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December 19, 2005

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

Re: Docket No. 2005D-0330: Draft Guidance for Industry and FDA Review Staff, Collection of Platelets by Automated Methods

Dear Docket Officer:

On October 3, 2005, the Food and Drug Administration published in the Federal Register a proposed rule entitled, "Draft Guidance for Industry and FDA Review Staff, Collection of Platelets by Automated Methods". The Northwest Florida Blood Center (NFBC) would like to take this opportunity to provide our comments.

NFBC commends the FDA for their efforts to update guidance for the Collection of Platelets by Automated Methods. Updating the guidance to include scientific and industry advances is vital to assure the safety, purity, and potency of the volunteer blood supply.

On behalf of the Executive, QA, and Medical Staff at NFBC, I would like to provide the following specific comments for your consideration:

1. **Donor Selection (Page 5):** The ingestion of aspirin (ASA)/ASA-containing drugs would require deferral of donor for 5 days from last dose.

Please consider that the efficacy of extending aspirin deferrals from 3 to 5 days might not be in the best interest of maintaining an adequate platelet supply. Medical studies indicate that the effect of aspirin on platelet adhesiveness can be as long as 2 weeks. Therefore, unless there are medical studies that support this proposed two-day extension, mandating such might be a needless action that could significantly shrink the donor pool. Most physicians suggest that healthy people over 50 years of age take daily aspirin prophylactically. Some physicians recommend commencing aspirin prophylaxis at age 40. If compliant individuals perceive that 5-days' abstention from aspirin prophylaxis might adversely affect their health, they may choose to forego donation, which in turn could have a significant impact on the available pool of platelet donors.

2005D-0330

Page 1 of 5

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2. **Donor Management** (Page 5, Platelet Count): “For any collection facility that cannot perform a pre-donation platelet count (for example, a mobile collection site), you should use a platelet count as specified by the device manufacturer, or a post-donation count from a previous collection to set the target platelet yield.

Please consider allowing a pre-donation count from a previous collection to set the target platelet yield. Using a lower post-donation count would actually require the donor to unnecessarily be on the machine longer to obtain the required dose of platelets.

3. **Donor Management** (Pages 6 - 7, Donation Frequency): We have three comments on this section.

- A. “You should collect no more than 24 total Platelets, Pheresis components in a 12-month period.” (Page 6).

We recommend that donors be allowed 24 donations, regardless if single, double, or triple. With many centers collecting more than 50% doubles, to limit based on the number of products could seriously and negatively impact the supply of platelets on a local, regional, and national level. We are not aware of any negative health consequences on multi-gallon platelet donors that meet all current requirements and donate double products up to 24 times per year.

- B. “A post-donation platelet count should be performed after each collection.” (Page 6).

We recommend that you allow a sample collected before the procedure to have a platelet count run after the procedure is finished (i.e. at a later time in a central lab). Does a post-donation platelet count add to the safety of the donor as long as the other criteria for weight, pre-count, donation frequency, volume, and time on the machine are met? A post-donation sample would also add to the total red cell loss.

- C. “The total volume (excluding anticoagulant) of all blood components retained per collection of Platelets, Pheresis should not exceed 500 mL (600 mL for donors weighing 175 lbs or greater) or the volume described in the labeling for the device, whichever is less.” (Page 7).

We recommend that the allowable volume be based on a mL of product / kg of body weight formula.

4. **Medical Coverage** (Page 7): “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. 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.”

We request that you reconsider this requirement. Most physicians in non-emergency health care environments, such as blood centers, are pathologists or clinical pathologists who do not possess the certified skills to sufficiently care for critically ill patients in an emergency situation, especially if needed medical equipment is not readily available. Additionally, one such pathologist may be responsible for overseeing collections at branch facilities that are 10-50 miles from his office. This extends to many such environments in general and specifically to blood collection facilities. That is the primary reason for the need for highly trained emergency medical technicians with all the tools available to them in mobile assets.

