



Advancing Transfusion and
Cellular Therapies Worldwide

December 3, 2004

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

RE Docket 2004D-0443, 04 October 2004, Draft “Guidance for Industry, Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations”

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 commends the Food and Drug Administration and especially the Quality System Guidance Development working group (QS working group) for putting this draft document together. AABB through its standards and accreditation processes emphasizes a quality systems approach to all aspects of blood banking and is pleased to note that FDA is also advocating a quality systems approach.

It is AABB’s understanding that, as a drug regulated under 21 CFR 211, blood and blood products are covered by the recommendations of this new draft guidance. Furthermore, it is our understanding that this document supplements the 1995 “Guideline for Quality Assurance in Blood Establishments” (11 July 1995) and does not supersede the earlier guideline. AABB requests that clarification of the manner in which these two documents will be used together be emphasized in the final version of this guidance document. This is especially important should a conflict arise between the documents.

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Food and Drug Administration
Draft Guidance for Industry
Docket No. 2004D-0443
Page 2

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

Questions concerning these comments may be directed to M. Allene Carr-Greer, Deputy Director, Regulatory Affairs, AABB acarrgreer@aabb.org

Sincerely,

A handwritten signature in black ink, appearing to read "Karen Shoos-Lipton".

Karen Shoos-Lipton, JD
Chief Executive Officer

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