DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Request for Notification From Consumer Organizations Interested in Participating in the Selection Process for Nominations for Voting and/or Nonvoting Consumer Representatives and 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 February 2013.

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 email stating that interest to FDA (see **ADDRESSES**) by March 14, 2012, for vacancies listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA (see **ADDRESSES**) by March 14, 2012.

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, *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 and upcoming vacancies	Approximate date needed
Allergenic Products—Knowledgeable in the field of allergenic extracts that are used for the diagnosis and treatment of allergic diseases such as allergic rhinitis (''hay fever''), allergic sinusitis, allergic conjunctivitis, bee venom allergy, and food allergy.	1—Voting	08/31/12.
Peripheral and Central Nervous Systems—Knowledgeable in the fields of neurology, neuropharmacology, neuropathology, otolaryngology, epidemiology or statistics, and related specialties.	1—Voting	01/31/13.
Non-Prescription Drugs—Knowledgeable in the fields of internal medicine, family practice, clinical toxicology, clinical pharmacology, pharmacy, dentistry, and related specialties.	1—Voting	01/31/13.
National Mammography Quality Assurance—Knowledgeable in clinical practice, research specialization, or professional work that has a significant focus on mammography.	2—Nonvoting	01/31/13.
Certain Panels of the Medical Devices Advisory Committee		
Clinical Chemistry and Clinical Toxicology Devices—Knowledgeable in the fields of clinical chemistry and toxicology in vitro diagnostic devices (IVDs); clinical use of related IVDs in laboratories and in home; data concerning safety and effectiveness of related IVDs for clinical use in diseases/disorders/conditions such as diabetes, cardiovascular disease, endocrine disorders, women's health, drug abuse, therapeutic drug monitoring, and general chemistry conditions.	1—Nonvoting	02/28/13.
Microbiology Devices Panel—Knowledgeable in infectious and pulmonary disease, pediatric infectious diseases, tropical diseases, and clinical microbiology.	1—Voting	Immediately.

I. Functions

A. Allergenic Products Advisory Committee

The Committee reviews and evaluates available data concerning the safety, effectiveness, and adequacy of labeling of marketed and investigational allergenic biological products or materials that are administered to humans for the diagnosis, prevention, or treatment of allergies and allergic disease, and makes appropriate recommendations to the Commissioner of Food and Drugs of its findings.

B. Peripheral and Central Nervous Systems Advisory Committee

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

C. Non-Prescription Drugs Advisory Committee

The Committee reviews and evaluates available data concerning the safety and effectiveness of over-the-counter (non-prescription) human drug products, or any other FDA-regulated product, for use in the treatment of a broad spectrum of human symptoms and diseases and advises the Commissioner either on the promulgation of monographs establishing conditions under which these drugs are generally recognized as

safe and effective and not misbranded or on the approval of new drug applications for such drugs. The Committee will serve as a forum for the exchange of views regarding the prescription and non-prescription status, including switches from one status to another, of these various drug products and combinations thereof. The Committee may also conduct peer review of Agency-sponsored intramural and extramural scientific biomedical programs in support of FDA's mission and regulatory responsibilities.

D. National Mammography and Quality Assurance Advisory Committee

The Committee reviews and evaluates (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 that should be considered in the oversight of mammography facilities; and (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.

E. 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 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.

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 email 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.

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
Donald Jehn, Center for Biologics Evaluation and Research, Food and Drug Administration, 5515 Security Lane, Rockwall Bldg. 2 (HFM–71), rm. 1118, , Rockville, MD 20852, 301–827–1293, Fax: 301–827–0294, *Donald.Jehn@fda.hhs.gov*.	Allergenic Products.
CDR Diem-Kieu Ngo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2412, Silver Spring, MD 20993–0002, 301–796–9021, Fax: 301–847–8533, *Diem.Ngo@fda.hhs.gov*.	Peripheral and Central Nervous Systems Drugs.
CDR Diem-Kieu Ngo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2412, Silver Spring, MD 20993–0002, 301–796–9021, Fax: 301–847–8533, *Diem.Ngo@fda.hhs.gov*.	Non-Prescription Drugs.
LCDR Sara J. Anderson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1544, Silver Spring, MD 20993–0002, 301–796–7047, Fax: 301–847–8121, *Sara.Anderson@fda.hhs.gov*.	National Mammography and Quality Assurance.
LCDR Sara J. Anderson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1544, Silver Spring, MD 20993–0002, 301–796–7047, Fax: 301–847–8121, *Sara.Anderson@fda.hhs.gov*.	Clinical Chemistry and Clinical Toxicology Devices.
Jamie Waterhouse, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1544, Silver Spring, MD 20993–0003, 301–796–3063, Fax: 301–847–8121, *Jamie.Waterhouse@fda.hhs.gov*.	Ear, Nose, and Throat Devices.
Shanika Craig, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1613, Silver Spring, MD 20993–0003, 301–796–6639, Fax: 301–847–8121, *Shanika.Craig@fda.hhs.gov*.	Microbiology Devices Panel.

Dated: February 7, 2012.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

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BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Reports Clearance Officer at (301) 443–0165.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the Agency; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Uncompensated Services Assurance Report (OMB No. 0915–0077)—[Extension]

Under the Hill-Burton Act, the Government provides grants and loans for construction or renovation of health care facilities. As a condition of receiving this construction assistance, facilities are required to provide services to persons unable to pay. A condition of receiving this assistance requires facilities to provide periodic assurances that the required level of uncompensated care is being provided, and that certain notification and record keeping procedures are being followed. These standard requirements are referred to as the uncompensated services assurance.

The annual estimate of burden is as follows:

ESTIMATE OF INFORMATION COLLECTION BURDEN

Type of requirement and regulatory citation	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Disclosure Burden (42 CFR):					
Published Notices (124.504(c))	63	1	63	0.75	47.25
Individual Notices (124.504(c))	63	1	63	43.60	2,746.80
Determinations of Eligibility (124.507)	63	63	3,969	0.75	2,976.75
SUBTOTAL DISCLOSURE BURDEN					5,770.80

Type of requirement and regulatory citation	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Reporting:					
Uncompensated Services Report—HRSA–710 Form (124.509(a))	10	1	10	11.00	110.00