

quality of clinical trials; and enhance the safety of trial participants. Senior FDA staff will communicate directly with clinical investigators on issues of greatest importance for successful clinical research.

**Date and Time:** The training course will be held on November 7 and 8, 2011, from 8 a.m. to 5 p.m., and on November 9, 2011, from 8 a.m. to 3:30 p.m.

**Location:** The course will be held at the National Labor College, 10000 New Hampshire Ave., Silver Spring, MD 20903-0002.

**Contact Person:** Leonard Sacks, Office of Critical Path Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4174, Silver Spring, MD 20993, 301-796-8502.

**Registration:** Register by October 21, 2011. The registration fee is \$400 per person. The fee includes course materials and onsite lunch. Early registration is recommended because seating is limited. There will be no onsite registration.

Register online for the training course at the registration/information Web site at <https://www.trialstransformation.org/fda-clinical-investigator-training-course> or by FAX to 919-660-1769. An e-mail will be sent confirming your registration.

Attendees are responsible for their own accommodations. A block of rooms has been reserved under "FDA Clinical Investigator Course" at the National Labor College at a reduced conference rate. Reservations can be made at [https://www.supportnlc.org/Room\\_Reservations.html](https://www.supportnlc.org/Room_Reservations.html) or by calling 301-431-6400. FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.

Registration materials, payment procedures, accommodation information, and a detailed description of the course can be found at <https://www.trialstransformation.org/fda-clinical-investigator-training-course>.

If you need special accommodations due to a disability, please contact Leonard Sacks at least 7 days in advance. Persons attending the course are advised that FDA is not responsible for providing access to electrical outlets.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

Clinical trial investigators play a critical role in the development of medical products. They bear the responsibility for ensuring the safe and ethical treatment of study subjects and for acquiring adequate and reliable data to support regulatory decisions. This

course is intended to assist clinical investigators in understanding what preclinical and clinical information is needed to support the investigational use of medical products, as well as the scientific, regulatory, and ethical considerations involved in the conduct of clinical trials. The course will cover a wide variety of key topics, including material on novel safety concerns, adverse event monitoring, compliance with the legal and ethical obligations of clinical research, and acceptable scientific and analytic standards in the design and conduct of clinical studies. The faculty will include a diverse representation of senior FDA staff, enabling FDA to communicate directly with clinical investigators on issues of greatest importance for successful clinical research.

##### **II. Description of the Training Course**

###### *A. Purpose*

The training course is designed to provide clinical investigators with an overview of the following information:

- The essential toxicological, pharmacological, and manufacturing data to support investigational use in humans;
- Fundamental issues in the design and conduct of clinical trials;
- Statistical and analytic considerations in the interpretation of trial data;
- Appropriate safety evaluation during studies; and
- The ethical considerations and regulatory requirements for clinical trials.

In addition, the course should do the following:

- Foster a cadre of clinical investigators with knowledge, experience, and commitment to investigational medicine;
- Promote communication between clinical investigators and FDA;
- Enhance investigators' understanding of FDA's role in experimental medicine; and
- Improve the quality of data while enhancing subject protection in the performance of clinical trials.

###### *B. Proposed Agenda*

The course will be conducted over 3 days and will comprise approximately 26 lectures, each lasting between 30 and 45 minutes. The course will be presented mainly by senior FDA staff, with guest lecturers presenting selected topics.

On November 7, 2011, the course will address the role of FDA in clinical studies, regulatory considerations for clinical trials, and review of the material

generally appearing in an "investigator's brochure," *i.e.*, the preclinical information (toxicology, animal studies, and chemistry/manufacturing information) that supports initial clinical trials in humans. Presentations will also discuss the role of clinical pharmacology in early clinical studies and how this information is used in the design of subsequent studies. On November 8, 2011, the course will include discussions of scientific, statistical, ethical, and regulatory aspects of clinical studies. On November 9, 2011, participants will choose among three breakout sessions that explain how to put together an application to FDA for drugs, biologics, or devices.

###### *C. Target Audience*

The course is targeted at health care professionals responsible for, or involved in, the conduct and/or design of clinical trials.

Dated: July 25, 2011.

**David Dorsey,**

*Acting Deputy Commissioner for Policy, Planning and Budget.*

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

[Docket No. FDA-2011-N-0002]

#### **Request for Nominations for Members on a Public Advisory Committee; Medical Imaging Drugs Advisory Committee**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is requesting nominations for 12 members to serve on the Medical Imaging Drugs Advisory Committee in the Center for Drug Evaluation and Research.

