

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0002]

Cellular, Tissue and Gene Therapies 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: Cellular, Tissue and Gene Therapies 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 September 22 and 23, 2011, from 8 a.m. to 5 p.m.

Location: Hilton Hotel, Washington DC North/Gaithersburg, 620 Perry Pkwy., Gaithersburg, MD 20977, 301-977-8900. For those unable to attend in person, the meeting will also be available by Web cast. On September 22, 2011, the link for the Web cast is available at

<http://fda.yorkcast.com/webcast/Viewer/?peid=637f14248dca4236a5f9a3b622e6501e1d> . On September 23, 2011, the link for the Web cast is available at

<http://fda.yorkcast.com/webcast/Viewer/?peid=2e8b3eb7638d42ca9652c328a854efb51d>.

Contact Person: Gail Dapolito or Sheryl Clark (HFM-71), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20853, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-

443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. 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 September 22, 2011, the committee will discuss BLA 125397, Umbilical Cord Blood, New York Blood Center, indicated for hematologic malignancies, bone marrow failure, primary immunodeficiency diseases, beta thalassemia, Hurler syndrome, Krabbe disease, and X-linked adrenoleukodystrophy. On September 23, 2011, the Committee will discuss HDE BH110018, CliniMACS CD34 Selection System, Miltenyi Biotec, for processing allogeneic HLA-matched hematopoietic progenitor cells-apheresis (HPC-C) from a related donor to obtain a CD34<sup>+</sup> Cell population intended for hematopoietic reconstitution following a Myeloablative preparative regimen without the need for additional graft-vs-host disease (GVHD) prophylaxis in patients with acute myelogenous leukemia in first or second morphologic complete remission.

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 15, 2011. Oral presentations from the public will be scheduled on September 22, 2011, between approximately 11 a.m. and 12 noon and on September 23, 2011, between approximately 11:30 a.m. and 12:30 p.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 7, 2011. 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, 2011.

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 Gail Dapolito 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: August 8, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.