

TRANDATE (labetalol hydrochloride) tablets, 300 mg and 400 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that TRANDATE (labetalol hydrochloride) tablets, 300 mg and 400 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of TRANDATE (labetalol hydrochloride) tablets, 300 mg and 400 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events and have found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list TRANDATE (labetalol hydrochloride) tablets, 300 mg and 400 mg, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to the TRANDATE products listed in this document. Additional ANDAs that refer to these products may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: December 21, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010-32507 Filed 12-27-10; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0001]

#### Anesthetic and Life Support 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:* Anesthetic and Life Support 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 10, 2011, from 8 a.m. to 4:30 p.m.

*Location:* FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (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 "White Oak Conference Center Parking and Transportation Information for FDA Advisory Committee Meetings". Please note that visitors to the White Oak Campus must enter through Building 1.

*Contact Person:* Kalyani Bhatt, 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, e-mail: [kalyani.bhatt@fda.hhs.gov](mailto:kalyani.bhatt@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. 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 and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

*Agenda:* On March 10, 2011, the committee will: (1) Receive updates regarding neurodegenerative findings (findings related to degeneration in the nervous system) in juvenile animals exposed to anesthetic drugs, as well as results from human epidemiological studies using anesthesia in children (information related to studies of patterns and causes of disease); (2) discuss the relevance of these findings to pediatric patients and provide guidance for future preclinical and clinical studies; and (3) discuss the potential implications of these data upon the practice of pediatric anesthesia as well as the communication of the risk of sedative/anesthetic agents to prescribers and parents.

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 February 24, 2011. 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 February 15, 2011. 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 February 16, 2011.

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/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: December 21, 2010.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2010-32591 Filed 12-27-10; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0001]

#### Request for Notification From Consumer Organizations Interested in Participating in the Selection Process for Nominations for Voting and/or Nonvoting Consumer Representatives on Public Advisory Committees or Panels 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 December 2011.

**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 January 27, 2011, for vacancies listed in this document. Concurrently, nomination materials for prospective candidates should be sent to FDA (*see ADDRESSES*) by January 27, 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 GENERAL 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, e-mail: [Doreen.Brandes@fda.hhs.gov](mailto:Doreen.Brandes@fda.hhs.gov).

For questions relating to specific advisory committees or panels, contact the following persons listed in table 1 of this document:

