

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pediatric Ethics Subcommittee; 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 Ethics Subcommittee of the Pediatric Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Pediatric Advisory Committee on FDA and certain Department of Health and Human Services (DHHS) regulatory issues.

Date and Time: The meeting will be held on Monday, June 9 2008, from 8:30 a.m. to 5:30 p.m. and Tuesday, June 10, 2008, from 8:00 a.m. to 1:00 p.m.

Location: Hilton, Washington DC North/Gaithersburg, Grand Ballroom, 620 Perry Parkway, Gaithersburg, Maryland.

Contact Person: Carlos Peña, Office of Science and Health Coordination, Office of the Commissioner (HF-33), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, rm. 14B-08) Rockville, MD 20857, 301-827-3340, or by e-mail: Carlos.Peña@fda.hhs.gov or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 8732310001. Please call the Information Line for up to date information on this meeting. 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 website and call the appropriate advisory committee hotline/phone line to learn about possible modifications before coming to the meeting.

Agenda: On Monday, June 9, 2008 the Pediatric Ethics Subcommittee (Subcommittee) of the Pediatric Advisory Committee will meet to discuss the application of 21 CFR 50.52 (Clinical investigations involving greater than minimal risk but presenting the prospect of direct benefit to individual subjects) to FDA-regulated research. The discussion will be illustrated with hypothetical case examples of research involving HIV vaccines in adolescents and controlled trials of inhaled corticosteroids in children with asthma. On Tuesday, June 10, 2008 the Subcommittee will meet to discuss the application of 21 CFR 50.52 to FDA-regulated research illustrated with a hypothetical case example of research using stem cells for treating periventricular white matter injury in children.

FDA intends to make background material available to the public no later than two business days before the meeting. If FDA is unable to post the background material on its website 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 website after the meeting. Background material is available at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>, click on the year 2008 and 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 May 9, 2008. Oral presentations from the public will be scheduled between approximately 1:00 p.m. to 1:30 p.m. on June 9, 2008 and 8:00 a.m. to 8:30 a.m. on June 10, 2008. Those desiring to make 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 May 9, 2008. 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. Persons making oral presentations should arrive early to be sure that they are present to make their presentation in case the schedule advances. The contact person will notify interested persons regarding their request to speak by May 12, 2008.

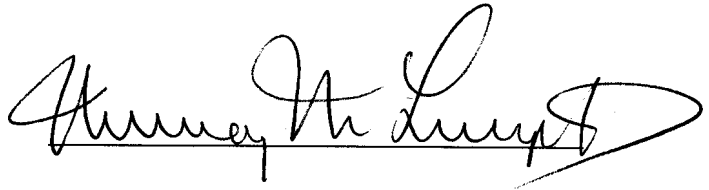
Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

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 Dr. Carlos Peña at least seven 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/oc/advisory/default.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 MAR 25 2008

A handwritten signature in black ink, appearing to read "Murray M. Lumpkin", written over a horizontal line.

Murray M. Lumpkin, M.D.
Deputy Commissioner for International and
Special Programs, FDA