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*.

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.

[FR Doc. 2011–19067 Filed 7–28–11; 8:45 am]

BILLING CODE 4160–01–P

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,* 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.*

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:

TABLE 1

Committee/panel/areas of expertise needed	Current & upcoming vacancies	Approximate date needed
Drug Safety and Risk Communication—Knowledgeable in risk communication, risk management, drug safety, medical, behavioral, and biological sciences as they apply to risk management, and drug abuse.	1-Voting	5/31/12
Gastrointestinal Drugs—Knowledgeable in the fields of gastroenterology, endocrinology, surgery, clinical pharmacology, physiology, pathology, liver function, motility, esophagitis, and statistics.	1-Voting	6/30/12
Medical Imaging—Knowledgeable in the fields of nuclear medicine, radiology, epidemiology or statistics, and related specialties.	1-Voting	immediately
Blood Products—Knowledgeable in the fields of clinical and administrative medicine, hematology, immunology, blood banking, surgery, internal medicine, biochemistry, engineering, biological and physical sciences, biotechnology, computer technology, statistics, epidemiology, sociology/ethics, and other related professions.	1-Voting	immediately
Cellular Tissue and Gene Therapies—Knowledgeable in the fields of cellular therapies, tissue transplantation, gene transfer therapies and xenotransplantation including biostatistics, bioethics, hematology/oncology, human tissues and transplantation, reproductive medicine, general medicine and various medical specialties including surgery and oncology, immunology, virology, molecular biology, cell biology, developmental biology, tumor biology, biochemistry, rDNA technology, nuclear medicine, gene therapy, infectious diseases, and cellular kinetics.	1-Voting	3/31/12
Transmissible Spongiform Encephalopathies—Knowledgeable in the fields of clinical and administrative medicine, hematology, virology, neurovirology, neurology, infectious diseases, immunology, transfusion medicine, surgery, internal medicine, biochemistry, biostatistics, epidemiology, biological and physical sciences, sociology/ethics, and other related professions.	1-Voting	immediately
Vaccines and Related Biological Products—Knowledgeable in the fields of immunology, molecular biology, rDNA, virology, bacteriology, epidemiology or biostatistics, allergy, preventive medicine, infectious diseases, pediatrics, microbiology, and biochemistry.	1-Voting	3/31/12
Radiological Device Panel—Knowledgeable in diagnostic and therapeutic radiological and nuclear medical devices, engineering and operating mechanisms of radiologic devices.	1-Non voting	1/31/12

I. Functions

A. Drug Safety and Risk Management

The Committee reviews and evaluates information on risk management, risk communication, and quantitative evaluation of spontaneous reports for drugs for human use and for any other product for which FDA has regulatory responsibility. The Committee also advises the Commissioner of Food and Drugs (the Commissioner) regarding the scientific and medical evaluation of all information gathered by the Department of Health and Human Services and the Department of Justice with regard to safety, efficacy, and abuse potential of drugs or other substances, and recommends actions to be taken by the Department of Health and Human Services with regard to the marketing, investigation, and control of such drugs or other substances.

B. Gastrointestinal Drugs

The Committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of gastrointestinal diseases and makes appropriate recommendations to the Commissioner.

C. Medical Imaging Drugs

The Committee 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. (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 voting members and a request for nominations of nonvoting industry representative members.)

D. Blood Products

The Committee reviews and evaluates available data concerning the safety, effectiveness, and appropriate use of blood products derived from blood and serum or biotechnology which are intended for use in the diagnosis, prevention, or treatment of human diseases as well as the safety, effectiveness, and labeling of the products, on clinical and laboratory studies involving such products, on the affirmation or revocation of biological product licenses, and on the quality and relevance of FDA's research program which provides the scientific support for regulating these products.

E. Cellular Tissue and Gene Therapy

The Committee reviews and evaluates available data relating to the safety, effectiveness, and appropriate use of human cells, human tissues, gene transfer therapies and xenotransplantation products which are intended for transplantation, implantation, infusion, and transfer in the prevention and treatment of a broad spectrum of human diseases and in the reconstruction, repair, or replacement of tissues for various conditions. The Committee also considers the quality and relevance of FDA's research program which provides scientific support for the regulation of these products, and makes appropriate recommendations to the Commissioner.

