



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0001]

Pediatric Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

Name of Committee: Pediatric Advisory Committee.

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

Date and Time: The meeting will be held on Wednesday, September 16, 2015, from 8:30 a.m. to 5:30 p.m.

Location: Double Tree by Hilton, 8727 Colesville Rd., Silver Spring, MD 20910, 301-589-5200. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://doubletree3.hilton.com/en/hotels/maryland/doubletree-by-hilton-hotel-washington-dc-silver-spring-DCASSDT/index.html>

Contact Person: Walter Ellenberg, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5154, Silver Spring, MD 20993,

301-796-0885, email: walter.ellenberg@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: On September 16, 2015, the Pediatric Advisory Committee (PAC) will meet to discuss pediatric-focused safety reviews, as mandated by the Best Pharmaceuticals for Children Act (Pub. L. 107-109) and the Pediatric Research Equity Act (Pub. L. 108-155). The PAC will meet to discuss the following products:

1. DUREZOL (difluprednate ophthalmic emulsion) 0.05%, Phenylephrine Hydrochloride Ophthalmic Solution,
2. ZYLET (loteprednol etabonate and tobramycin ophthalmic suspension),
3. BETHKIS (tobramycin Inhalation Solution),
4. INTELENCE (etravirine),
5. PREZISTA (darunavir),
6. VIRAMUNE XR (nevirapine),
7. EPIDUO (adapalene and benzoyl peroxide),
8. EXJADE (deferasirox),
9. DOTAREM (gadoterate meglumine),
10. FYCOMPA (perampanel),

11. RECOTHROM (thrombin, topical [recombinant]),
12. PREVNAR 13 (Pneumococcal 13-valent Conjugate Vaccine [Diphtheria CRM₁₉₇ Protein]),
13. PLEXIMMUNE,
14. ELANA SURGICAL KIT (HUD),
15. BERLIN HEART EXCOR PEDIATRIC VENTRICULAR ASSIST DEVICE (VAD),
16. ENTERRA THERAPY SYSTEM, and
17. CONTEGRA Pulmonary Valved Conduit.

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 link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before September 8, 2015. Oral presentations from the public will be scheduled between approximately 9 a.m. and 10 a.m. 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 September 1, 2015. 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 September 8, 2015.

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 physical disabilities or special needs. If you require special accommodations due to a disability, please contact Walter Ellenberg at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website 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: August 5, 2015.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2015-19729 Filed: 8/11/2015 08:45 am; Publication Date: 8/12/2015]