

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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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1698]

Food and Drug Administration Activities for Patient Participation in Medical Product Discussions; Report on Stakeholder Views; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is

making available the summary report of the public comments received during the open period from November 4 to December 4, 2014, on FDA activities under the Food and Drug Administration Safety and Innovation Act (FDASIA), Patient Participation in Medical Product Discussions. The purpose of this notice is to announce the public availability of the report on stakeholder views based on the comments received in the docket.

ADDRESSES: An electronic copy of the summary report is available at <http://www.fda.gov/ForPatients/About/ucm483931.htm>.

The summary report is also available in Docket No. FDA-2014-N-1698.

FOR FURTHER INFORMATION CONTACT:

Andrea Furia-Helms, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5319, Silver Spring MD 20993-0002, Andrea.Furia@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

Background

On July 9, 2012, the President signed into law FDASIA (Pub. L. 112-144). FDASIA expands FDA's authorities and strengthens the Agency's ability to safeguard and advance public health in several areas including increasing stakeholder involvement in FDA regulatory processes. Specifically, section 1137 of FDASIA directs the Secretary of Health and Human Services to develop and implement strategies to solicit the views of patients during the medical product development process and consider the perspectives of patients during regulatory discussions, including by fostering participation of a patient representative who may serve as a special government employee in appropriate Agency meetings with medical product sponsors and investigators and exploring means to provide for identification of patient representatives who do not have any, or have minimal, financial interests in the medical products industry.

FDA formed an Agency-wide working group to explore approaches and procedures as well as to align strategies across the Agency for patient participation in accordance with the statute.

Dated: February 16, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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