



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0584]

Anesthetic and Analgesic Drug Products Advisory Committee, the Drug Safety and Risk Management Advisory Committee, and the Pediatric Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

This notice announces a forthcoming meeting of public advisory committees of the Food and Drug Administration (FDA). The meeting will be open to the public.

Names of Committees: Anesthetic and Analgesic Drug Products Advisory Committee, the Drug Safety and Risk Management Advisory Committee, and the Pediatric Advisory Committee.

General Function of the Committees: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 15, 2016, from 8 a.m. to 5 p.m. and September 16, 2016, from 8 a.m. to 5 p.m.

Addresses: FDA is opening a docket for public comment on this meeting. The docket number is FDA-2016-N-0584. The docket will open for public comment on [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The docket will close on September 30, 2016. Interested persons may submit either electronic or written comments regarding this meeting. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630

Fishers Lane, rm. 1061, Rockville, MD 20852. All comments received will be posted without change, including any personal information provided. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. Comments received on or before August 31, 2016, will be provided to the committee before the meeting.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at:

<http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

Contact Person: Stephanie L. Begansky, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, email: AADPAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the Federal Register about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The purpose of this public advisory committee meeting is to discuss the appropriate development plans for establishing the safety and efficacy of prescription opioid

analgesics for pediatric patients, including obtaining pharmacokinetic data and the use of extrapolation.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committees. All electronic and written submissions submitted to the docket (see Addresses) on or before August 31, 2016, will be provided to the committees. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 10:30 a.m. on September 16, 2016. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before August 23, 2016. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by August 24, 2016.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Stephanie L. Begansky at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at

<http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 16, 2016.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

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