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STATEMENT

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Draft Guidance on Platelet Pheresis

Statement before the Blood Products Advisory Committee

Celso Bianco, M.D., Executive Vice President

March 9, 2006 – Dear Committee Members:

We need your help in the review of this guidance. In recent times, platelet collections by apheresis have gradually expanded to a level that almost always fulfills patient's needs. There have been many product developments that led to better instrumentation cleared by FDA. In the last year, the blood banking community introduced bacterial detection for 100 percent of these products using quality control reagents that were cleared for this purpose and increasing the safety of this component. In addition, many of our centers are preparing or have prepared SOPs and submissions for extension of platelet apheresis dating according to the approach recently developed by FDA.

The publishing of the draft guidance surprised many of us in the community. There have been no obvious problems with donor or patient safety or product efficacy. There have been no clear public health issues. We did not see obvious reasons for the implementation of regulatory changes of such magnitude. We are extremely concerned about the proposals contained in the guidance because they can seriously impair our ability to provide this component to patients. Actually, many of the requirements are so burdensome that they may steer collecting facilities away from platelets obtained by apheresis, and may favor a return to platelets from random donors. These are a fine product for many indications. However, for donors with chronic needs, this change would substantially increase the number of donor exposures, the risks of alloimmunization and the risks of bacterial sepsis.

We hope that the committee will carefully consider and modify the proposals in the draft guidance:

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1. The increase in temporary deferrals for donors who take aspirin and NSIAD will make the scheduling of the millions of donors who take a daily baby aspirin to prevent heart disease more difficult. We hope the criteria will be changed to a shorter period of time.
2. We do not understand the requirement for the 500 cultures with a maximum of one positive result for validation of the process, when every product will be tested for bacterial contamination. We hope the requirement will be modified or deleted.
3. We are seriously concerned about the limits in the number of components and their effect in availability. There has been no evidence of donor harm, as shown by substantial amount of data presented at this meeting.
4. WBC counts and post-donation platelet counts do not contribute to safety of the donor or product in the same way that hemoglobin determinations made after a whole blood donation would not contribute to the safety of the donor or product. We hope this requirement will be deleted.
5. We sincerely hope that requirements for a blood bank physician with 15 min of the collection site will be dropped. Emergence Medical Technicians provide better assistance than blood bank physicians. We hope this requirement will be deleted.

We thank the Committee and the FDA for the opportunity to present these comments.

About ABC

Founded in 1962, America's Blood Centers is North America's largest network of community-based blood programs. Seventy-seven blood centers operate more than 600 collection sites in 45 U.S. states and Canada, providing half of the United States, and all of Canada's volunteer donor blood supply. These blood centers serve more than 180 million people and provide blood products and services to more than 4,200 hospitals and health care facilities across North America. ABC's U.S. members are licensed and regulated by the U.S. Food & Drug Administration. Canadian members are regulated by Health Canada.

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