FDA has a special interest in ensuring that women, minority groups, and individuals with physical disabilities are adequately represented on advisory committees and, therefore, extends particular encouragement to nominations for appropriately qualified female, minority, or physically challenged candidates. Final selection from each vacancy will be determined by the expertise required to meet specific Agency needs and in a manner to ensure appropriate balance on membership.

**DATES:** Nominations should be received before September 27, 2011.

**ADDRESSES:** All nominations for membership, except for consumer-nominated members and industry representatives members, should be sent to Minh Doan (see **FOR FURTHER INFORMATION CONTACT**).

**FOR FURTHER INFORMATION CONTACT:**

Minh Doan, Center for Drug Evaluation and Research, Food and Drug Administration, Bldg. 31, rm. 2417, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-9001, Fax: 301-847-8533, E-mail: [MIDAC@fda.hhs.gov](mailto:MIDAC@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** FDA is requesting nominations for voting members on the Medical Imaging Drugs Advisory Committee (the Committee). (Elsewhere in this issue of the **Federal Register** is a final rule adding the Medical Imaging Drugs Advisory Committee to the list of FDA standing advisory committees in 21 CFR 14.100 as well as a request for nominations of nonvoting industry representatives, and a request for nominations of voting and nonvoting consumer representatives.)

### I. Function

The Committee advises the Commissioner of Food and Drugs or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility. The Committee also reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in diagnostic and therapeutic procedures using radioactive pharmaceuticals and contrast media used in diagnostic radiology.

### II. Criteria for Members

Persons nominated for membership on the Committee must have adequately diversified research and/or clinical experience appropriate to the work of the committee in such fields as nuclear medicine, radiology, epidemiology or statistics, and related specialties.

The specialized training and experience necessary to qualify the nominee as an expert suitable for appointment is subject to review, but may include experience in medical practice, teaching, research, and/or public service relevant to the field of

activity of the committee. The term of office is up to 4 years.

### III. Nomination Procedure

Any interested person may nominate one or more qualified persons for membership on the Committee. Self-nominations are also accepted. Nominations must include a current, complete resume or curriculum vitae for each nominee, current business and/or home address, telephone number, and e-mail address if available. Nominations must specify the advisory committee for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination, unless self-nominated. Potential candidates will be required to provide detailed information concerning such matters as financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflicts of interest.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: July 22, 2011.

**David Dorsey,**

*Acting Deputy Commissioner for Policy, Planning and Budget.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0002]

#### Request for Notification From Consumer Organizations Interested in Participating in the Selection Process for Nominations for Voting and/or Nonvoting Consumer Representatives and Request for Nominations for Voting and/or Nonvoting Consumer Representatives on Public Advisory Committees or Panels

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is requesting that any consumer organizations interested in participating in the selection of voting and/or nonvoting consumer representatives to serve on its advisory committees or panels notify FDA in

writing. FDA is also requesting nominations for voting and/or nonvoting consumer representatives to serve on advisory committees and/or panels for which vacancies currently exist or are expected to occur in the near future. Nominees recommended to serve as a voting or nonvoting consumer representative may either be self-nominated or may be nominated by a consumer organization. Nominations will be accepted for current vacancies and for those that will or may occur through June 2012.

**DATES:** Any consumer organization interested in participating in the selection of an appropriate voting or nonvoting member to represent consumer interests on an FDA advisory committee or panel may send a letter or e-mail stating that interest to FDA (see **ADDRESSES**) by August 29, 2011, for vacancies listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA (see **ADDRESSES**) by August 29, 2011.

**ADDRESSES:** All statements of interest from consumer organizations interested in participating in the selection process and consumer representative nominations should be sent electronically to [CV@OC.FDA.GOV](mailto:CV@OC.FDA.GOV), by mail to Advisory Committee Oversight and Management Staff, 10903 New Hampshire Ave., Bldg. 32, rm. 5129, Silver Spring MD 20993-0002, or by fax to 301-847-8640. Information about becoming a member of an FDA advisory committee can be obtained by visiting FDA's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm>.

**FOR FURTHER INFORMATION CONTACT:**

Doreen Brandes, Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5122, Silver Spring, MD 20993-0002, 301-796-8858, or e-mail: [Doreen.Brandes@fda.hhs.gov](mailto:Doreen.Brandes@fda.hhs.gov).

For questions relating to specific advisory committees or panels, contact the persons listed in table 2 in the **SUPPLEMENTARY INFORMATION** section of this document.

**SUPPLEMENTARY INFORMATION:** FDA is requesting nominations for voting and/or nonvoting consumer representatives for the vacancies listed in table 1 of this document: