Advancing Transfusion and
Cellular Therapies Worldwide

October 3, 2007

**VIA EMAIL**

James Lousararian
Chief Executive Officer
Verax Biomedical Inc.
4 Biotech
377 Plantation Street
Worcester, MA 01605
JLousararian@veraxbiomedical.com

Joe R. Sanders, Sr.
Senior Vice President, Marketing and Business Development
Verax Biomedical Inc.
4 Biotech
377 Plantation Street
Worcester, MA 01605
JSanders@veraxbiomedical.com

Dear Sirs:

The AABB Bacterial Contamination Standard Task Force discussed the implications of clearance of the Verax PGD® assay as it relates to the AABB standard that requires facilities to have methods to limit and detect bacterial contamination in all platelet components.

Our consensus is that your device holds great promise to improve platelet transfusion safety, but that an obvious opportunity for greater impact was missed in pursuit of the least critical indication for its use. The most urgent unfilled need for detection of bacterial contamination is a method suitable for use at, or shortly before, issue of pools of platelets derived from whole blood that were not cultured early in storage.

We understand that early culture of apheresis platelets misses some bacterial contamination when small inocula are missed for stochastic reasons, and that the Verax PGD® will identify a portion of those components when used near or at the time of release for transfusion. Having said that, the logistic difficulty of performing early culture on units of platelets derived from whole blood means most pools of

8101 Glenbrook Road
Bethesda, MD 20814-2749
301.907.6977 MAIN
301.907.6895 FAX
www.aabb.org

whole blood derived platelets are now tested with less optimal tests. This has created among some in the blood community a perception that there are two tiers of safety where platelets are concerned, and this must be addressed.

You are clearly aware of this issue, and that institutions represented on this task force offered, early in your clearance process, to assist in performing the trials needed for the critical claim for whole blood derived platelet pools. We understand that regulatory imperatives contributed to the route chosen, but we urge you to assist us by obtaining data to document the performance of the test in the situation where it is most needed.

Members of this task force ask that you move rapidly to support clinical trials of your device on non-leukoreduced and leukoreduced pools of platelets from whole blood. We will assist you in identifying sites for their performance and designing the effort if they are not already planned. I may be reached at 563-359-5401 or lkatz@mvrbc.com.

Sincerely,

Louis M. Katz, MD, Chair
AABB Bacterial Contamination Standards Task Force

cc: Jay S. Epstein, MD
Director, Office of Blood Research and Review
FDA

Jonathan C. Goldsmith, MD
Deputy Director, OBRR
FDA

Jaroslav G. Vostal, MD, PhD
Director, Laboratory of Cellular Hematology
Department of Hematology, OBRR
FDA

cc: Greg Sunset,
Director, US Marketing Transfusion Sector
Abbott Diagnostics Division

Bacterial Contamination Standard Task Force:
Louis M. Katz, MD – chair
Roger Y. Dodd, PhD – chair, AABB Transfusion Transmitted Diseases Committee
James P. AuBuchon, MD – AABB
Steven Kleinman, MD – AABB Medical Director
Arthur Bracey, MD – AABB
Mark E. Brecher, MD – AABB
Nora V. Hirschler, MD – AABB
Stephen G. Beardsley, MS, MT(ASCP)SBB – Armed Services Blood Program Office
Karen Shoos Lipton, JD – Chief Executive Office, AABB
Kent Sepkowitz, MD – Infectious Disease Society of America
Roslyn Yomtovian, MD – AABB
Patricia Pisciotto, MD – AABB Board of Directors
Kathleen Sazama, MD, JD – AABB
Thomas H. Price, MD – chair, AABB Blood Banks and Transfusion Services Standards Program Unit
Richard J. Benjamin, MBChB, PhD - American Red Cross
Mindy Goldman, MD – AABB Clinical Transfusion Medicine Committee