Location: Marriott Conference Centers, UMUC Inn and Conference Center, 3501 University Blvd. East, Adelphi, MD. The hotel telephone number is 301–985–7385.

Contact Person: Elaine Ferguson, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *elaine.ferguson@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512533. 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: The committee will discuss new drug application (NDA) 22–425, dronedarone 400 milligrams oral tablets, Sanofi Aventis, for the proposed indication in patients with a history of, or current atrial fibrillation or atrial flutter, for the reduction of the risk of cardiovascular hospitalization or death. 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/ohrms/dockets/ac/acmenu.htm*, click on the year 2008 and 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 March 4, 2009. Oral presentations from the public will be scheduled approximately between 1 p.m. to 2 p.m. Those desiring to make 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 24, 2009. 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 25, 2009.

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 Elaine Ferguson 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/oc/advisory/default.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: February 4, 2009.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E9–2862 Filed 2–10–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

Request for Nominations for Voting and Nonvoting Consumer Representative Members on Public Advisory Committee and Panels

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for voting and nonvoting consumer representatives to serve on the National Mammography Quality Assurance Advisory Committee (NMQAAC) and certain devices panels of the Medical Devices Advisory Committee in the Center for Devices and Radiological Health (CDRH).

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

DATES: Nominations will be accepted for current vacancies and for those that will or may occur through October 31, 2009. Because vacancies occur on various dates throughout the year, there is no cutoff date for the receipt of nominations.

ADDRESSES: All nominations for membership should be sent electronically to *CV@OC.FDA.GOV* or by mail to Advisory Committee Oversight and Management Staff (HF–4), 5600 Fishers Lane, Rockville, MD 20857. Information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's Web site at *http://www.fda.gov/oc/advisory/default.htm*.

FOR FURTHER INFORMATION CONTACT: For specific committee questions, contact the following persons listed in table 1 of this document:

TABLE 1

Contact Person	Committee/Panel
Geretta P. Wood, Center for Devices and Radiological Health (HFZ–400), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3993, e-mail: *Geretta.Wood@fda.hhs.gov*	Certain Device Panels of the Medical Devices Advisory Committee
Nancy M. Wynne, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, e-mail: *Nancy.Wynne@fda.hhs.gov*	National Mammography Quality Assurance Advisory Committee

SUPPLEMENTARY INFORMATION:

I. Vacancies

FDA is requesting nominations for voting and nonvoting consumer representatives for the vacancies listed in table 2 of this document:

TABLE 2

Committee/Panel Expertise Needed	Current & Upcoming Vacancies	Approximate Date Needed
Circulatory System Devices Panel of the Medical Devices Advisory Committee—interventional cardiologists, electrophysiologists, invasive (vascular) radiologists, vascular and cardiothoracic surgeons, and cardiologists with special interest in congestive heart failure	1—nonvoting	Immediately
Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices Advisory Committee—doctors of medicine or philosophy with experience in clinical chemistry, clinical toxicology, clinical pathology, clinical laboratory medicine, endocrinology, and diabetes	1—nonvoting	March 1, 2009
Dental Products Panel of the Medical Devices Advisory Committee—dentists, engineers and scientists who have expertise in the areas of dental implants, dental materials, periodontology, tissue engineering, and dental anatomy	1—nonvoting	November 1, 2009
General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee—surgeons (general, plastic, reconstructive, pediatric, thoracic, abdominal, pelvic and endoscopic); dermatologists; experts in biomaterials, lasers, wound healing, and quality of life; and biostatisticians	1–nonvoting	Immediately
Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee—experts with broad, cross-cutting scientific, clinical, analytical or mediation skills	1–nonvoting	Immediately
Microbiology Devices Panel of the Medical Devices Advisory Committee—infectious disease clinicians, e.g., pulmonary disease specialists, sexually transmitted disease specialists, pediatric infectious disease specialists, experts in tropical medicine and emerging infectious diseases, biofilm development; mycologists; clinical microbiologists and virologists; clinical virology and microbiology laboratory directors, with expertise in clinical diagnosis and in vitro diagnostic assays, e.g., hepatologists; molecular biologists	1–nonvoting	March 1, 2009
Ophthalmic Devices Panel of the Medical Devices Advisory Committee—ophthalmologists specializing in cataract and refractive surgery and vitreo-retinal surgery, in addition to vision scientists, optometrists, and biostatisticians practiced in ophthalmic clinical trials	1–nonvoting	November 1, 2009
Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee—orthopedic surgeons (joint, spine, trauma, and pediatric); rheumatologists; engineers (biomedical, biomaterials, and biomechanical); experts in rehabilitation medicine, sports medicine, and connective tissue engineering; and biostatisticians	1	January 31, 2009
National Mammography Quality Assurance Advisory Committee—physicians, practitioners, or other health professionals whose clinical practice, research specialization, or professional expertise include a significant focus on mammography	2–nonvoting	February 1, 2009

II. Functions

A. NMQAAC

The committee advises FDA on the following topics: (1) Developing appropriate quality standards and regulations for mammography facilities; (2) developing appropriate standards and regulations for bodies accrediting mammography facilities under this program; (3) developing regulations with respect to sanctions; (4) developing procedures for monitoring compliance with standards; (5) establishing a mechanism to investigate consumer complaints; (6) reporting new developments concerning breast imaging which should be considered in the oversight of mammography facilities; (7) determining whether there exists a shortage of mammography facilities in rural and health professional shortage areas and determining the effects of personnel on access to the services of such facilities in such areas; (8) determining whether there will exist a sufficient number of medical physicists after October 1, 1999; and (9) determining the costs and benefits of compliance with these requirements.

