



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0001]

Request for Nominations for Voting Members on a Public Advisory Committee; Pharmacy Compounding Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for 12 voting members to serve on the Pharmacy Compounding Advisory Committee, Center for Drug Evaluation and Research.

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees, and therefore, encourages nominations of appropriately qualified candidates from these groups.

DATES: Nominations received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] will be given first consideration for membership on the Pharmacy Compounding Advisory Committee. Nominations received after [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] will be considered for nomination to the committee if nominees are still needed.

ADDRESSES: All nominations for membership should be sent electronically to cv@oc.fda.gov, or by mail to Advisory Committee Oversight and Management Staff, 10903 New Hampshire Ave., Bldg. 32, rm. 5103, Silver Spring, MD 20993-0002. 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/AdvisoryCommittees/default.htm>.

FOR FURTHER INFORMATION CONTACT: Jayne E. Peterson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993, 301-796-9001; FAX: 301-847-8533, email: PCAC@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for voting members on the Pharmacy Compounding Advisory Committee (the Committee).

I. General Description of the Committee's Duties

The Committee provides advice on scientific, technical, and medical issues concerning drug compounding under sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353a and 353b), and as required, any other product for which FDA has regulatory responsibility. The Committee also makes appropriate recommendations to the Commissioner of Food and Drugs.

II. Criteria for Voting Members

Persons nominated for membership must have adequately diversified research and/or experience appropriate to the work of the Committee in such fields as pharmaceutical compounding, pharmaceutical manufacturing, pharmacy, medicine, and related specialties. These members will include representatives from the National Association of Boards of Pharmacy, the United States Pharmacopoeia, pharmacists with current experience and expertise in compounding, physicians with background and knowledge in compounding, and patient and public health advocacy organizations.

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,

pharmacy practice, teaching, research, and/or public service relevant to the field of activity of the Committee. Members will be invited to serve for terms of up to 4 years.

III. Nomination Procedure

Any interested person may nominate one or more qualified persons for membership on the Committee. Self-nominations are also accepted. Nominations should include a cover letter and a current, complete résumé or curriculum vitae for each nominee, including a current business address and/or home address, telephone number, and email address if available. Nominations should also specify the advisory committee for which the nominee is recommended. Nominations should state that the nominee is aware of the nomination unless self-nominated. Nominations should also state that the nominee is willing to serve as a member of the advisory committee if selected and appears to have no conflict of interest. FDA will ask potential candidates to provide detailed information concerning such matters as financial holdings, employment, and research grants and/or contracts in order to permit evaluation of possible sources of conflict of interest.

Elsewhere in this issue of the Federal Register, FDA is publishing a notice for industry organizations to participate in the nominations for and selection of industry representatives for the Committee, a notice for consumer organizations to participate in the nominations for and selection of the consumer representative for the Committee, and a final rule updating information regarding the Committee.

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: January 7, 2014.

Jill Hartzler Warner.

Acting Associate Commissioner for Special Medical Programs.

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