



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-6266]

Request for Nominations 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 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 IN THE *FEDERAL REGISTER*] (see sections I and II of this document for further details). Concurrently, nomination materials for prospective candidates should be sent to FDA by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Nominations received on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] will be given first consideration for membership on the Pediatric Advisory Committee. Nominations received after [INSERT DATE 30 DAYS AFTER DATE

OF PUBLICATION IN THE *FEDERAL REGISTER*] will be considered for nomination to the committee as later vacancies occur.

ADDRESSES: All statements of interest from industry organizations interested in participating in the selection process of nonvoting industry representative nomination should be sent to Marieann Brill (see FOR FURTHER INFORMATION CONTACT). All nominations for nonvoting industry representatives should be sent electronically by logging into the FDA Advisory Nomination

Portal:<https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm> or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 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 website at <https://www.fda.gov/AdvisoryCommittees/default.htm>.

FOR FURTHER INFORMATION CONTACT: Regarding all nomination questions for nonvoting industry representative the primary contact is: Marieann Brill, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5154, Silver Spring, MD 20993, 240-402-3838, email: [marieann.brill@fda.hhs.gov](mailto:marieann.brill@fda.hhs.gov).

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for nonvoting industry representative(s) on the Pediatric Advisory Committee:

#### I. General Description of the Committee Duties

The Committee reviews and evaluates and makes recommendations to the Commissioner of Food and Drugs (the Commissioner) regarding (1) pediatric research conducted under sections 351, 409I, and 499 of the Public Health Service Act (42 U.S.C. 262, 284m, and 290b) and sections 501, 502, 505, 505A, 505B, 510(k), 515, and 520(m) of the Federal Food, Drug, and

Cosmetic Act (21 U.S.C. 351, 352, 355, 355a, 355c, 360(k), 360e, and 360j(m)); (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 Pub. L. 107-109, Pub. L. 110-85, and Pub. L. 112-144; (5) pediatric labeling changes as specified in Pub. L. 107-109, Pub. L. 110-85, and Pub. L. 112-144; (6) adverse event reports for drugs studied under Pub. L. 107-109, Pub. L. 110-85, and Pub. L. 112-144; (7) any safety issues that may occur as specified Pub. L. 107-109, Pub. L. 110-85, and Pub. L. 112-144; (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 of Health and Human Services (Secretary) (HHS) directly or to the Secretary through the Commissioner on research involving children as subjects that is conducted or supported by HHS 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 résumés. 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. Nomination Procedures

Any interested person may nominate one or more qualified individuals for membership on the advisory committee. Self-nominations are also accepted. Nominations must include a current, complete résumé or curriculum vitae for each nominee and a signed copy of the Acknowledgement and Consent form available at the FDA Advisory Nomination Portal (see ADDRESSES). Nominations must also specify the advisory committee for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. 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.

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: October 30, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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