

from or about consumers. Specifically, the proposed order requires Accretive Health to:

- Designate an employee or employees to coordinate and be accountable for the information security program;
- identify material internal and external risks to the security, confidentiality, and integrity of personal information that could result in the unauthorized disclosure, misuse, loss, alteration, destruction, or other compromise of such information, and assess the sufficiency of any safeguards in place to control these risks;
- design and implement reasonable safeguards to control the risks identified through risk assessment, and regularly test or monitor the effectiveness of the safeguards' key controls, systems, and procedures;
- develop and use reasonable steps to select and retain service providers capable of appropriately safeguarding personal information they receive from Accretive Health, and require service providers by contract to implement and maintain appropriate safeguards; and
- evaluate and adjust its information security program in light of the results of testing and monitoring, any material changes to operations or business arrangement, or any other circumstances that it knows or has reason to know may have a material impact on its information security program.

Part III of the proposed order requires Accretive Health to obtain within the first one hundred eighty (180) days after service of the order, and on a biennial basis thereafter for a period of twenty (20) years, an assessment and report from a qualified, objective, independent third-party professional, certifying, among other things, that: (1) It has in place a security program that provides protections that meet or exceed the protections required by Part II of the proposed order; and (2) its security program is operating with sufficient effectiveness to provide reasonable assurance that the security, confidentiality, and integrity of sensitive consumer, information has been protected.

Parts IV through VIII of the proposed order are reporting and compliance provisions. Part IV requires Accretive Health to retain documents relating to its compliance with the order. For most records, the order requires that the documents be retained for a five-year period. For the third-party assessments and supporting documents, Accretive Health must retain the documents for a period of three years after the date that each assessment is prepared. Part V requires dissemination of the order now

and in the future to all current and future principals, officers, directors, and managers, and to persons with responsibilities relating to the subject matter of the order. Part VI ensures notification to the FTC of changes in corporate status. Part VII mandates that Accretive Health submit a compliance report to the FTC within 60 days, and periodically thereafter as requested. Part VIII is a provision "sunsetting" the order after twenty (20) years, with certain exceptions.

The purpose of this analysis is to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the proposed complaint or order or to modify the order's terms in any way.

By direction of the Commission.

Janice Podoll Frankle,

Acting Secretary.

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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 February 12, 2014, for the vacancies listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA by February 12, 2014.

ADDRESSES: All letters of interest and nominations should be submitted electronically to 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.

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.

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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 February 12, 2014.

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 February 12, 2014, for the vacancy in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA (see **ADDRESSES**) by February 12, 2014.

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, 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.spelllesane@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.

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