

**San Diego  
Blood Bank**  
Saving Lives Since 1950



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December 28, 2005

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

Response to FDA:

Dear Docket Officer,

The San Diego Blood Bank (SDBB) appreciates this opportunity to provide comments on *Draft Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods*.

The SDBB is an independent, not-for-profit community blood center. It was established in 1950 through the support of the San Diego County Medical Society to meet the blood needs of the local community as well as provide blood-related services. Our organization collects over 110,000 red blood cell donations and more than 15,000 automated blood product collections per year. We are a member of the AABB, America's Blood Centers, and Blood Centers of America.

The SDBB appreciates and respects the role of the FDA in providing oversight to ensure the safety, purity and potency of blood products collected in the United States as well as the safety of blood donors. In response to your request, we welcome the opportunity to comment on the draft guidance.

The SDBB strongly urges the FDA to reconsider the formula for calculating donation frequency listed in Section III.B.2:

Following the FDA's 1988 memorandum regarding the frequency of automated collections, the SDBB and the vast majority of other blood centers interpreted that memorandum as recommending no more than 24 collection visits in one year. The draft guidance, however, considers a double collection of platelets to count as 2 collection products for a maximum of 24 collection products within 12 months.

Experience since the FDA 1988 memorandum regarding frequency of automated collections has not suggested clinically apparent adverse effects by adhering to that collection frequency. The short shelf-life of platelet products and the

2005D-D330

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challenges in recruiting platelet donors have resulted in shortages of platelets for transfusion services. The further restriction of donation frequency proposed by the draft guidance will result in major platelet shortages and possible increases in morbidity and mortality for patients needing platelet transfusions. At a minimum, the number of non-ABO matched platelet transfusions would likely increase resulting in more transfusions of ABO-incompatible plasma. We strongly urge the FDA guidance to (1) calculate donation frequency limit as a maximum of 24 Platelet, Pheresis collection events within 12 months and (2) consider a double or triple collection of platelets to count as 1 Platelet, Pheresis collection event.

Additionally, the SDBB strongly urges the FDA to reconsider the recommendation in Section III.D. that a physician should be present on the premises during the collection of Platelets, Pheresis:

In the event of a life-threatening reaction, calling 911 is an appropriate, immediate response that enables a donor to be transported to an emergency medical facility immediately. Waiting 15 minutes for a physician to physically arrive on-site prior to calling 911 may delay the critical medical care a donor may require for a life-threatening reaction. Collections staff are trained to respond immediately to donor reactions, and a physician should be available by phone to provide immediate consultation. Most blood collection organizations have multiple collection sites, geographically separated for the convenience of platelet donors. Requiring the presence of a physician within 15 minutes of each site would markedly increase the costs required for platelet collection and likely necessitate the closing of collection sites without significantly improving the level of donor care.

The SDBB strongly urges the FDA to reconsider the recommendation in Section III.A. regarding the collection of Platelets, Pheresis from donors who have ingested drugs that adversely affect platelet function:

Recommendations should be consistent with previous FDA recommendations concerning medication deferrals. The FDA guidance document for Donor Health Questionnaire addresses aspirin use 48 hours prior to donation. AABB standards also support a 48-hour deferral period following aspirin ingestion. No deferral is necessary for donors who have taken NSAIDS. NSAIDS effect on platelet function is highly reversible and should not adversely affect recipients.

We agree with a 5-day deferral for Plavix (Clopidogrel) and 14-day deferral for Ticlid (Ticlopidine) but we think these recommendations should be listed in a revised FDA guidance document for Universal Donor Health Questionnaire and not in this guidance.

Additionally, in Section III.B.2. concerning the safety of the donor, the SDBB requests that the FDA reconsider the recommendation that the required interval between collection of a double Platelets, Pheresis and any subsequent collection of Platelets, Pheresis should

be at least 7 days, and that the required interval between collection of a triple Platelets, Pheresis and any subsequent collection of Platelets, Pheresis should be at least 14 days.

The FDA's memorandum in 1988 recommended an interval of 48 hours between procedures and that a donor should not undergo more than two procedures within a 7-day period. The SDBB believes that the frequency recommendation in the 1988 FDA memorandum has been adopted by the blood banking community and is a more reasonable donation interval than those stated in the recent draft guidance. Experience since 1988 has not suggested clinically apparent adverse effects by adhering to that collection frequency.

