



Advancing Transfusion and
Cellular Therapies Worldwide

September 19, 2007

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE Docket 2007D-029, 26 July 2007, Guidance for Industry: Cell Selection Devices for Point of Care Production of Minimally Manipulated Autologous Peripheral Blood Stem Cells (PBSCs)

Via electronic submission:

<http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm?AGENCY=FDA>

Dear FDA Dockets Manager:

AABB is an international association dedicated to advancing transfusion and cellular therapies worldwide. Our members include more than 1,800 hospital and community blood centers and transfusion and transplantation services as well as approximately 8,000 individuals involved in activities related to transfusion, cellular therapies and transplantation medicine. For over 50 years, AABB has established voluntary standards for, and accredited institutions involved in, these activities. AABB is focused on improving health through the advancement of science and the practice of transfusion medicine and related biological therapies, developing and delivering programs and services to optimize patient and donor care and safety.

AABB appreciates this opportunity to comment on this guidance document. The limited scope of the document raises concern. AABB believes that since the scope of the document is so narrow, there does not appear to be a requirement for this guidance document. The document is specifically targeted to a small group of practitioners harvesting and selecting peripheral blood stem cells (PBSCs) from autologous donors to be infused during the same surgical procedure. The limited scope of the document does not lend its self to be a practical/useful tool for most establishments.

AABB requests that FDA consider the following when preparing the final guidance document.

- Expand the scope of products that can be collected to include autologous bone marrow and other tissues that contain hematopoietic stem/progenitor cells.
- Address device manufacturers who currently have a device cleared for laboratory use for the isolation of another cell source (i.e. bone marrow or PBSC).
 - Will there be a need to file an IDE?
 - Will additional clinical studies, in which the identical device is use to isolate hematopoietic stem/progenitor cells from autologous bone marrow or PBSCs, be performed?

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AABB strongly supports initiatives that improve the safety of patients and donors and stand ready to interact with FDA as necessary. AABB requests that FDA carefully consider product availability and patient safety issues when evaluating the recommendations put forth in this guidance document.

Questions concerning these comments may be directed to Joseph L. Giglio, Deputy Director, Regulatory Affairs, AABB jgiglio@aabb.org

Sincerely,



M. Allene Carr-Greer, MT(ASCP)SBB
Director, Regulatory Affairs
AABB