



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Request for Nominations for a Voting Consumer Representative on the Pharmacy Compounding Advisory Committee and Request for Notification From Consumer Organizations Interested in Participating in the Selection Process for Nominations for a Voting Consumer Representative on the Pharmacy Compounding Advisory Committee

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 a voting consumer representative to serve on the Pharmacy Compounding Advisory Committee notify FDA in writing. FDA is also requesting nominations for a voting consumer representative to serve on the Pharmacy Compounding Advisory Committee for which a vacancy currently exists. Nominees recommended to serve as the voting consumer representative may be self-nominated or nominated by a consumer organization. Nominations will be accepted for the current vacancy through [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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: Any consumer organization interested in participating in the selection of an appropriate voting member to represent consumer interests on an FDA advisory committee should send a letter or email stating that interest to FDA (see ADDRESSES) by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], for the vacancy in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA (see ADDRESSES) by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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](mailto:cv@oc.fda.gov), or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5129, Silver Spring, MD 20993-0002, FAX: 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: Dornette Spell-LeSane, Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5129, Silver Spring, MD 20993-0002, 301-796-8224, email: [dornette.spellesane@fda.hhs.gov](mailto:dornette.spellesane@fda.hhs.gov).

For questions relating to the Pharmacy Compounding Advisory Committee, 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](mailto:PCAC@fda.hhs.gov).

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for a voting consumer representative listed in table 1:

Table 1.--Committee Description, Type of Consumer Representative Vacancy, and Approximate Date Needed

Committee Areas of Expertise Needed	Current Vacancies	Approximate Date Needed
Pharmacy Compounding--Knowledgeable in the fields of pharmaceutical compounding; pharmaceutical manufacturing; pharmacy, medicine, and related specialties.	1-Voting	Immediately

### I. Pharmacy Compounding Drugs Advisory Committee

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, and makes appropriate recommendations to the Commissioner of Food and Drugs.

### II. Criteria for Members

Persons nominated for membership as consumer representatives on committees 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) be able to discuss benefits and risks; and (5) be able to 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 consumer advocacy groups. These organizations recommend nominees for the Agency's selection. Representatives

from the consumer health branches of Federal, State, and local governments may also participate in the selection process. Any consumer organization interested in participating in the selection of an appropriate voting 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 at least two qualified nominees selected by the Agency based on the nominations received, along with each nominee's current curriculum vitae or résumé. 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.

#### 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. 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, email address if available, and a list of consumer- or community-based organizations for which the candidate can demonstrate active participation.

Nominations also should specify the advisory committee for which the nominee is recommended. In addition, nominations should include confirmation that the nominee is aware of the nomination, 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 conflicts of interest.

Members will be invited to serve for terms of up to 4 years.

FDA will review all nominations received within the specified timeframes and prepare a ballot containing the names of qualified nominees. Names not selected will remain on a list of eligible nominees and will 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 consumer representatives will not participate in the selection process.

Elsewhere in this issue of the Federal Register, FDA is publishing a notice requesting nominations for voting members of the Committee, a notice for industry organizations to participate in the nominations for and selection of the industry representatives 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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