



**REQUEST FOR NOMINATIONS
FOR
PATIENT REPRESENTATION ON FDA ADVISORY COMMITTEES**

The purpose for this notice is to solicit nominees to serve as Patient Representatives on the Food and Drug Administration's (FDA) Advisory Committees that consider therapies for serious and life-threatening diseases, including pediatric patients with Attention-Deficit/Hyperactivity Disorder (ADHD).

The FDA depends on advisory committees to provide independent, outside expert, scientific advice to the agency in its evaluation of regulated products and to help the agency make sound decisions grounded in the application of scientific principle. Advisory committees weigh available evidence and provide scientific and medical advice on the safety, effectiveness, and appropriate use of products under FDA jurisdiction.

The FDA believes that involving patients with serious and life-threatening diseases in the advisory committee process brings a valuable perspective to the review and deliberations of new therapies and products. Patient Representatives provide insights on problems or questions pertinent to the viewpoint of pediatric patients living with ADHD.

Patient Representatives should be able to understand the analysis of scientific data and research design, discuss risk and benefit analysis, and contribute to discussions based on technical and clinical considerations. Patient Representatives should not only be well informed about the issues to be discussed at advisory committee meetings, but they should also be able to represent the community as broadly as possible. This would include a familiarity with the issues and concerns related to pediatric patients affected by ADHD.

Patient Representatives will be asked to disclose financial and other interests that might represent a potential conflict with issues under consideration by advisory committees.

Advisory committee meetings are usually one to two days in duration and are generally held in the Washington, D. C. metropolitan area. The FDA will pay the travel costs and per diem for individuals selected to serve as Patient Representatives.

Individuals, patient advocacy groups, or professional organizations may submit nominations. Self-nominations will also be accepted. Submit your candidate nomination(s) (see attached Nomination Guide) by fax (301-443-4555) or mail to:

Patient Representative Program
Office of Special Health Issues (HF-12)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

If you have any questions or would like additional clarification, please telephone Ms. Lyvon Covington at (301) 827-4460.



**NOMINATION GUIDE
FOR THE SELECTION OF
PATIENT REPRESENTATIVES
FOR
FDA ADVISORY COMMITTEES**

Anyone may nominate a candidate to serve as a Patient Representative on FDA Advisory Committees. The nominee must be aware and supportive of his/her nomination. Self-nominations are also accepted. Nominations must include the following information:

- A resume or curriculum vitae
- An addendum that addresses the following selection criteria:
 - Personal experience with attention deficit/hyperactivity disorder (ADHD) as a pediatric patient or as a supporter of a pediatric patient (i.e., spouse, partner, parent, sibling, grandparent, or caregiver).
 - Experience in patient advocacy;
 - Ability to represent the interests of patients;
 - Ability to communicate the perspective of patients;
 - Ability to identify issues that are important to patients;
 - Ability to understand scientific data and technical information about research studies; and/or personal experience as a participant in research studies that would enable the nominee to participate in Advisory Committee discussions related to research for ADHD;
 - Ability to disseminate information about his/her experience as an advisory committee member to the patient community.

Note: If a nominee does not have experience under one criterion, but is highly qualified under another, he/she will still be considered as a Patient Representative candidate.