4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0781]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that any industry organizations interested in participating in the selection of a nonvoting industry representative to serve on the Pediatric Advisory Committee for the Office of the Commissioner (OC) notify FDA in writing. FDA is also requesting nominations for a nonvoting industry representative(s) to serve on the Pediatric Advisory Committee. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for current vacancies effective with this notice.

DATES: Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating that interest to FDA by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION], for the vacancy listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION].

ADDRESSES: All letters of interest and nominations should be submitted in writing to Walter Ellenberg (see FOR FURTHER INFORMATION CONTACT).

FOR FURTHER INFORMATION CONTACT:

Walter Ellenberg,

Office of the Commissioner,

Food and Drug Administration,

10903 New Hampshire Ave.,

Bldg. 32, rm. 5154,

Silver Spring, MD 20993,

301-796-0885,

FAX: 301-847-8640,

walter.ellenberg@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The Agency intends to add a nonvoting industry representative(s) to the following advisory committee:

I. OC Advisory Committee

Pediatric Advisory Committee

The Committee reviews and evaluates and makes recommendations to the Commissioner of Food and Drugs regarding: (1) Pediatric research conducted under sections 351, 409I, and 499 of the Public Health Service Act and sections 501, 502, 505, 505A, and 505B, 510K, 515, and 520m of the Federal Food, Drug, and Cosmetic Act; (2) identification of research priorities related to pediatric therapeutics (including drugs and biological products) and medical devices for pediatric populations and the need for additional diagnostics and treatments of specific pediatric diseases or conditions, (3) the ethics, design, and analysis of clinical trials related to

pediatric therapeutics (including drugs and biological products) and medical devices, (4) pediatric labeling disputes as specified in Public Law 107-109 and Public Law 110-85, (5) pediatric labeling changes as specified in Public Law 107-109 and Public Law 110-85, (6) adverse event reports for drugs studied under Public Law 107-109 and 110-85 and labeled, (7) any safety issues that may occur as specified Public Law 107-109 and Public Law 110-85, (8) any other pediatric issue or pediatric labeling dispute involving FDA-regulated products, (9) pediatric ethical issues including research involving children as subjects as specified in 21 CFR 50.54; and (10) any other matter involving pediatrics for which FDA has regulatory responsibility.

The Committee also advises and makes recommendations to the Secretary directly or to the Secretary through the Commissioner on research involving children as subjects that is conducted or supported by the Department of Health and Human Services as specified in 45 CFR 46.407.

II. Selection Procedure

Any industry 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 organization that has expressed an interest, attaching a complete list of all such organizations; and a list of all nominees along with their current resumes. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry interests for the committee. The interested organizations are not bound by the list of

nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner will select the nonvoting member to represent industry interests.

III. Application Procedure

Individuals may self nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. Contact information, a current curriculum vitae, and the name of the committee of interest 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).

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 pediatric pharmaceutical research and biotechnology manufacturing industry.

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: August 7, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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