DDM

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Display Date 10-12-07
Publication Date 10-15-07
Certifier A Corbin

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. The committee also advises and makes recommendations to the Secretary of Health and Human Services under 45 CFR 46.407 on research involving children as subjects that is conducted or supported by the Department of Health and Human Services , when that research is also regulated by FDA.

Date and Time: The meeting will be held on Thursday, November 29, 2007, from 8 a.m. to 4 p.m.

Location: Hilton, Washington DC North/Gaithersburg, Grand Ballroom, 620 Perry Pkwy., Gaithersburg, MD.

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, e-mail: *Carlos.Peña@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC

oc07239 2007-4326 HM1

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 Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: The Pediatric Advisory Committee will hear and discuss issues related to FDA's draft guidance for Industry entitled "Clinical Lactation Studies—Study Design, Data Analysis, and Recommendations for Labeling," that published in the **Federal Register** of Tuesday, February 8, 2005 (70 FR 6697). As part of the review and consideration of public comments received by FDA in response to this draft guidance, the Pediatric Advisory Committee will hear and discuss information on: Labeling of drugs for use by lactating women; breastfeeding physiology, benefits, and current research; the physiology and pharmacology of drug transfer into breast milk; and ethical issues related to studying breastfeeding mother/infant pairs.

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 will be available at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*, click on the year 2007 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 November 5, 2007. Oral presentations from the public will be scheduled between approximately 1 p.m. to 2 p.m. 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 October 26, 2007. 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 October 29, 2007.

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 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/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: 10/8/07
October 8, 2007.

Randall W. Lutter,
Deputy Commissioner for Policy.

[FR Doc. 07–????? Filed ??–??–07; 8:45 am]

BILLING CODE 4160–01–S

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL