**SUPPLEMENTARY INFORMATION:** FDA is announcing a public workshop regarding potential clinical or surrogate endpoints and biomarkers for clinical trials of drugs and therapeutic biologics in kidney transplantation. This public workshop will include scientific discussion on the following topics:

- Patient and graft survival;
- Allograft rejection, both cellular and antibody-mediated, injury, and recurrent disease;
- Glomerular filtration rate, proteinuria, and other measures of renal function;
- Proteomic, genomic, and immunologic biomarkers;

- Measures of safety, including cardiovascular and metabolic outcomes;
- Medication adherence; and
- Consideration of composite endpoints.

The Agency encourages individuals, patient advocates, industry, consumer groups, health care professionals, researchers, and other interested persons to attend this public workshop.

**Transcripts:** Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. Transcripts will also be available on the Internet at <http://www.fda.gov/Drugs/NewsEvents/ucm305308.htm> approximately 45 days after the workshop.

Dated: August 10, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0001]

#### Food and Drug Administration Clinical Trial Requirements, Compliance, and Good Clinical Practice; Public Workshop

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop.

The Food and Drug Administration (FDA), Baltimore District Office, in cosponsorship with the Society of Clinical Research Associates (SoCRA), is announcing a public workshop. The public workshop on FDA's clinical trial requirements is designed to aid the clinical research professional's understanding of the mission, responsibilities, and authority of the FDA and to facilitate interaction with FDA representatives. The program will focus on the relationships among FDA and clinical trial staff, investigators, and institutional review boards (IRB). Individual FDA representatives will

discuss the informed consent process and informed consent documents; regulation, relating to drugs, devices, and biologics; as well as inspections of clinical investigators, of IRB, and research sponsors.

**Date and Time:** The public workshop will be held on November 14 and 15, 2012, from 8 a.m. to 5 p.m.

**Location:** The public workshop will be held at the Radisson Plaza Lord Baltimore Hotel, 20 West Baltimore St., Baltimore, MD 21201, 410-539-8400. Attendees are responsible for their own accommodations. Please mention SoCRA to receive the hotel room rate of \$129.00 plus applicable taxes (available until October 13, 2012, or until the SoCRA room block is filled).

**Contact:** Cynthia A. Harris, Food and Drug Administration, 6000 Metro Dr., Suite 101, Baltimore, MD 21215, 410-779-5133, FAX: 410-779-5705; or Society of Clinical Research Associates (SoCRA), 530 West Butler Ave., Suite 109, Chalfont, PA 18914, 800-762-7292 or 215-822-8644; Fax: 215-822-8633, email: [SoCRAmail@aol.com](mailto:SoCRAmail@aol.com), Web site: <http://www.socra.org>.

**Registration:** The registration fee will cover actual expenses including refreshments, lunch, materials, and speaker expenses. Seats are limited; please submit your registration as soon as possible. Workshop space will be filled in order of receipt of registration. Those accepted into the public workshop will receive confirmation. The cost of the registration is as follows:

#### COST OF REGISTRATION

|                                        |             |
|----------------------------------------|-------------|
| SoCRA member .....                     | \$575.00.   |
| SoCRA nonmember (includes membership). | \$650.00.   |
| Federal Government SoCRA member.       | \$525.00.   |
| Federal Government SoCRA nonmember.    | \$450.00.   |
| FDA Employee .....                     | Fee Waived. |

If you need special accommodations due to a disability, please contact SoCRA or Cynthia Harris (see *Contact*) at least 21 days in advance.

Extended periods of question and answer and discussion have been included in the program schedule. SoCRA designates this education activity for a maximum of 13.3 Continuing Education (CE) Credits for SoCRA CE and continuing nurse education (CNE). SoCRA designates this educational activity for a maximum of 13.3 American Medical Association Physician's Recognition Award Category 1 Credit(s)<sup>TM</sup>. Physicians should claim only the credit commensurate with the extent of their participation. SoCRA is