Wellmont
Holston Valley Medical Center

February 14, 2001

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857

RE: Wellmont Health System
License Number 1246

To Whom It May Concern:

In reference to the draft guidance document *Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion*, I wish to comment on the proposed recommendation to directly test every leukocyte-reduced component intended to be used in lieu of CMV-negative units for residual leukocytes.

Our small blood center provides the majority of leukocyte-reduced components to a single medical center that has active neonatal and oncology transfusion programs. However, the demand for CMV reduced-risk red cells will always be sporadic and unpredictable. Given that we already adhere to strict process control in the manufacture of leukocyte-reduced components for which we are licensed, I do not believe it would be advantageous—and certainly it would not be cost-effective—to count residual leukocytes in *all* components given in lieu of CMV-negative units. Provision of CMV reduced-risk platelets would present a special problem. Since the whole blood platelets from our center are not leukocyte-reduced, it was our intent to provide CMV reduced-risk platelets to premature infants by leukocyte-reducing the whole blood platelet unit upon receipt of order to transfuse. While we can show validation that the filtered unit contains fewer than 1.6 x 10^5 leukocytes, it will not be practical to perform a Nageotte leukocyte count on every platelet unit awaiting transfusion.

It is my opinion that managing an inventory of counted vs. uncounted leukocyte-reduced red cells and platelets would preclude our use of leukocyte-reduced products in lieu of CMV-negative components altogether. The cost of performing a small daily batch of CMV antibody tests by solid phase is a fraction of the cost of performing several Nageotte leukocyte counts. As a result, we would be forced to continue routine CMV testing, and I don't believe that is the intended effect of this guidance.

Sincerely,

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