Logistically, new algorithms for determining donor deferral would be required to be developed and implemented with possible increases in donor eligibility errors during the implementation process and increased financial burdens for blood centers in developing those algorithms. The short shelf-life of platelet products and challenges in recruiting platelet donors has resulted in difficulty for the blood collection community to consistently provide a reliable supply of platelets to transfusion services. Further restricting donation frequency by limiting collection frequency from multiple platelet product donors would result in major platelet shortages and likely increases in mortality for patients requiring platelet transfusions.

The SDBB requests that the FDA reconsider the recommendation listed in Section IV, concerning the requirement that the donor be provided with a description of the number of Whole Blood, Apheresis Red Blood Cells or Plateletpheresis collection procedures and/or components that may be collected per year, and the donation interval for each.

While this can be easily created and given to donors, the true value to the donor of such information is questionable.

The SDBB requests clarification of Section V.A.

The phrase "single uninterrupted venipuncture" might be interpreted to mean that only one venipuncture can be attempted per donation visit. In cases where the collection kit is contaminated with blood or air exposure, products must not be collected with those kits. However, there are situations where a second venipuncture in the same or opposite arm with a non-contaminated collection kit would result in a successful donation. In cases where venous access is adequate, it is reasonable to perform a second venipuncture with donor approval.

The SDBB requests clarification in Section VI.D. and Section VII.C.2. regarding "Residual WBC count be performed within 24 hours of collection, or per the manufacturer's directions for the cell counting methodology."

This may be interpreted as 24 hours from the time of collection of either apheresis product or collection of the sample for WBC testing. Requiring the collection of

a sample for residual WBC count within 24 hours of product collection creates tremendous logistical problems since collection centers are required to obtain a sample for bacterial testing AFTER 24 hours from platelet collection time. Two separate samples would need to be obtained at different time periods, increasing the possibility of introducing bacterial contamination during sampling. In order to minimize manipulation of the product, we believe the best practice is to obtain a sample for WBC count at the same time a sample for bacterial contamination is obtained. This interpretation is supported by section VII.C.2. recommendation "... or per the manufacturer's directions for the counting device or method used."

The SDBB requests that the FDA reconsider the recommendation listed in Section VI.D. for testing one third of components 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.

We attempt to distribute products for transfusion quickly after collection. Holding one third of products collected for qualification until day 5 post-collection will increase platelet expiration rates since the effective shelf-life of those products is less than one day.

The SDBB requests clarification of section VII.A.2. The actual platelet yield for each collection of Platelets, Pheresis is available to the transfusion facility if requested but not routinely printed on each label.

Providing the actual platelet yield available to the transfusion service upon request appears to be more consistent with the intent of section IX of the draft guidance.

The SDBB requests clarification of Section VII.A.2. recommendation that a blood center's SOP should state the maximum acceptable WBC limits for each automated blood cell separator device in use.

Are these limits meant to apply for all non-leukoreduced collections?

The SDBB requests clarification of Section VII.B.2. recommendation that, before a subsequent donation, a donor who has experienced an adverse reaction should be evaluated by a qualified physician or designee.

The term adverse reaction is not defined and many adverse reactions are very mild and may include such things as superficial bruising. The final guidance should clarify that "donors experiencing severe reactions (such as those requiring hospitalization) may require evaluation by a qualified physician or designee prior to subsequent donation".

The SDBB recommends that the FDA increase the pH requirement stated in Section VII.C.2. from 6.0 to 6.2.

We agree with the earlier FDA statements in this draft guidance that platelets stored at a pH of less than 6.2 have poor recovery, and we would suggest that the FDA should consistently use a minimum pH value of 6.2 instead of 6.0 when a specific pH value is measured.

The San Diego Blood Bank requests that the FDA define the phrase "at the end of the storage period" consistently in section VII.C.2.

The phrase is defined as including "testing at the time of issue" early in the section and "testing within 12 hours of expiration" later in the section. Two separate definitions for the time period term is confusing. We recommend "testing at the time of issue" is the preferred definition in order to decrease the number of expired products.

The San Diego Blood Bank appreciates the opportunity to provide comments on this draft guidance.



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