

March 29, 2002

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
12420 Parklawn Dr. Room 1-23  
Rockville, MD 20857

**Re: Docket No 97N-0497 Request for Proposed Standards for Unrelated Allogeneic Peripheral and Placental Umbilical Cord Blood Hematopoietic Stem/Progenitor Cell Products; Request for Comments**

Dear Docket Officer:

The American Association of Blood Banks (AABB) is the professional society for over 8,000 individuals involved in blood banking and transfusion medicine and represents approximately 2,000 institutional members, including blood collection centers, hospital-based blood banks, and transfusion services as they collect, process, distribute, and transfuse blood and blood components and hematopoietic stem cells. Our members are responsible for virtually all of the blood collected and more than 80 percent of the blood transfused in this country. For over 50 years, the AABB's highest priority has been to maintain and enhance the safety and availability of the nation's blood supply.

The AABB has recently published the third edition of *Standards for Hematopoietic Progenitor Cell and Cellular Product Services*. These *Standards* become effective on May 1, 2002, and the requirements must be met in order to obtain AABB accreditation. The AABB submits these *Standards for Hematopoietic Progenitor Cell and Cellular Product Services* in response to the FDA request for proposed product standards. The format of *Standards for Hematopoietic Progenitor Cell and Cellular Product Services* is to state the general quality standards at the beginning of each chapter, followed by the technical requirements.

The AABB has previously submitted the second edition of *Standards for Hematopoietic Progenitor Cell Services*, and the first edition of *Standards for Cord Blood Services*. As new editions of these *Standards* are published, the AABB plans to submit those new editions for FDA consideration.

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The AABB appreciates the opportunity to comment on this draft guidance. Any questions may be directed to Kay Gregory, Director of Regulatory Affairs, at 910-842-2790, or [kayg@aabb.org](mailto:kayg@aabb.org).

Sincerely,

A handwritten signature in black ink that reads "Dale R Malloy". The signature is written in a cursive style with a large, looped "D" and "M".

Dale Malloy, DPA, MT(ASCE)SBB  
President

Enclosures