

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 December 4, 2017 (see sections I and II of this document for further details). Concurrently, nomination materials for prospective candidates should be sent to FDA by December 4, 2017. Nominations received on or before December 4, 2017 will be given first consideration for membership on the Pediatric Advisory Committee. Nominations received after December 4, 2017 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

Web site 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.

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 Public Law 107-109, Public Law 110-85, and Public Law 112-144; (5) pediatric labeling changes as specified in Public Law 107-109, Public Law 110-85, and Public Law 112-144; (6) adverse event reports for drugs studied under Public Law 107-109, Public Law 110-85, and Public Law 112-144; (7) any safety issues that may occur as specified Public Law 107-109, Public Law 110-85, and Public Law 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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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-6129]

Assessment of Food and Drug Administration Hiring and Retention; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public meeting entitled “Assessment of FDA Hiring and Retention”. The purpose of the public meeting is to share high-level findings from a recently completed diagnostic assessment of FDA’s hiring process conducted by a qualified, independent contractor with expertise in assessing human resources operations and transformation. The purpose also is to outline a set of near-term actions FDA will or can take to improve the hiring process, provide an update on FDA’s progress toward Prescription Drug User Fee Act (PDUFA) and Biosimilar User Fee Act (BsUFA) user fee hiring and retention commitments, and solicit input on actions FDA is taking and any further recommendations or priorities FDA should pursue with regard to the hiring process.

DATES: The public meeting will be held on November 30, 2017, from 9 a.m. to 12 noon. Submit either electronic or written comments on this public workshop by January 15, 2018. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held at the FDA’s White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Section A, Silver Spring, MD 20993. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to <https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

A summary report of evaluation findings related to the hiring process, conducted by an independent third party contractor, will be published in the docket by November 15, 2017, and will be titled “Initial Assessment of FDA Hiring and Retention.”

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 15, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of January 15, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and

identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2017-N-6129 for “Assessment of FDA Hiring and Retention; Public Meeting; Request for Comments.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Daniel Brounstein, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 1312, Silver Spring,