4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-6928]

Pediatric Advisory Committee; Establishment of a Public Docket; Request for Comments; 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). This meeting was announced in the *Federal Register* of January 2, 2018. The amendment is being made to reflect a change in the Center for Devices and Radiological Health (CDRH) products portion of the document and to include the topics that will be discussed during the meeting. There are no other changes.

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 INFORMATON: In the *Federal Register* of January 2, 2018 (83 FR 125), FDA announced that a meeting of the Pediatric Advisory Committee would be held on March 23, 2018.

FDA will provide updates on the following topics without vote by the committee:

- Update regarding labeling change for inhaled corticosteroid long-acting β-2 agonists (ICS/LABAs);
- Safety labeling for gadolinium products;
- Overview of the FDA Adverse Event Reporting System (FAERS) and reports on reduced or lack of efficacy for certain generic drugs; and
- Generic drug approval process; and discussion on the differences in the approval process for brand name drugs versus generic drugs; exceptions.

On page 126, in the third column, the CDRH products portion of the document is changed to read as follows:

The PAC will meet to discuss the following products (listed by FDA Center):

(2) Center for Devices and Radiological Health

a. MEDTRONIC ACTIVA DYSTONIA THERAPY (Humanitarian Device Exemption (HDE))

b. LIPOSORBER LA-15 SYSTEM (HDE)

CDRH will update the committee on the regulatory status of a previously reviewed HDE.

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: February 12, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-03231 Filed: 2/15/2018 8:45 am; Publication Date: 2/16/2018]