TABLE 1

Contact person	Committee/panel
Walter Ellenberg, 10903 New Hampshire Ave., Bldg. 32, rm. 5488, Silver Spring, MD 20993-0002; phone: 301-796-3873; e-mail: <a href="mailto:Walter.Ellenberg@fda.hhs.gov">Walter.Ellenberg@fda.hhs.gov</a> .	Pediatrics Advisory Committee.
Martha Monser, 10903 New Hampshire Ave., Bldg. 32, rm. 4286, Silver Spring, MD 20993-0002; phone: 301-796-4627; e-mail: <a href="mailto:Martha.Monser@fda.hhs.gov">Martha.Monser@fda.hhs.gov</a> .	Science Board.
Yvette Waples (Acting), 10903 New Hampshire Ave., Bldg. 31, rm. 2410, Silver Spring, MD 20993-0002; phone: 301-796-9034; e-mail: <a href="mailto:Yvette.Waples@fda.hhs.gov">Yvette.Waples@fda.hhs.gov</a> .	Advisory Committee for Pharmaceutical Science and Clinical Pharmacology Dermatologic, Ophthalmic Drugs and Psychopharmacologic Drugs.
Minh Doan, 10903 New Hampshire Ave., Bldg. 31, rm. 2432, Silver Spring, MD 20993-0002; phone: 301-796-9009; e-mail: <a href="mailto:Minh.Doan@fda.hhs.gov">Minh.Doan@fda.hhs.gov</a> .	Arthritis Drugs.
Kalyani Bhatt, 10903 New Hampshire Ave., Bldg. 31, rm. 3438, Silver Spring, MD 20993-0002; phone: 301-796-9005; e-mail: <a href="mailto:Kalyani.Bhatt@fda.hhs.gov">Kalyani.Bhatt@fda.hhs.gov</a> .	Anesthetic & Life Support Drugs.
Paul Tran, 10903 New Hampshire Ave., Bldg. 31, rm. 2404, Silver Spring, MD 20993-0002; phone: 301-796-9029; e-mail: <a href="mailto:Paul.Tran@fda.hhs.gov">Paul.Tran@fda.hhs.gov</a> .	Anti-Viral Drugs
Caleb Briggs, 10903 New Hampshire Ave., Bldg. 31, rm. 2428, Silver Spring, MD 20993-0002; phone: 301-796-9022; e-mail: <a href="mailto:Caleb.Briggs@fda.hhs.gov">Caleb.Briggs@fda.hhs.gov</a> .	Oncologic Drugs.
Bryan Emery, Rockwall Building (HFM-71), 5515 Security Lane, rm. 1312, Rockville, MD 20852; phone: 301-827-1277; e-mail: <a href="mailto:Bryan.Emery@fda.hhs.gov">Bryan.Emery@fda.hhs.gov</a> .	Blood Products and Transmissible Spongiform Encephalopathies
Margaret Miller, 10903 New Hampshire Ave., Bldg. 32, rm. 2208, Silver Spring, MD 20993-0002; phone: 301-796-8890; e-mail: <a href="mailto:Margaret.Miller@fda.hhs.gov">Margaret.Miller@fda.hhs.gov</a> .	Science Advisory Board to the National Center of Toxicological Research.
Shanika Craig, 10903 New Hampshire Ave., Bldg. 66, rm. 1613, Silver Spring, MD 20993-0002; phone: 301-796-6639; e-mail: <a href="mailto:Shanika.Craig@fda.hhs.gov">Shanika.Craig@fda.hhs.gov</a> .	Anesthesiology and Respiratory Therapy Devices Panel and General Hospital and Personal Use Devices Panel.
Margaret McCabe-Janicki, 10903 New Hampshire Ave., Bldg. 66, rm. 1535, Silver Spring, MD 20993-0002; phone: 301-796-7029; e-mail: <a href="mailto:Margaret.McCabe-Janicki@fda.hhs.gov">Margaret.McCabe-Janicki@fda.hhs.gov</a> .	Gastroenterology and Urology General Plastic Surgery.
Olga Claudio, 10903 New Hampshire Ave., Bldg. 66, rm. 1611, Silver Spring, MD 20993-0002; phone: 301-796-7608; e-mail: <a href="mailto:Olga.Claudio@fda.hhs.gov">Olga.Claudio@fda.hhs.gov</a> .	Immunology Devices Panel, Dental Products Devices Panel and National Mammography Quality Assurance Advisory Committee.
James Swink, 10903 New Hampshire Ave., Bldg. 66, rm. 1609, Silver Spring, MD 20993-0002; phone: 301-796-6313; e-mail: <a href="mailto:James.Swink@fda.hhs.gov">James.Swink@fda.hhs.gov</a> .	Molecular and Clinical Genetics.
James Engles, 10903 New Hampshire Ave., Bldg. 66, rm. 1566, Silver Spring, MD 20993-0002; phone: 301-796-7543; e-mail: <a href="mailto:James.Engles@fda.hhs.gov">James.Engles@fda.hhs.gov</a> .	Neurological Devices Panel and Ophthalmic Devices Panel.

**SUPPLEMENTARY INFORMATION:** FDA is requesting nominations for voting and/or nonvoting consumer representatives

for the vacancies listed in table 2 of this document:

TABLE 2

Committee/panel/areas of expertise needed	Current and upcoming vacancies	Approximate date needed
Pediatrics Advisory Committee: Knowledgeable in pediatric research, pediatric subspecialties, statistics, and/or biomedical ethics.	1-Voting .....	immediately.

