

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0578]

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Certifier D. Hawkins

**Pediatric Ethics Subcommittee; Notice of Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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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 Tuesday, December 9, 2008, from 9 a.m. to 3 p.m.

*Location:* The Legacy Hotel & Meeting Centre, 1775 Rockville Pike, Rockville, MD 20852.

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

*Agenda:* On December 9, 2008, the Pediatric Ethics Subcommittee (subcommittee) of the Pediatric Advisory Committee will meet to discuss a referral by an Institutional Review Board (IRB) of a clinical investigation that involves both an FDA regulated product and research involving children as subjects that is conducted or supported by DHHS. The clinical investigation is entitled "Children's Oncology Group Protocol ASCT0631: A Phase III Randomized Trial of Granulocyte Colony Stimulating Factor (G-CSF) Stimulated Bone Marrow vs. Conventional Bone Marrow as a Stem Cell Source in Matched Sibling Donor Transplantation." Because the clinical investigation would be regulated by FDA, and conducted or supported by the DHHS, both FDA and the Office for Human Research Protections, DHHS, will participate in the meeting.

After presentation of an overview of the IRB referral process, background information on the use of G-CSF stimulated bone marrow in stem cell transplantation, an overview of the protocol and the referring IRB's deliberations on the protocol, and a summary of public comments received concerning whether the protocol should proceed, the subcommittee will discuss the proposed protocol and develop a recommendation regarding whether the protocol should proceed. The subcommittee's recommendation will then be presented to the FDA Pediatric Advisory Committee on December

9, 2008; the announcement of the December 9, 2008, Pediatric Advisory Committee meeting can be found elsewhere in this issue of the **Federal Register**.

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/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 subcommittee. Written submissions may be made to the contact person on or before December 2, 2008. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on December 9, 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 November 24, 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. The contact person will notify interested persons regarding their request to speak by November 25, 2008.

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Electronic comments should be submitted to <http://www.regulations.gov>. Select Docket No. FDA-2008-N-0578 entitled "G-CSF Stimulated Bone Marrow IRB Referral" and follow the prompts to submit your statement. Written comments should be submitted to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please submit comments by 4:30 p.m. on December 2, 2008. Received comments may be viewed at <http://www.regulations.gov> or may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

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 Carlos Peña at least 7 days in advance of the meeting.

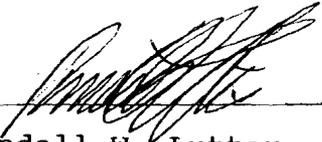
FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/oc/advisory/default.htm> for procedures on public conduct during advisory committee meetings.

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Notice of this meeting is given under the Federal Advisory Committee Act

(5 U.S.C. app. 2).

Dated: 11/5/08  
November 5, 2008.

  
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Randall W. Lutter,  
Deputy Commissioner for Policy.

[FR Doc. 08-????? Filed ??-??-08; 8:45 am]

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