ST. LUKE'S
Episcopal
Hospital
Blood Center

December 30, 2005

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

www.fda.gov/dockets/ecomments

Reference Docket Number 2005D-0330

Dear Sir or Madam:

The following are comments for consideration related to the draft "Guidance for Industry and FDA Review Staff – Collection of Platelets by Automated Methods" published by FDA on September 30, 2005.

In section III: Donor Selection and Management, Section A. Donor Selection:

"Prior to the first donation, test Platelets, Pheresis donors for levels of the following laboratory values that are acceptable under the manufacturer's directions for use: WBC count and platelet count

Comment: *WBC is not currently reviewed with donation. The manufacturer has not established acceptable white count nor has an acceptable white cell count for apheresis donors been determined.*

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:

Medications:

Aspirin (ASA)/ASA-containing drugs - 5 days from last dose
Non-steroidal Anti-inflammatory Drugs (NSAIDS) - 3 days from last dose
Plavix (Clopidogrel) - 5 days from last dose
Ticlid (Ticlopidine) - 14 days from last dose

Comment: *This list does not agree with the Uniform Donor History Questionnaire. Current standard for ASA/ ASA-containing drugs is 2 days. A history of ingestion of NSAIDS is not included on the Uniform Donor History Questionnaire or the medication deferral list. Available studies indicate that NSAID-related platelet is reversible within 24 hours[1]. The 3 day deferral seems to be overly conservative.*

1. Goldenberg NA. Brief communication: duration of platelet dysfunction after a 7-day course of Ibuprofen. Ann Int Med. 2005;142:506-509.

In section III: Donor Selection and Management, Section B. Number 2. Donation frequency

A donor should undergo no more than 24 Platelet, Pheresis collections in a 12-month period.

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.

The interval between each collection of Platelets, Pheresis should be at least two (2) days with no more than two procedures in a 7-day period.

The interval between collection of double Platelets, Pheresis and any subsequent collection of Platelets, Pheresis should be at least 7 days.

The interval between collection of a triple Platelets, Pheresis and any subsequent collection of Platelets, Pheresis should be at least 14 days.

Comment: *Current computer systems do not link number of products collected to number of donations and time deferral to number of products collected. This would require system modifications (modifications require FDA approval). Manual intervention /manipulation of data is subject to error and is not a good management of donors.*

Availability of apheresis platelets would decrease because many donors currently donating multiple times per year would be deferred after the 24 products are collected. The informed consent already states that the long-term effects of repeated platelet apheresis on the donor's platelet and leukocyte count is not understood.

Larger donors with high blood volumes and/or donors with high platelet counts often have multiple apheresis products collected with each donation. With each apheresis procedure, the donor's platelet count is checked. Each facility has acceptable values thus providing adequate protection for the donor.

A post-donation platelet count should be performed after each collection.

Comment: *Current apheresis set configurations does not have an option for post donation donor sampling. Testing samples are drawn into a diversion bag at the beginning of the collection. Obtaining a post donation platelet count would require an additional stick for the donor or would require modification of the donation sets by the manufacturer.*

In section III: Donor Selection and Management, Section B. Number 4. Medical Coverage

Under 21 CFR 640.22(c), the procedure for collection of Platelets, Pheresis, including the availability of medical care during the donation, must conform to the standards described in the biologics license application or supplement. We believe that a physician should be present on the premises during the collection of Platelets, Pheresis to ensure that necessary medical treatment be available to the donor in a timely fashion. We interpret "present on the premises" to include a qualified physician able to arrive at the premises within 15 minutes (Ref. 11). In case of an emergency, calling 911 may be used to obtain emergency medical care and transportation to another facility for further care, but we do not believe this is a sufficient substitute for an available physician as previously described.

Comment: *Each collection agency has established adverse reaction and apheresis reaction standard operations procedures. The SOPs allow sufficient guidance to protect the apheresis donor. Medical*

assistance in an emergency for whole blood donation utilizes emergency personnel (911). Medical coverage (physician) for apheresis donations would preclude mobile apheresis and reduce fixed site collection of apheresis. Again availability of apheresis platelets would decrease.

Section V: Component collection and management, Section A:

In addition, the phlebotomy must be performed by a single uninterrupted venipuncture with minimal damage to, and minimal manipulation of, the donor's tissue.

Comment: *Standard operating procedures from the manufacturer allow sterile dock of a new needle and continuation of a procedure if the original venipuncture site is compromised. Skilled venipuncture and minimization of damage, manipulation should always be practiced. There is currently no definition for manipulation for blood donor phlebotomy.*

In section V: Component collection and management, Section B: Target Platelet Yield

To assure that each component obtained from a multiple collection of Platelets, Pheresis results in an actual platelet yield of at least 3.0×10^{11} platelets, you should use the following targets. When collecting:

- Double components, the device's target platelet yield setting be at least 6.5×10^{11}.
- Triple components, the device's target platelet yield setting be at least 10.0×10^{11}.

Comment: *Current practice allows variance of draw setting based on optimal collection from donor. All products are measured for yield.*

Section VII: Section A: Component Storage and Shipping:

Draft states that Agitation is optional if platelets are stored at a temperature between 1-6C.

Comment: *Current storage of platelets is 20-24C.*

Section VII: Section B. Donor Monitoring

The medical director should be notified when a post platelet count is less than 100,000.

Comment: *Current apheresis set configurations do not have an option for post donation donor sampling. Testing samples are drawn into a diversion bag at the beginning of the collection. Obtaining a post donation platelet count would require an additional stick for the donor or would require modification of the donation sets by the manufacturer. A count slightly less than 100,00 would not require any specific intervention. The critical lower threshold for donor safety remains to be determined. Assessment of pre-collection counts seems to be an adequate donor safety measure. It does seem prudent to document donor safety in validating platelet collection; however, ongoing assessment seems unwarranted.*

Sincerely,

Paul M. Allison, M.D.
Medical Director
St. Luke's Episcopal Hospital
Blood Center

Arthur W. Bracey, M.D.
Medical Director
St. Luke's Episcopal Hospital
Transfusion Service