TABLE 2—Continued

Committee/panel/areas of expertise needed	Current and upcoming vacancies	Approximate date needed
Science Board: Knowledgeable in the fields of food safety, nutrition, chemistry, pharmacology, toxicology, clinical research of systems biology, healthcare devices, nanotechnology, medical imaging, robotics, cell and tissue based products, regenerative medicine and combination products.	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.
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.
Anesthetic and Life Support: Knowledgeable in the fields of anesthesiology, surgery, epidemiology or statistics, and related specialties.	1-Voting .....	04/01/11.
Antiviral Drugs: Knowledgeable in the fields of clinical pharmacology, internal medicine, infectious diseases, microbiology, virology, psychiatry, statistics, epidemiology, ophthalmology, immunology, pediatrics, hematology, and related specialties.	1-Voting .....	11/01/11.
Arthritis Drugs: Knowledgeable in the fields of arthritis, rheumatology, orthopedics, epidemiology or statistics, analgesics, and related specialties.	1-Voting .....	immediately.
Dermatologic and Ophthalmic Drugs: Knowledgeable in the fields of dermatology, ophthalmology, internal medicine, pathology, immunology, epidemiology or statistics, and other related professions.	1-Voting .....	09/01/11.
Oncologic Drugs: Knowledgeable in the fields of general oncology, pediatric oncology, hematologic oncology, immunologic oncology, biostatistics, and other related professions.	1-Voting .....	07/01/11.
Pharmaceutical Science and Clinical Pharmacology: Knowledgeable in the fields of pharmaceutical manufacturing, clinical pharmacology, pharmacokinetics, bioavailability and bioequivalence research, the design and evaluation of clinical trials, laboratory analytical techniques, pharmaceutical chemistry, physiochemistry, biochemistry, biostatistics and related biomedical and pharmacological specialties.	1-Voting .....	11/01/11.
Psychopharmacologic Drugs: Knowledgeable in the fields of psychopharmacology, psychiatry, epidemiology or statistics, and related specialties.	1-Voting .....	07/30/11.
Veterinary Advisory: Knowledgeable in the fields of companion animal medicine, food animal medicine, avian medicine, microbiology, biometrics, toxicology, pathology, pharmacology, animal science, chemistry, public health/epidemiology and minor species/minor use veterinary medicine.	1-Voting .....	immediately.
Science Board to the National Center for Toxicology: Knowledgeable in the fields related to toxicological research.	1-Voting .....	immediately.
National Mammography Quality Assurance Advisory Committee: Knowledgeable in clinical practice, research specialization, or professional work that has a significant focus on mammography.	2-Voting .....	Immediately.

**Certain Panels of the Medical Devices Advisory Committee**

Anesthesiology and Respiratory Therapy Devices: Knowledgeable in anesthesiology and pulmonary medicine or others who have specialized interests in ventilator support, pharmacology, physiology, or the effects and complications of anesthesia.	1-Nonvoting .....	12/01/10.
Dental Products Panel: Knowledgeable in the areas of dental implants, dental materials, periodontology, tissue engineering, and dental anatomy.	1-Nonvoting .....	immediately.
Gastroenterology and Urology Devices: Knowledgeable in the area of gastroenterology, urology, and nephrology.	1-Nonvoting .....	01/01/12.
General Hospital and Personal Use Devices: Nurses, biomedical engineers, microbiologists/infection control practitioners, or experts knowledgeable in the area of hospital and personal use devices.	1-Nonvoting .....	01/01/11.
Immunology Devices: Knowledgeable in medical, surgical, or clinical oncology, internal medicine, clinical immunology, allergy, molecular diagnostics, or clinical laboratory medicine.	1-Nonvoting .....	immediately.

TABLE 2—Continued

Committee/panel/areas of expertise needed	Current and upcoming vacancies	Approximate date needed
Molecular and Clinical Genetics Panel: Knowledgeable in human genetics and in the clinical management of patients with genetic disorders, e.g., candidates with training in inborn errors of metabolism, biochemical and/or molecular genetics, population genetics, epidemiology and related statistical training. Additionally, individuals with experience in genetic counseling, medical ethics as well as ancillary fields of study will be considered.	1-Nonvoting .....	immediately.
Neurological Devices: Knowledgeable in neurologic diseases and devices used to treat neurologic disorders.	1-Nonvoting .....	immediately.
Ophthalmic Devices: Knowledgeable in corneal-external disease, vitreo-retinal surgery, glaucoma, ocular immunology, ocular pathology; optometrists; vision scientists; ophthalmic professionals quality of life assessment, electrophysiology, low vision rehabilitation.	1-Nonvoting .....	immediately.

