



Advancing Transfusion and  
Cellular Therapies Worldwide

December 30, 2008

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

**RE Docket 2008-D-0520, October 09, 2008, Draft Guidance for Industry: Potency Tests for Cellular and Gene Therapy Products**

Via electronic submission:

<http://www.regulations.gov/fdmspublic/component/main?main=SubmitComment&o=0900006480741131>

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, and developing and delivering programs, and services to optimize patient and donor care and safety.

On behalf of the AABB Cellular Therapies Committee, comprised of industry experts, we appreciate the opportunity to comment on the draft "*Guidance for Industry: Potency Tests for Cellular and Gene Therapy Products*".

AABB applauds the FDA for recognizing and responding to the needs of the industry. Even though the contents of this draft guidance document are not new, the consolidation of the related guidance documents will enable manufacturers to digest and comply with the recommendations in a more efficient manner. Additionally, the draft document has achieved a balance with the recommendations that is not overly prescriptive, thus permitting facilities to develop mechanisms, which are appropriate for their establishment.

AABB strongly supports initiatives that improve the safety of patients and donors and stands ready to interact with FDA as necessary.

Please direct all questions regarding these comments or requests for additional information, to myself at 301-215-6515 or [jgiglio@aabb.org](mailto:jgiglio@aabb.org)

Sincerely,

A handwritten signature in black ink, appearing to read 'Joseph L. Giglio', is written over a light blue horizontal line.

Joseph L. Giglio, MS, MT(ASCP)SBB, CSQE(ASQ)CQA  
Deputy Director Regulatory Affairs, AABB

8101 Glenbrook Road  
Bethesda, MD 20814-2749  
301.907.6977 MAIN  
301.907.6895 FAX  
[www.aabb.org](http://www.aabb.org)