F. Transmissible Spongiform Encephalopathies

The Committee reviews and evaluates available scientific data concerning the safety of products which may be at risk for transmission of spongiform encephalopathies having an impact on the public health, as well as considers the quality and relevance of FDA's research program which provides scientific support for the regulation of these products.

G. Vaccines and Related Biologic Products

The Committee reviews and evaluates data concerning the safety, effectiveness, and appropriate use of vaccines and related biological products which are intended for use in the prevention, treatment, or diagnosis of human diseases, and, as required, any other product for which FDA has regulatory responsibility. The Committee also considers the quality

and relevance of FDA's research program which provides scientific support for the regulation of these products and makes appropriate recommendations to the Commissioner.

H. Certain Panels of the Medical Devices Advisory Committee

The Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, advises on the classification or reclassification of devices into one of three regulatory categories; advises on any possible risks to health associated with the use of devices; advises on formulation of product development protocols; reviews premarket approval applications for medical devices; reviews guidelines and guidance documents; recommends exemption of certain devices from the application of portions of the Federal Food, Drug, and Cosmetic Act; advises on the necessity to ban a device; and responds to requests from the Agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, may also make appropriate recommendations to the Commissioner on issues relating to the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices.

II. Criteria for Members

Persons nominated for membership as consumer representatives on the committees or panels should meet the following criteria: (1) Demonstrate ties to consumer and community-based organizations, (2) be able to analyze technical data, (3) understand research design, (4) discuss benefits and risks, and (5) evaluate the safety and efficacy of products under review. The consumer representative should be able to represent the consumer perspective on issues and actions before the advisory committee; serve as a liaison between the committee and interested consumers, associations, coalitions, and consumer organizations; and facilitate dialogue with the advisory committees on scientific issues that affect consumers.

III. Selection Procedures

Selection of members representing consumer interests is conducted through procedures that include the use of organizations representing the public interest and public advocacy groups. These organizations recommend nominees for the Agency's selection. Representatives from the consumer health branches of Federal, State, and local governments also may participate in the selection process. Any consumer organization interested in participating in the selection of an appropriate voting or nonvoting member to represent consumer interests should send a letter stating that interest to FDA (see **ADDRESSES**) within 30 days of publication of this document.

Within the subsequent 30 days, FDA will compile a list of consumer organizations that will participate in the selection process and will forward to each such organization a ballot listing three to five qualified nominees selected by the Agency based on the nominations received, together with each nominee's current curriculum vitae or resume. Ballots are to be filled out and returned to FDA within 30 days. The nominee receiving the highest number of votes ordinarily will be selected to serve as the member representing consumer interests for that particular advisory committee or panel.

IV. Nomination Procedures

Any interested person or organization may nominate one or more qualified persons to represent consumer interests on the Agency's advisory committees or panels. Self-nominations are also accepted. 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.

All nominations should include: A cover letter; a curriculum vitae or resume that includes the nominee's address, telephone number, and e-mail address; and a list of consumer or community-based organizations for which the candidate can demonstrate active participation.

Nominations also should specify the advisory committee(s) or panel(s) for which the nominee is recommended. In addition, nominations should include confirmation that the nominee is aware of the nomination and is willing to serve as a member of the advisory committee or panel if selected. The term of office is up to 4 years.

FDA will review all nominations received within the specified timeframes and prepare a ballot containing the names of 3 to 5 qualified nominees. Names not selected will remain on a list of eligible nominees and be reviewed periodically by FDA to determine continued interest. Upon selecting qualified nominees for the ballot, FDA will provide those consumer organizations that are participating in the selection process with the opportunity to vote on the listed nominees. Only organizations vote in the selection process. Persons who nominate themselves to serve as voting or nonvoting consumer representatives will not participate in the selection process.

FDA has a special interest in ensuring that women, minority groups, and individuals with physical disabilities are adequately represented on its advisory committees and panels and, therefore, encourages nominations for appropriately qualified candidates from these groups.

