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December 29, 2005

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

Re: Docket Number 2005D-0330, Draft Guidance for Industry and FDA Review Staff on
Collection of Platelets by Automated Methods

Dear Docket Officer:

LifeShare Blood Centers, established in 1942, is currently the largest collector of blood and blood components in Louisiana. We have six fixed collection sites, all with apheresis capabilities, and serve in excess of 80 healthcare facilities throughout Louisiana, southeast Texas, and southern Arkansas. We have been collecting Platelets, Apheresis for the past 20 years.

We feel compelled to comment on the above referenced FDA guidance document because of the profound negative effect it would have on our ability to provide for the patients in our service area if adopted without revision.

Donor Selection and Management

Page 5 of the documents recommends that donors be deferred for 5 days from the last dose of aspirin (ASA) or aspirin-containing medications.

Current AABB standards (23rd edition), on which the FDA has a liaison member, recommends a 36 hour deferral period following ASA ingestion. In addition, the FDA draft guidance document for an Acceptable Full-Length Donor History Questionnaire (April 2004) recommends a 48 hour deferral period.

We request that the deferral period for ASA ingestion be standardized at either 36 or 48 hours.

2005D-0330

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Page 6 of the document recommends that the total number of platelet components donated in a 12 month period be limited to 24 even though a donor may donate 24 times in that same period.

Over the last 12 months, LifeShare Blood Centers collected 11,575 donations from 2,275 donors which produced a total number of 17,529 apheresis platelet components. Of these donors, 14.5% donated 12 or more times, but this accounted for 51% of the total components produced. Although we are able to increase the number of individual donors, this is difficult to accomplish over the short-term. It is, therefore, necessary to increase the efficiency of our collections by producing more double products. We estimate a 25-30% shortfall of available apheresis components if we are to abide by the limit of 24 total components in a 12 month period.

We obtain a platelet count prior to every donation. Any donor who has a count less than 150,000/ μ L is deferred for at least 4 weeks and must have an acceptable platelet count before being allowed to donate again. We are most concerned about donor safety and feel that our current procedures address these issues.

We request that donors be allowed to donate a maximum of 24 times per 12 month period and that the requirement for a maximum of 24 individual components be deleted from the document.

Page 6 of the document recommends that a physician should be present on the premises during the apheresis platelet collection or that a qualified physician is able to arrive within 15 minutes if there is an adverse donor event.

We have been collecting apheresis platelets for the past 20 years and have never had a donor event that necessitated physician intervention. Our collection sites are spread over hundreds of miles at both fixed and mobile locations, and it is logistically impossible to have physicians available at all hours and at all sites. All apheresis staff are trained in CPR and in the rare event that emergency personnel are required, the response from calling 911 is superior to having a physician respond.

As a result of the proven safety record of apheresis collections, the rapid response time of 911, and the inability to have sufficient numbers of physicians available, we request that the recommendation of a physician on-site be deleted from the final document.

Product Performance Qualification (Component Collection)

On page 12, Table 1, the acceptance criteria for residual WBC is $<5 \times 10^6$ per collection and per component for split products.

Residual WBC determination is time-consuming and expensive. If the residual WBC count is $<5 \times 10^6$ in the “mother” bag, it will therefore meet criteria in any split products.

We request that individual facilities be allowed to determine whether to perform the residual WBC count in either the primary component or any split products as long as regulatory criteria are met.

Thank you for allowing us to comment on this draft guidance.

Sincerely,

A handwritten signature in black ink that reads "Gary J. Levy, MD". The signature is written in a cursive style with a large, stylized initial 'G'.

Gary J. Levy, MD
Medical Director

GJL:cl