



JAN -3 A9:23

December 28, 2005

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

Re: Docket number 2005D-0330, Collection of Platelets by Automated Methods

To Docket Officer:

Thank you for the opportunity to comment on the draft guidance document cited above. We represent Rock River Valley Blood Center, a community blood center that collected approximately 4700 plateletpheresis products in our FY 2005. We are concerned that implementation of some of the changes proposed in this document will affect the availability of platelets for transfusion.

Specifically:

Donor Selection

1. Proposed ASA deferral - 5 days from last dose

The 5-day deferral of donors who have taken aspirin will impact the many donors that currently are permitted by their physicians to stop taking their daily baby aspirin for 2 days in order to donate platelets. It is possible that some could be permitted to stop for 3 days, but it is highly unlikely that they will be able to donate if there is a 5-day deferral.

Also, Reference #9 ASBPO Donor Deferral Criteria: Drugs and Medication Impact on Donor Eligibility, that is used to reference the three other proposed medication deferrals, cites a 72 hour deferral.

2. Proposed Non-steroidal Anti-inflammatory Drugs (NSAIDS) deferral – 3 days from last dose.

Reference #9 ASBPO Donor Deferral Criteria: Drugs and Medication Impact on Donor Eligibility June 2004 cites 24-hour deferral, not 3 days.

Also, NSAIDs are reversible inhibitors of platelet cyclo-oxygenase. Platelets from these donors should resume function when transfused to a recipient. The requirement to defer for 3 days is overly restrictive and will affect a large number of donors.

Donor Management

1. Proposed: To protect the safety of the donor you should collect no more than 24 total Platelets, Pheresis components in a 12-month period.

There is no referenced study to support this statement. In our experience of collecting double and triple products and tracking plasma loss for several years, we have not noted any donor safety issues.

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Medical Coverage

1. Proposed: We believe that a physician should be “present on the premises” (defined as able to arrive at the premises within 15 minutes) during the collection of Platelets, Pheresis to ensure that necessary medical treatment be available to the donor in a timely fashion.

In most of the blood centers, it is not possible to have a medical director present on the premises during the duration of 12 hours of plateletpheresis collections. The apheresis instruments are so much better in the administration of citrate – there is less chance of a bolus of citrate to be inadvertently administered. And the incidence of air embolism is also a very rare occurrence. In either case of adverse donor reaction, having a physician available by phone to confer with is adequate.

In the rare instance of a life-threatening donor reaction, our community emergency response team, accessed through the 911 system, is the best medical option.

Thank you for your attention to these comments.

Sincerely,



Roger Hilbert, MD
Medical Director



Kathryn Alvarado
QA/Compliance Director