



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Request for Notification From Industry Organizations Interested in Participating in the Selection Process for Nonvoting Industry Representatives and Request for Nominations for Nonvoting Industry Representatives on the Pharmacy Compounding Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that industry organizations interested in participating in the selection of nonvoting industry representatives to represent the interests of the pharmacy compounding industry and the pharmaceutical manufacturing industry on the Pharmacy Compounding Advisory Committee for the Center for Drug Evaluation and Research notify FDA in writing. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for two vacancies effective with this notice.

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. Specifically, in this document, nominations for nonvoting representatives of industry interests are encouraged from the pharmacy compounding industry and the pharmaceutical manufacturing industry.

DATES: Any industry organization interested in participating in the selection of appropriate nonvoting members to represent the interests of the pharmacy compounding industry and the

pharmaceutical manufacturing industry should send a letter stating the interest to FDA by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], for the vacancies listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: All letters of interest and nominations should be submitted electronically to [PCAC@fda.hhs.gov](mailto:PCAC@fda.hhs.gov), or in writing by mail to 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.

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](mailto:PCAC@fda.hhs.gov).

SUPPLEMENTARY INFORMATION: The Agency requests nominations for nonvoting industry representatives on the Pharmacy Compounding Advisory Committee (the Committee) to represent the interests of the pharmacy compounding industry and the pharmaceutical manufacturing industry.

#### I. Pharmacy Compounding Advisory Committee

The Committee advises the Commissioner of Food and Drugs (the Commissioner) or designee in discharging responsibilities as they relate to the regulation of compounded drug products. 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.

The Committee will include one or more nonvoting members who represent industry interests. These members will include one representative of the pharmacy compounding industry and one representative of the pharmaceutical manufacturing industry. With this notice, nominations are being sought for one representative from the pharmacy compounding industry and one representative from the pharmaceutical manufacturing industry.

## II. Criteria for Nonvoting Members

Any pharmacy compounding organization and any pharmaceutical manufacturing organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (see FOR FURTHER INFORMATION CONTACT) within 30 days of publication of this document (see DATES).

Within the subsequent 30 days, FDA will send a letter to each pharmacy compounding organization that has expressed an interest and attach a complete list of all such organizations. A list of all nominees from the pharmacy compounding industry along with their current résumés will also be attached. The letter will also state that it is the responsibility of the interested organizations to confer with one another and select a candidate to serve as the nonvoting member to represent the pharmacy compounding industry on the committee within 60 days of receiving the FDA letter. FDA will send similar letters to the pharmaceutical manufacturing organizations that have expressed interest, and they will be expected to follow a similar process to select their nominee.

Interested organizations are not bound by the list of nominees when selecting a candidate. However, if no individual is selected within 60 days, the Commissioner will select the nonvoting member in each category to represent industry interests.

### III. Nomination Procedure

Individuals may self-nominate, and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. Nominations should include contact information and a current, complete résumé or curriculum vitae for each nominee. Nominations should also include the name of the Committee and should be sent to the FDA contact person (see FOR FURTHER INFORMATION CONTACT) within 30 days of publication of this document (see DATES). FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the Committee. (Persons who nominate themselves as nonvoting industry 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 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.