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Display Date	9-24-99
Publication Date	9-27-99
Certifier	M. Bell

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

**Request for Nominations for Members on Public Advisory Panels or Committees;
Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the establishment of the Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee (the Panel) in the Center for Devices and Radiological Health (CDRH). In this document, FDA is also requesting nominations for members to serve on the newly formed panel.

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. Final selection from among qualified candidates for each vacancy will be determined by the expertise required to meet specific agency needs and in a manner to ensure appropriate balance of membership.

DATES: Nominations should be received by *(insert date 30 days after date of publication in the Federal Register)*.

ADDRESSES: All nominations and curricula vitae, except for consumer-nominated and industry-nominated members, should be sent to Nancy J. Pluhowski (address below). All nominations and curricula vitae for the consumer-nominated members should be sent to Annette J. Funn (address below). All nominations for the industry-nominated members should be sent to Kathleen L. Walker (address below).

FOR FURTHER INFORMATION CONTACT:

Regarding all nominations for membership, except consumer-nominated and industry-

nominated members: Nancy J. Pluhowski, Office of Device Evaluation (HFZ-400), CDRH, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2022.

Regarding all nominations for consumer-nominated members: Annette J. Funn, Office of Consumer Affairs (HFE-88), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-5006.

Regarding all nominations for industry-nominated members: Kathleen L. Walker, Office of Systems and Management (HFZ-17), CDRH, Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-1283, ext. 114.

SUPPLEMENTARY INFORMATION: The Panel was created on August 18, 1999. FDA is requesting nominations for members to serve on the new advisory panel. Persons nominated for membership should have expertise in the activity of the Panel as identified below.

Functions

The functions of the medical devices panels of the Medical Devices Advisory Committee are to: (1) Review and evaluate data on the safety and effectiveness of marketed and investigational devices and make recommendations for their regulation; (2) advise the Commissioner of Food and Drugs regarding recommended classification or reclassification of these devices into one of three regulatory categories; (3) advise on any possible risks to health associated with the use of devices; (4) advise on formulation of product development protocols; (5) review premarket approval applications for medical devices; (6) review guidelines and guidance documents; (7) recommend exemption to certain devices from the application of portions of the Federal Food, Drug, and Cosmetic Act (the act); (8) advise on the necessity to ban a device; (9) respond to requests from the agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices; and (10) make recommendations on the quality in the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices.

Specifically, the function of the Molecular and Clinical Genetics Panel is to provide advice to the Commissioner on the appropriate scientific criteria to diagnostically test for human genes. In addition to the functions of the Medical Devices Advisory Committee, this panel shall review guidance and recommend criteria and classification of tests for human genes.

Criteria for Members

Persons nominated for membership on the Panel shall have expertise in human genetics and in the clinical management of patients with genetic disorders, e.g., pediatricians, obstetricians, and neonatologists. The agency is also interested in considering 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. The term of office is up to 4 years.

The Panel will also include technically qualified members who are identified with consumer interests and representatives of industry interests.

Nomination Procedures

Any interested person may nominate one or more qualified persons for membership on the Panel. Self-nominations are also accepted. Nominations shall include a complete curriculum vitae of each nominee, current business address and telephone number, and shall state that the nominee is aware of the nomination, is willing to serve as a member, and appears to have no conflict of interest that would preclude Panel membership. FDA will ask the potential candidates to provide detailed information concerning such matters as financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflict of interest.

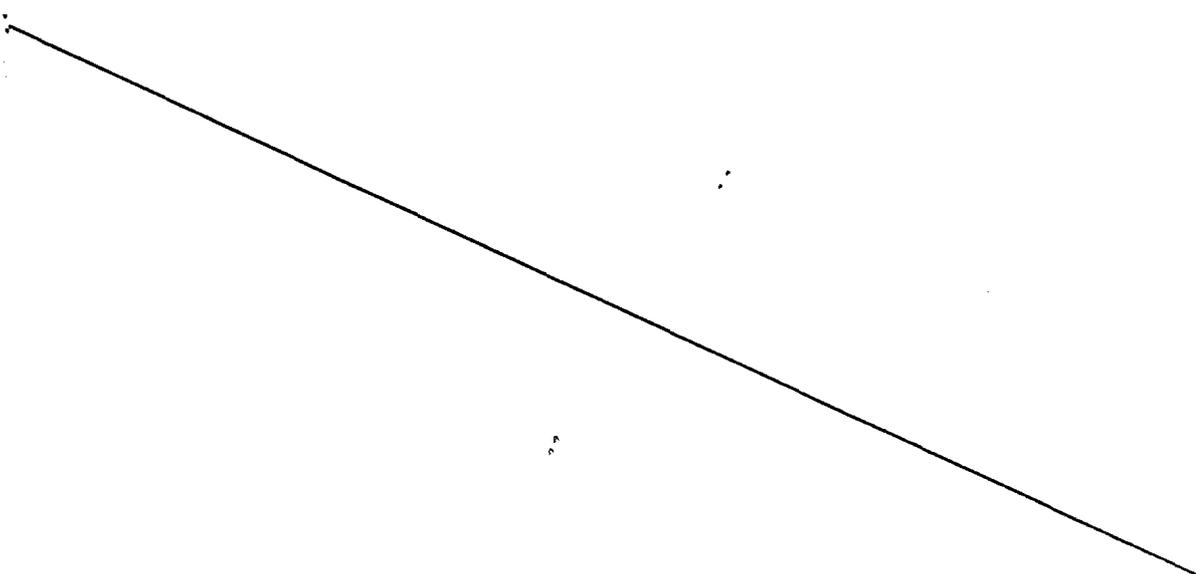
Criteria for Consumer-Nominated Members

Selection of members representing consumer interests is conducted through procedures that include use of a consortium of consumer organizations which has the responsibility for screening, interviewing and recommending candidates for the agency's selection. Candidates from this group,

like all other candidates for membership on the Panel, should possess appropriate qualifications to understand and contribute to the Panel's work.

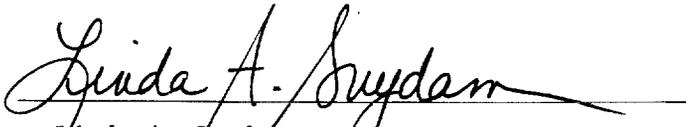
Industry Representatives

Regarding nominations for members representing industry interests, a letter will be sent to each person or organization that has made a nomination and to other organizations that have expressed an interest in participating in the selection process together with a complete list of all such organizations and the nominees. The letter will state that it is the responsibility of each nominator or organization that has expressed an interest in participating in the selection process to consult with the others to provide a consensus slate of possible members representing industry interests within 60 days. In the event that a slate of nominees has not been provided within 60 days, the agency will select an industry representative for each such vacancy from the entire list of industry nominees to avoid delay or disruption of the work of the Panel. The agency is particularly interested in nominees that possess the essential scientific credentials needed to participate fully and knowledgeably in the Panel's deliberations. In addition to this expertise, the agency believes that it would be an advantage to the Panel's work if the individual had special insight and direct experience into specific industrywide issues, practices, and concerns that might not otherwise be available to others not similarly situated.



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: September 17, 1999


Linda A. Suydam
Senior Associate Commissioner

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

BILLING CODE 4160-01-F

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