For questions relating to specific advisory committees or panels, contact the following persons listed in table 2 of this document:

TABLE 2

Contact person	Committee/panel
Kristina Toliver, Center for Drug Evaluation and Research, Food and Drug Administration, White Oak Bldg. 31, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, Phone: 301–796–0063, Fax: 301–847–8533, E-mail: *Kristina.Toliver@fda.hhs.gov*.	Drug Safety and Risk Management.
Kristine T. Khuc, Center for Drug Evaluation and Research, Food and Drug Administration, White Oak Bldg. 31, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, Phone: 301–796–9005, Fax: 301–847–8533, E-mail: *Kristine.Khuc@fda.hhs.gov*.	Gastrointestinal Drugs.
Minh Doan, Center for Drug Evaluation and Research, Food and Drug Administration, White Oak Bldg. 31, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, Phone: 301–796–9009, Fax: 301–847–8533, E-mail: *ming.doan@fda.hhs.gov*.	Medical Imaging Drugs.

TABLE 2—Continued

Contact person	Committee/panel
Bryan Emery, Center for Biologics Evaluation & Research, Food and Drug Administration, 1401 Rockville Pike (HFM–71), Rockville, MD 20852, Phone: 301–827–1277, Fax: 301–827–0294, E-mail: *bryan.emery@fda.hhs.gov*.	Blood Products and Transmissible Spongiform Encephalopathies.
Gail Dapolito, Center for Biologics Evaluation & Research, Food and Drug Administration, 1401 Rockville Pike (HFM–71), Rockville, MD 20852–1448, Phone: 301–827–1289, Fax: 301–827–0294, E-mail: *gail.dapolito@fda.hhs.gov*.	Cellular Tissue and Gene Therapy.
Donald Jehn, Center for Biologics Evaluation & Research, Food and Drug Administration, 1401 Rockville Pike (HFM–71), Rockville, MD 20852, Phone: 301–827–1293, Fax: 301–827–0294, E-mail: *donald.jehn@fda.hhs.gov*.	Vaccines and Related Biological Products.
Shanika Craig, Center for Devices and Radiological Health, Food and Drug Administration, White Oak Bldg. 66, rm. 1613, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, Phone: 301–796–6639, E-mail: *Shanika.Craig@fda.hhs.gov*.	Radiological Devices Panel.

Dated: July 22, 2011.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2011–19066 Filed 7–28–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Request for Notification From Industry Organizations Interested in Participating in the Selection Process for Nonvoting Industry Representatives and Request for Nominations for Nonvoting Industry Representatives on Public Advisory Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that any industry organizations interested in participating in the selection of nonvoting industry representatives to serve on its public advisory committees for the Center for Drug Evaluation and Research (CDER) notify FDA in writing. FDA is also requesting nominations for nonvoting industry representatives to serve on CDER's public advisory committees. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for current vacancies effective with this notice.

DATES: Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating that interest to the FDA by *August 29, 2011,* for vacancies listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA by *August 29, 2011.*

ADDRESSES: All letters of interest and nominations should be submitted in writing to Cicely Reese (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Cicely Reese, 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, e-mail: *Cicely.Reese@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 120 of the FDA Modernization Act of 1997 (FDAMA) (21 U.S.C. 355) requires that newly formed FDA advisory committees include representatives from the drug manufacturing industries. Although not required for committees existing prior to the passage of FDAMA, to keep within the spirit of FDAMA, the Agency has added nonvoting industry representatives to CDER advisory committees identified in the following paragraphs.

I. CDER Advisory Committees

A. Advisory Committee for Pharmaceutical Science and Clinical Pharmacology

Advises on scientific and technical issues concerning the safety and effectiveness of human generic drug products for use in the treatment of a broad spectrum of human diseases.

B. Advisory Committee for Reproductive Health Drugs

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in obstetrics, gynecology, and contraception.

C. Anesthetic and Life Support Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in anesthesiology and surgery.

D. Anti-Infective Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of infectious diseases and disorders.

E. Antiviral Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of acquired immune deficiency syndrome (AIDS), HIV-related illnesses, and other viral, fungal, and mycobacterial infections.

F. Arthritis Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of arthritis, rheumatism, and related diseases.

G. Cardiovascular and Renal Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cardiovascular and renal disorders.

H. Dermatologic and Ophthalmic Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of dermatologic and ophthalmic disorders.

I. Drug Safety and Risk Management Advisory Committee

Advises the Commissioner of Food and Drugs (the Commissioner) regarding the scientific and medical evaluation of all information gathered by the