



December 21, 2005

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

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Re: Docket Number 2005D-0330: Draft Guidance for Industry and FDA Review Staff; Collection of Platelets by Automated Methods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 "Guidance for Industry and FDA Review Staff, Collection of Platelets by Automated Methods" The Blood Bank of Alaska (BBA) would to take this opportunity to provide our comments.

BBA appreciates the FDA efforts to update the 16 year old guidance for the collection of platelets by apheresis. Updates to the guidance should include scientific and industry advances vital to assure the safety, purity and potency of the volunteer blood supply, and the safety of the volunteer donors themselves. However, many of the changes do not appear to be based on relevant scientific data. We provide the following specific comments for your consideration:

1. Page 5, III., A. Donor Selection

- WBC count should be performed prior to first donation:
The requirement to perform a WBC count requires additional time and resources, and there is no scientific literature to support the need for pre-donation WBC testing on the donor. Concerns about WBC depletion, which have diminished significantly with newer technologies, should be addressed if necessary by changes in the volumes and/or interval of donations. Pre-donation WBC testing is not required on donors of other FDA licensed products (e.g., plasma and RBC).

It is not clear if the guidance specifies that both pre- and post- donation platelet counts and WBC counts be done routinely, or that a post donation count be performed ONLY if a pre-donation counts were not performed on the donor. We do not believe it is necessary to perform BOTH a pre-donation and post donation platelet count. If no post-donation count was done, the donor would need a pre-donation count prior to the next platelet donation.

- Ingested drugs that inhibit platelet function (reference to ASBPO)
The deferral for consumption of aspirin-containing medication was increased from 36 hours as listed in the current Guidance, to 120 hours. AABB requires a 72 hour deferral. An increase to 120 hours will adversely affect the availability of eligible donors, and should not occur without proper scientific justification.

Reference is made to the ASBPO Drug and Medication Donor Deferral document in several places in this draft guidance. We believe it is inappropriate to reference this document in the Guidance. The type/class of medications that requires a deferral should be listed, not a document in use by another blood collection entity.

2. Page 5/6, III., B., Donor Management, Item 2, Donation Frequency

- *We believe that the limit of 24 Platelets Pheresis collections in a 12-month period should not include the number of components collected at each procedure (i.e., doubles count as two and triples count as three towards the 24 limit). Limits on the procedures should be based on plasma VOLUMES, not the number of components collected at each procedure.*

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*It is more cost effective and therefore preferable to collect a double or triple platelet product from an eligible donor. The table below shows that the annual plasma loss from donors who donate **only** double or triple platelet products has been reduced from the current 14,400 mLs (for donors weighing >175 pounds) annually to only 7200 for double platelet donors or 4800 mLs for triple platelet donors. This huge reduction in the allowable annual plasma volume loss will result in our inability to provide platelet products in adequate number. Additionally, we would need to develop a manual system to track the number of components collected at each donation, in addition to our existing system which tracks platelet donations (not the number of platelet components at each donation)*

	Proposed			Current
	Maximum Volume Loss based on Mfg. specifications, or FDA limit, per Guidance	Maximum collection frequency, per Guidance	Maximum annual loss	Annual volume loss at 24 donations/year
Single collection	400 mLs* (1 component at max. of 400 mL)	24	9600 mLs	9,600 mLs
Double collection	600 mLs** (2 components at 300mLs each)	12 (24 divided by 2)	7200 mLs	14,400 mLs
Triple collection	600 mLs** (3 components at 200mLs each)	8 (24 divided by 3)	4800 mLs	14,400 mLs
*Mfg's spec for maximum volume in one bag				
** FDA limit, donor >175 lbs				

The maximum annual plasma loss limit of 12,000mL or 14,400 mL for donors weighing 175 pounds or greater has been in place for decades, and are still used in the Source Plasma Industry. Although these limits are included in the draft guidance document on page 15, under Quality Assurance and Monitoring, there is no possibility of double/triple platelet donors ever reaching them.