B. 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. The panels engage in a number of activities to fulfill the functions of the Federal Food, Drug, and Cosmetic Act's (the act) envisions for device advisory panels. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, does the following: (1) Advises the Commissioner of Food and Drugs (the Commissioner) regarding recommended classification or reclassification of devices into one of three regulatory categories, (2) advises on any possible risks to health associated with the use of devices, (3) advises on formulation of product development protocols, (4) reviews premarket approval applications for medical devices, (5) reviews guidelines and guidance documents, (6) recommends exemption of certain devices from the application of portions of the act, (7) advises on the necessity to ban a device, and (8) 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.

III. Criteria for Members

Persons nominated for membership as a consumer representatives on the committee/panels must 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 must 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.

IV. Selection Procedures

Selection of members representing consumer interests is conducted through procedures that include the use of organizations representing the public interest and consumer advocacy groups. The organizations have the responsibility of recommending candidates of the agency's selection.

V. Nomination Procedures

All nominations must include a cover letter, a curriculum vita or resume (that includes the nominee's 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 will specify the advisory committee or panel(s) for which the nominee is recommended. Nominations will include confirmation that the nominee is aware of the nomination.

Any interested person or organization may nominate one or more qualified persons for membership as consumer representatives on the advisory committee/panels. Self-nominations are also accepted. Potential candidates will be required to provide detail information concerning such matters as financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of a conflict of interest. The nomination should specify the committee/panels of interest. The term of office is up to 4 years, depending on the appointment date.

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

Dated: February 4, 2009.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E9–2845 Filed 2–10–09; 8:45 am]

BILLING CODE 4160–01–S

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.

ADDRESSES: 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.

HTLV–II Vector and Methods of Use

Description of Technology: The invention hereby offered for licensing is in the field of vaccines and vaccine vectors. More specifically the invention provides compositions and methods of use of HTLV–II viral vector. The vector comprises at least a portion of the HTLV–II genome encoding the gag, pro, and pol genes and lacking all or a portion of the pX region. A heterologous gene is inserted within the deletion of the pX region. The gene of interest may encode all or a portion of a protein that corresponds to a viral protein of a foreign virus. The viral vectors thus constructed are useful for inducing immune response to the viral protein from the foreign virus. In particular the invention claims vaccines against HIV and SIV.

Applications: The technology can be used for DNA-based vaccines.

Advantages:

- Vaccines based on HTLV–II vectors have exhibited the capability to eliciting T cell response effectively. In particular they induce specific CD4+ and CD8+ T cell response. Antibody response to the HTLV–II vector is almost undetectable. The vector is infectious, but highly attenuated, with respect to the wild type HTLV–II. Desirably, the HTLV–II viral vector induces antibodies that can participate in Antibody-Dependent-Cell-Mediated Cytotoxicity (ADCC), a mechanism that enhances its effectiveness.
- Most of the T-cell vaccines developed for HIV are based on microbial vectors that have limited replication capacity and do not persist in the host. Such vaccines do not protect macaques from SIV infection and their ability to protect against high virus load is merely transient (approximately six months). They are perceived to elicit too ''small T-cell responses'' that expand ''too late''. In addition, few of these vectors target mucosal sites, the first portal of HIV entry. In contrast, an HTLV–II based vaccine is anticipated to infect macaques and replicate at very low level in lymphoid tissue and particularly in the gut which may enable them to maintain sufficient level of effectors CD8 memory cells to decrease early seeding of the virus, and sufficient level of central memory cells in lymph nodes that may limit the broadcasting of the virus at distal sites. These features make an HTLV–II based vaccine for HIV an excellent unique candidate to target mucosal tissues and provide long lasting mucosal immunity to HIV. In addition, the HTLV–II infects dendritic cells both in vivo and in vitro, and the HTLV–II infected dendritic cells have a mature phenotype, suggesting that HIV antigens expressed within dendritic cells could be effectively presented to the immune system.
- HTLV–II is a human retrovirus with no clear disease associations neither in healthy nor in HIV infected individuals.
- HTLV shares many biological and molecular characteristics of HIV, including routes of transmission, a T-cell tropism and gut tropism.
- Based on the above, it is believed that HIV vaccines based on HTLV–II vector will exhibit superiority compared to other vaccines in development.

Development Status: At the present only in vitro as well as animal (macaques) data that demonstrate the