



**Gulf Coast Regional  
Blood Center**

January 5, 2006

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

Re: Docket Number 2005D-0330, Draft Guidance on the Collection of Platelets by Automated Methods

On October 3, 2005, the Food and Drug Administration published in the Federal Register a Draft Guidance for Industry and FDA Review Staff on Collection of Platelets by Automated Methods. The Gulf Coast Regional Blood Center would like to take this opportunity to provide our comments.

We have reviewed the extensive comments prepared by the AABB and America's Blood Centers (ABC). Each of these documents raise significant points of concern with the Draft Guidance. We support the major recommendations of each group. In particular, we feel that a workshop or similar public forum is an appropriate place to present and discuss data relating to issues raised by the Draft Guidance.

The following is an outline of our major concerns:

**Donor Safety and Medical Supervision:**

This proposed requirement would result in limitations to draw sites and inability to appropriately staff our draw sites with physicians without a corresponding increase in donor safety. Years of experience have taught that plateletpheresis donation is safe. Local emergency services (911) are adequate to provide necessary care to donors in a timely manner. We have reviewed all donor reactions for the first 11 months of 2005. Plateletpheresis donors have fewer moderate and severe donor reactions than whole blood donors, approximately one-third the rate. This makes a serious reaction in a plateletpheresis donor a very rare event. Moreover, the requirement for physician availability within 15 minutes would markedly restrict our ability to collect plateletpheresis in our extended geographic area, with approximately 13 neighborhood donor centers covering greater Houston and large parts of East Texas. A physician is routinely available only at our headquarters center, where approximately 11% of our collections occur. A loss of 89% of our apheresis platelet components for transfusion would require major restructuring of our collection efforts and transfusion practice at the hospitals we serve.

**Frequency of donations:**

The reduction in the number of apheresis products that could be collected per year would have a significant impact on our ability to provide an adequate supply of apheresis platelets to our hospital and other customers. It is unclear what prompted this restriction of the number of products collected from individual donors per year. Eligibility for donation is calculated by our licensed software for a plateletpheresis collection, not by the specific products collected. Using the number of products would be cumbersome and potentially problematic since manual methods would be necessary to determine donor eligibility.

**Platelet Counts:** Our concern is that donors will naturally have a drop in platelet counts following an apheresis donation and we find the guidance unclear as to the purpose of the post donation platelet count. Post-donation counts are difficult to collect from the apheresis line and are notoriously subject to artifact from dilution. Performing a second phlebotomy for such a purpose is also not desirable. Our donors are carefully monitored to ensure that the platelet count of anyone undergoing apheresis is at

2005D-0330 *Commit for Life.*

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## Gulf Coast Regional Blood Center

least 150,000. These methods have been used for years, in many centers. These measures are adequate to ensure donor safety.

### Scan statistics:

Our concern centers on the clarity of the suggested data collection methods. While this method may be entirely appropriate and represent a useful innovation, it has not been tested in a blood center environment, and its impact upon the quality of our products and on our operations are both unknown. We encourage further studies, including pilot studies, of these methods before their use is more widely mandated. From the document, we are unclear about the number of products of various types to be tested. We also feel that the discussion would be strengthened by a clearer definition of process versus non-process failures, as this is clearly a key to the effective implementation of this method.

### Medications:

Our proposal would be to utilize a peer reviewed medication list as opposed to the ASBPO medication list. This list was not created for a broad use, and does not necessarily rest upon sound science. In particular, the extended deferral for aspirin ingestion and a new deferral for non-steroidal anti-inflammatory drugs do not seem to be warranted by a review of the literature. In view of the large number of anti-thrombotic agents that are coming to market, there is clearly a need for a scientific group to review effects on components drawn from platelet donors taking these drugs. This is best left to a professional organization, such as the AABB Standards committee.

Thank you for taking the time to consider our comments and concerns.

Sincerely,

Susan N. Rossmann, M.D., Ph.D.  
Chief Medical Officer

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