Due to the heavily regulated and mandated donor screening process, we have eliminated a number of potentially unhealthy candidates for blood and/or platelet donations. We understand that emergencies may arise while donating and that the screening process may not eliminate all potentially unhealthy candidates. For a physician to respond to such an emergency, however, blood centers would need "crash" carts, defibrillators, and experienced critical care personnel at every collection facility. The more realistic scenario is one in which CPR trained personnel be available to assist in keeping a patient alive until highly trained emergency medical personnel arrive to assist in a patient's care. Blood centers are not licensed critical care facilities, trauma centers, or medical treatment facilities and should not be held to that level of care. To require that blood centers perform to the standard of care provided in hospitals could become practically and fiscally prohibitive. Mandating that blood centers have a physician on the premises or within 15 minutes of the premises, during drawing hours would be an undue burden that would negligibly increase donor safety. Well-trained front-line staff members that are trained in emergency management of donors until skilled emergency responders arrive are more beneficial to the organization and donors.

5. **Product Performance Qualification (Component Collection) (Pages 10 - 11):** We have several comments on this section.

A. “Test a minimum of 60 consecutive single (30 for double and 20 for triple) collections for each type of automated blood cell separator for (1) actual platelet yield, pH, volume, visible RBCs; and (2) for residual WBC count and percent recovery (Ref. 2), with 0 failures in each category.” (Page 11).

Please clarify the intent. For a collection site, collecting singles, doubles, and triples, would the requirement be 110 consecutive procedures (180 products)? This seems excessive.

- B. “Perform bacterial contamination testing on 500 collections with 0 failures.” (Page 11).

Please consider requiring the same number of tests as required for the other parameters in order to complete the performance qualification. Bacterial contamination testing will be on going after the initial performance qualification.

- C. “Product performance qualification should be completed for each automated blood cell separator used in your establishment.” (Page 11).

Please clarify the intent. Is the intent to perform the prescribed number of tests on products collected on *each* instrument (serial number) or instrument *type* (manufacturer or model)? Is the intent simply that we include *each* instrument (serial number) as we work towards performing the prescribed number of tests on products?

- D. “Residual WBC count be performed within 24 hours of collection, or per the manufacturer’s directions for the cell counting methodology.” (Page 11).

Please consider allowing within 48 hours of collection or per the manufacturer’s directions for the cell counting methodology. There are many blood centers with outlying collection sites that hold products overnight, before shipping to a central lab.

- E. “Test one third of the components collected for qualification during the first third of the dating period; one third during the second third of the dating period, and one third the day of outdate. For example, for Platelets, Pheresis with a 5-day dating period, test one third at 1-2 days, one third at 3-4 days and the final third on day 5 after collection.” (Bottom page 11).

Please clarify which parameters to test. This seems to conflict with the earlier requirement to perform the WBC count within 24 hours. Furthermore, the manufacturers already have approval to store product in their bags for 5 days. Holding products for several days after collection will cause excessive product outdating and affect product availability. Is this necessary?

6. **Table 1. Collection Performance Qualification Criteria** (Page 12): Acceptance criteria for residual WBC count are listed as “ $< 5.0 \times 10^6$ per collection and per component for double and triple collections”.

We request that you maintain the requirement that products contain $< 5.0 \times 10^6$ WBC. Maybe consider a requirement that collections with $>5.0 \times 10^6$ WBC must have a residual WBC count performed on individual products prior to being labeled as leuko-reduced.

7. **Labeling** (Page 16): “You should determine the final component volume to be stated on the label after removal of samples for platelet count determination, QC and/or bacterial contamination testing.”

We consider this a prudent requirement, especially with the relatively large volumes need for bacterial contamination testing. However, we would like to see an exception for a small volume (up to 1 –2 mL) to be removed, specifically at the time of issue, for QC testing. This represents less than 1% of the typical product volume.

Thank you for the opportunity to comment.

Sincerely,

A handwritten signature in cursive script that reads "Scott Robertson".

Scott G. Robertson, MT (ASCP)
Vice President, Hospital/Laboratory Services

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