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Cellular Therapies Worldwide

## AABB Statement to the Food and Drug Administration's Blood Products Advisory Committee

04 April 2017

### Blood Donor Deferral Policy for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products

Presented by Sharon Carayiannis, Director, Regulatory Affairs

AABB is pleased to have this opportunity to express our support for FDA's commitment to reevaluate and update blood donor deferral policies as new scientific information becomes available. AABB's top priority remains the safety of our volunteer blood donors and the patients in need of lifesaving blood products.

AABB, America's Blood Centers and the American Red Cross submitted joint comments in November of 2016 in response to the FDA's request in the July 2016 Federal Register notice. Our joint comments identified key issues that should be considered as part of risk-based decision-making on the feasibility of moving from the existing time-based deferrals related to risk behaviors to alternate deferral options. We wish to underscore the importance of maintaining a safe *and adequate* blood supply while studies are completed and after implementation of any new deferral policy. Additionally, any changes in the deferral policies should focus on an effective assessment of individuals to identify risks for transfusion-transmitted infections. The views of all stakeholders should be considered and adequately addressed, including the concerns regarding the continued safety of transfusion recipients served by the blood community.

AABB is an international, not-for-profit association representing individuals and institutions involved in the field of transfusion medicine and cellular therapies. Our association is committed to improving health by developing and delivering standards, accreditation and educational programs that focus on optimizing patient and donor care and safety. AABB membership consists of nearly 2,000 institutions and 8,000 individuals, including physicians, nurses, scientists, researchers, administrators, medical technologists and other health care providers. AABB members are located in more than 80 countries.

Thank you for the opportunity to provide these comments today.