

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Request for Nominations for Members on Public Advisory Committees; Drug Safety and Risk Management Advisory Committee (Formally Drug Abuse Advisory Committee)

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for four members to serve on the Drug Safety and Risk Management Advisory Committee in the Center for Drug Evaluation and Research.

FDA has a special interest in ensuring that women, minority groups, and the physically challenged are adequately represented on advisory committees and, therefore, extends particular encouragement to nominations for appropriately qualified female, minority, or physically challenged candidates. Final selection from each vacancy will be determined by the expertise required to meet specific agency needs and in a manner to ensure appropriate balance on membership.

DATES: Nominations should be received before September 1, 2002.

ADDRESSES: All nominations for membership should be sent to Kimberly Topper, and all nominations for consumer-nominated members should be sent to Linda Sherman (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Kimberly Topper, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600

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Fishers Lane, Rockville, MD 20857, 301–827–7001, e-mail:
topperk@cdcr.fda.gov; or

Linda Sherman, Advisory Committee Oversight and Management Staff
(HF–4), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD
20857, 301–827–1220, e-mail: lsherman@oc.fda.gov.

SUPPLEMENTARY INFORMATION: On June 1, 2002, the Drug Safety and Risk
Management Advisory Committee (formerly Drug Abuse Advisory Committee)
was rechartered with 9 of the proposed 13 members. Accordingly, FDA is
requesting nominations for members to serve on the Drug Safety and Risk
Management Advisory Committee (formerly Drug Abuse Advisory Committee).

Function: The committee advises the Commissioner of Food and Drugs
regarding the scientific and medical evaluation of all information gathered by
the Department of Health and Human Services (DHHS) and the Department
of Justice with regard to safety, abuse potential, risk management, risk
communication, and quantitative evaluation of spontaneous reports, and
recommends actions to be taken by DHHS with regard to marketing,
investigation, and control of such drugs or other substances.

Criteria for Members

Persons nominated for membership on the committees described
previously in this document must have adequately diversified research and/
or clinical experience appropriate to the work of the committee in such fields
as anesthesiology, surgery, internal medicine, infectious disease, asthma,
rheumatology, microbiology, pediatrics, ophthalmology, cardiology, clinical/
medical oncology, hematology, radiology, nuclear medicine, biostatistics,
epidemiology, dermatopathology/immunodermatology, dermatology,

psychopharmacology, neurochemistry, neuropharmacology, endocrinology, obstetrics and gynecology, reproductive endocrinology, gastroenterology, pharmacology, clinical pharmacology, hepatology, virology, pharmaceutical manufacturing, bioavailability and bioequivalence research, pharmacokinetics, neurology, psychiatry, psychology, neuropharmacology, neuropathology, pulmonary disease, allergy, immunology, clinical immunology, safety, abuse potential, risk management, risk communication and quantitative evaluation of spontaneous reports or other appropriate areas of expertise.

The specialized training and experience necessary to qualify the nominee as an expert suitable for appointment is subject to review, but may include experience in medical practice, teaching, research, and/or public service relevant to the field of activity of the committee. The term of office is up to 4 years.