## I. Functions

### A. Pediatric Advisory Committee

Advises and makes recommendations regarding (1) Pediatric research; (2) identification of research priorities related to pediatric therapeutics and the need for additional treatments of specific pediatric diseases or conditions; (3) the ethics, design, and analysis of clinical trials related to pediatric therapeutics; (4) pediatric labeling disputes; (5) pediatric labeling changes; (6) adverse event reports for drugs granted pediatric exclusivity and any safety issues that may occur; (7) any other pediatric issue or pediatric labeling dispute involving FDA regulated products; (8) research involving children as subjects; and (9) any other matter involving pediatrics for which FDA has regulatory responsibility.

### B. Science Board

Provides advice primarily to the Commissioner of Food and Drugs and other appropriate officials on specific complex and technical issues as well as emerging issues in the scientific community, industry, and academia. Additionally, the Board will provide advice to the Agency on keeping pace with technical and scientific evolutions in the fields of regulatory science, on formulating an appropriate research agenda, and on upgrading its scientific and research facilities to keep pace with these changes. It will also provide the means for critical review of Agency sponsored intramural and extramural scientific research programs.

### C. Blood Products

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.

### D. Transmissible Spongiform Encephalopathies

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.

### E. Anesthetic and Life Support Drugs

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

### F. Antiviral Drugs

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.

### G. Arthritis Drugs

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

### H. Oncologic Drugs

Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cancer.

### I. Pharmaceutical Science & Clinical Pharmacology

Provides advice 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, and as required, any other product for which the FDA has regulatory responsibility. The committee may also review Agency sponsored intramural and extramural biomedical research programs in support of FDA's generic drug regulatory responsibilities.

### J. Psychopharmacologic Drugs

Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the practice of psychiatry and related fields.

### K. Veterinary Medicine

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational new animal drugs, feeds, and devices for use in the treatment and prevention of animal diseases and increased animal production.

### L. Technical Electronic Product Radiation Standards Advisory Committee

Reviews and evaluates the technical feasibility, reasonableness, and practicability of performance standards for electronic products to control the emission of radiation from such products, and may recommend electronic product radiation safety standards.

### M. Science Advisory Board to the National Center for Toxicological Research

Reviews and advises the Agency on the establishment, implementation, and evaluation of the research programs that meet current and future scientific needs of the Agency. The Board also provides

an extra-agency review in ensuring that the research programs at NCTR are scientifically sound and relevant to the regulatory needs of the Agency.

*N. National Mammography Quality Assurance Advisory Committee*

Advises the Agency on development of appropriate quality standards and regulations for mammography facilities; standards and regulations for bodies accrediting mammography facilities under this program; regulations with respect to sanctions; procedures for monitoring compliance with standards; and establishing a mechanism to investigate consumer complaints; reporting new developments concerning breast imaging which should be considered in the oversight of mammography facilities. Also determines whether there exists a shortage of mammography facilities in rural and health professional shortage areas and determines the effects of personnel on access to the services of such facilities in such areas; determining whether there will exist a sufficient number of medical physicists after October 1, 1999; and determining the costs and benefits of compliance with these requirements.

*O. Certain Panels of the Medical Devices Advisory 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 of Food and Drugs on issues relating to the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices. The Dental

Products Panel also functions at times as a dental drug panel. The functions of the dental drug panel are to evaluate and recommend whether various prescription drug products should be changed to over-the-counter status and to evaluate data and make recommendations concerning the approval of new dental drug products for human use.

## 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 home or office 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 three to five 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.

Dated: December 22, 2010.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

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