



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-0045]

Pediatric Advisory Committee and the Endocrinologic and Metabolic Drugs Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Pediatric Advisory Committee (PAC) and the Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC). This meeting was announced in the *Federal Register* of January 23, 2018. The amendment is being made to reflect a change in the agenda for the open session of the meeting and to extend the amount of time allotted for the closed session. There are no other changes.

DATES: The meeting will be held on March 22, 2018, from 8 a.m. to 6 p.m.

FOR FURTHER INFORMATION CONTACT: 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, marieann.brill@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of January 23, 2018 (83 FR 3156), FDA announced that a meeting of the PAC and EMDAC would be held on March 22, 2018.

FDA is revising the first paragraph of the agenda for that meeting to read as follows:

On Thursday, March 22, 2018, the PAC and EMDAC will meet to discuss drug development for the treatment of children with achondroplasia (ACH). The following topics should be considered for discussion: evidence required to establish dose-response, study design, study duration, intended population, and endpoints. In the open session, the committee does not intend to discuss any individual research programs.

FDA is also changing the meeting procedure and closed committee deliberations as follows:

Procedure: On March 22, 2018, from 12 p.m. to 6 p.m., the meeting is open to the public.

Closed Committee Deliberations: On March 22, 2018, from 8 a.m. to 11 a.m., the meeting will be closed to permit committee review and discussion of trade secret and/or confidential commercial information.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: March 13, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-05413 Filed: 3/15/2018 8:45 am; Publication Date: 3/16/2018]