

December 29, 2005

Dear Docket Officer:

The South Texas Blood and Tissue Center is a non-profit facility that partners with volunteer donors to provide the highest quality blood and tissue components to patients in South Texas region. On our partners behalf, we offer our comments on *Guidance for Industry and FDA Review Staff, Collection of Platelets by Automated Methods, September 2005*. This proposal contains requirements that will have a profound impact on Platelet availability and consequently on patient care in South Texas.

The following are our major concerns with the draft guidance document:

1. (Page 6, Section III B, 2) Restriction of the number of products collected from individual donors to no more than 24 products per year.
 - 100% of patient needs (in 70 plus hospitals within our service) are filled with Platelets collected by Automated Methods. Whole Blood platelets are not used in our community.
 - Limiting the donor base to 24 products per year will significantly decrease product availability to patients in our community.
 - Current computer systems do not have the ability to determine donor eligibility (as defined in the Guidance) on a product per year basis. Major re-work of our computer system will be required with extensive validations.
 - No adverse effects in our donors have been noted using the current guidelines for donation frequency.

Recommendation: Retain the current guidelines for donation frequency of platelet apheresis procedures.

2. Page 7, Section III D) The draft guidance requires a physician on donation premises or able to arrive within 15 minutes.
 - This requirement actually lowers the standard of care given to a donor experiencing an adverse reaction. The most qualified medical professionals to deal with an emergency are trained, practicing emergency physicians or emergency medical technicians using the proper equipment and have the ability to transport an unstable patient to an appropriate health care facility.
 - The availability of a physician at donation sites within 15 minutes would significantly impact platelet product availability by restricting hours of operations.

Recommendation: Delete this interpretation of medical care and allow centers to develop appropriate emergency response plans to maximize donor safety.

3. (Page 5, Section III A) The draft Guidance makes several recommendations for determination of White Blood Cell Counts (WBC) prior to and after donation.
 - This requirement will significantly increase the amount of resources required to facilitate automated collection at satellite facilities.
 - There is no current requirement of WBC counts prior to or after collection. No manufacturer's recommendations or parameters for donor acceptance have been established.

Recommendation: Delete the requirement for WBC counts.

After thorough review of the draft guidance several areas were identified that need additional clarification and/or explanation.

1. Standardization is needed in regards to pH specifications.
2. Clarification is needed as to whether FDA considers bacterial detection a quality control check or release criteria.
3. There is a requirement to label each product with the platelet count. Will this require changes to appropriate labeling regulations or can the platelet count be added to the component without impacting the product label (such as a tie tag)?
4. Additional clarification is needed to define "adverse reactions". Would the requirement apply to mild reactions?
5. There is a statement that indicates that tests for residual WBC be performed within 24 hours of collection, while bacterial detection testing is specified as after 24 hours. Clarification is needed to allow for simultaneous testing.

The implementation of the proposed guidance document would be overly burdensome on our Center and would definitely impact our ability to effectively meet the needs of patients in our community with high quality platelet products.

Thank you for the opportunity to provide feedback on this docket.

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