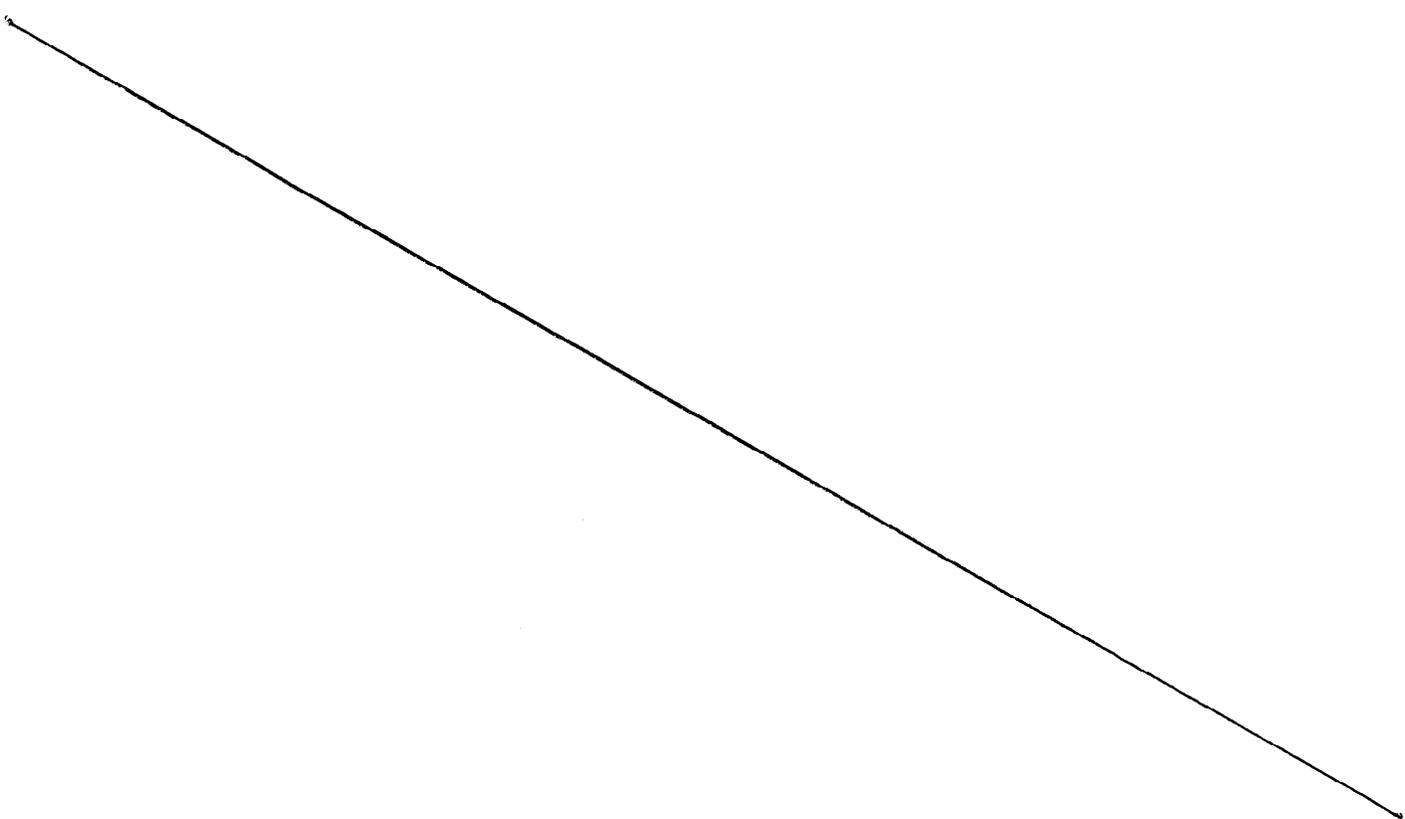
Criteria for Consumer-Nominated Members

FDA currently attempts to place on each of the committees described previously in this document one voting member who is nominated by consumer organizations. These members are recommended by consumer organizations which have the responsibility for screening, interviewing, and recommending candidates with appropriate scientific credentials. Candidates are sought who are aware of the consumer impact of committee issues, but who also possess enough technical background to understand and contribute to the committee's work. This would involve, for example, an understanding of research design, benefit/risk and the legal requirements for safety and efficacy of the products under review, and considerations regarding individual products. The agency notes, however, that for some advisory committees, it may require such nominees to meet the same technical qualifications and

specialized training required of other expert members of the committee. The term of office for these members is up to 4 years. Nominations for all committees listed previously in this document are invited for consideration for membership as openings become available.

Nomination Procedure

Any interested person may nominate one or more qualified persons for membership on one or more of the advisory committees. Nominations shall specify the committee for which the nominee is recommended. Nominations shall state that the nominee is aware of the nomination, is willing to serve as a member of the advisory committee, and appears to have no conflict of interest that would preclude committee membership. Potential candidates will be asked by FDA to provide detailed information concerning such matters as financial holdings, consultancies, and research grants or contracts in order to permit evaluation of possible sources of conflict of interest.



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: July 5, 2002
July 5, 2002.



William K. Hubbard,
Senior Associate Commissioner for Policy, Planning, and Legislation.

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