The justification for limiting platelet donors' loss should be evaluated. We would like to see the maximum 24 apply to procedures, not components, and retain the maximum annual volume loss and the maximum procedure loss as specified.

- The interval between a triple platelet collection and any subsequent platelet collection should be reduced from the 14 days specified in the guidance to 7 days. Once again, the total volume loss limits per collection procedure specified in the guidance, with the limit of 24 procedures per year, is sufficient.*

3. Page 6 III., B., Donor Management, Item 3, RBC Loss prior to Platelet Pheresis Collection

*Throughout this section, the restrictions on allowable WB/RBC loss prior to platelet pheresis collection should be stated in terms of the **volume** of RBCs lost, rather than the phrases "unit of whole blood (450ml)" or "two units of RBCs by apheresis". We suggest use of the phrase "donated the equivalent of (>200mLs/>300mLs) RBC in the previous (8/16) weeks" would eliminate any ambiguity.*

With all the possible combinations of donation opportunities available, WB bag size variances, incomplete apheresis procedures, and the possibility of no rinseback on any apheresis procedure, generic terms such as "unit of 450 mL whole blood", "double RBCs", or "single RBCs" does not provide enough guidance on RBC loss limits.

4. Page 7, III., D., Medical Coverage

We request that the requirement that a physician be on the premises to ensure that necessary medical treatment be available to the donor if needed be reevaluated. We strongly agree that necessary medical treatment for donors be available if needed, but the requirement that it be rendered/directed by a "qualified" physician who is available within 15 minutes is unrealistic. Many Blood Centers have as their Medical Director a physician (pathologist or researcher) whose expertise and training is not that of emergency medicine.

On the rare occasions that we have called 911, the response time has always been less than 9 minutes. We would like you to consider the continued use of 911 in such situations, or that a physician substitute, (with appropriate training, certifications, and/or licensing as determined by you) be considered.

5. Page 8, Section V., B., Target Platelet Yields

We believe that specifying the setting for target yields on multiple collection of platelets pheresis is unnecessary and should be left as a center's operational decision. Enforcing the current FDA regulation requiring that each component from a multiple collection of platelets pheresis contain at least 3×10^{11} platelets, combined with the requirement that a count be performed on each unit, will require centers to set the target yields at a level that ensures suitable product outcome.

6. Page 11, D. Product Performance Qualification

- The platelets pheresis we manufacture are leuko-reduced by centrifugation by the apheresis equipment in use. We are unable to calculate the percent recovery. Percent recovery should apply only to those products that are filtered post collection.
- The time limit of 24 hours from collection to performance of residual WBC counts is restrictive. If Nageotte counts are performed, there is no manufacturer's recommendation available to extend this time. Other methodologies allow for greater than 24 hours before residual counts be performed. We request that this time limit be extended to 48 hours.

7. Page 17, B. Donor Monitoring

- Delete requirement to notify the Medical Director if donor's post donation platelet count is less than 100,000; a pre-count of 150,000 is necessary for donation, and no post count should be required if pre-count is performed.
- The requirement for a qualified physician or designee to evaluate a donor who has had an "adverse reaction" needs to be clarified. You state an RBC loss within the past 8 weeks should be included as an "adverse reaction". We do not understand the intent or purpose of including RBC loss. Also, we document many occurrence as "adverse reactions": dizziness, hematomas, etc. Do all of these necessitate review by a physician before a subsequent donation?
- Clarification is needed when you state that donors undergoing frequent multiple component collection of platelets need to be monitored for platelet recovery. What is considered frequent? What is considered adequate platelet recovery?

We appreciate the opportunity to comment on the draft guidance. The significant changes and new provisions incorporated in the draft document are numerous. An extended comment period, or public discussions may be warranted.

Thank you.

Very truly yours,
BLOOD BANK OF ALASKA, INC.



V. Gaye Hurley
Director of Quality Assurance