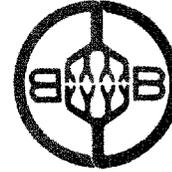


**CENTRAL TEXAS
REGIONAL
BLOOD & TISSUE CENTER**



0172 6 JAN -4 11:52 *Affiliated Medical Organization*

December 19, 2005

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane Rm. 1061
Rockville, MD 20852

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

To whom it may concern:

We appreciate the opportunity to comment on the above referenced document. The Central Texas Blood and Tissue Center (BTC), located in Austin, TX, is submitting these comments in addition to the anticipated response from American Blood Centers, the association of independent FDA licensed community blood centers, of which we have been an active member since 1988. We collect, process and distribute blood and blood products, including approximately 5,340 units of platelets, pheresis annually to our ten-county area in central Texas.

The proposed changes in the guidance draft cause concern regarding the impact of the availability and supply of platelet, pheresis components to our community. This in turn would adversely affect patient care in our area.

III.B.2 bullet 2: You should collect no more than 24 total Platelets, Pheresis components in a 12-month period. Two components collected from a double collection of Platelets, Pheresis and three components collected from a triple collection of Platelets, Pheresis would be counted as two components and three components respectively.

BTC currently allows 24 donations per donor per year and BTC performs double collection of qualified donors but not triple collection. The post-collection platelet count in the primary bag determines when a product is split, not the operator. The proposed change would result in a 30% reduction in the current volume of donations allowed and would possibly be affected even more due to alienating donors that may not understand the proposed restrictions. It would also force our organization to commit additional resources to recruiting an additional 30% of donors to try to replenish the deficiency created.

In addition, the proposed guideline is not clear in presenting the scientific evidence of harm to the donor. Donations of multiple product output have been done for many years without evidence of adverse affects. Apheresis technology, including the implementation of bacterial detection system, has been developed to make collection safer and more efficient. BTC monitors patient plasma and red blood cell loss per current FDA guidelines and decreased platelet counts for trends.

2005D-0330

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CENTRAL TEXAS REGIONAL BLOOD & TISSUE CENTER



An Affiliated Medical Organization

Another major area of concern to our blood bank is the proposed requirement of the Medical Director to be within 15 minutes of the facility. For BTC, this would mean hiring a local physician as Medical Director at high, unbudgeted salary. The result of this requirement would be an increase in the cost of blood products locally.

III.D. "... We interpret "present on the premises" to include a qualified physician able to arrive at the premises within 15 minutes."

Currently, BTC apheresis technicians are trained in addressing and documenting adverse reactions and in performing basic CPR. Additionally, we do have two RNs on staff to address any adverse reactions that occur, and there is a physician available by phone at all times. Our Medical Director is located in Dallas, TX at Carter BloodCare and cannot arrive to our site in Austin, TX within 15 minutes. In addition, BTC does not have resuscitative equipment or necessary medications on site and thus, would call 911 in the case of a severe adverse reaction even with a physician on site. Response time for EMS to BTC is three to five minutes. Currently, our Medical Director reviews all documentation of severe adverse reactions that occur in Austin.

Finally, the proposed drug deferral changes, specifically for NSAIDS, appear unwarranted in that there is no scientific evidence provided to support the need for the change.

"You should not collect Platelets, Pheresis from donors who have ingested drugs that adversely affect platelet function. These include, but may not be limited to:

- *Non-steroidal Anti-inflammatory Drugs (NSAIDS) – 3 days from last dose*

According to our Medical Director, NSAID are reversible inhibitors of platelet cyclooxygenase and platelets will regain function when no longer suspended in donor plasma. Therefore, the deferral is unjustified, again, ultimately causing collections to decline.

We would also like to request that the deadline for submitting responses to the Draft Guidance, **Docket number 2005D-0330, Collection of Platelets by Automated Methods**, be extended to give our facility ample time to compile relevant data to support our arguments stated above. Again, we appreciate the opportunity to respond to this proposed guidance and have confidence that with input from blood banks nationwide, the outcome will be a document that represents the needs of the industry as well as donor safety.

Sincerely,

A handwritten signature in black ink that reads "Wendy Bailey". The signature is written in a cursive, flowing style.

Wendy Bailey
QA Compliance Manager