BloodSource™
SACRAMENTO

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Re: Docket Number 03D-0163
Guidance for Industry Recommendations for the Assessment of Donor Suitability and Blood Product Safety in Cases of Suspected SARS or Exposure to SARS.

Dear Sir/Madam:

Thank you for the opportunity to comment on your guidance regarding reducing the risk of SARS through blood transfusions. While I would like to compliment the FDA on its ability to put out a 10-page guidance document so quickly, unfortunately, in its haste, the guidance does not appear to be optimal nor very practical.

The basis for the SARS guidance appears to be the theoretical possibility that the agent of SARS can be transmitted by transfusions from individuals incubating this illness. As there is no real evidence for this, the means to reduce this risk should be straightforward and more public health oriented. The PHS should advise SARS patients not to donate blood for a period of time after recovering from their illness, for example, 28 days. In addition, the CDC should inform individuals, returning from countries listed as having an increased risk of SARS, not to donate blood for at least 14 days after returning from the affected area. As SARS spreads (and this is quite likely), one of the most important points would be to have the PHS recommend that those who had been in close contact with a patient with SARS should not donate blood for at least 14 days.

Instead of using the lengthy and complex FDA SARS guidance, we are using a much simpler approach. Our goal is not only to prevent the theoretical transmission of SARS by transfusions, but also reduce

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risk to our staff and other donors of contracting SARS. We are providing a short informational sheet to all individuals who present to donate at mobile sites and fixed centers. This simple information sheet addresses the theoretical risk of transmission of SARS by a blood transfusion, and the implementation of a temporary measure. The temporary measure is to ask individuals who have been in close contact with a patient with SARS or who have traveled to a geographic area identified by the Centers for Disease Control and Prevention as an area affected by SARS from donating blood for at least 14 days following contact or return to the U.S.

The reporting of cases of SARS in donors or recipients to local health authorities should be done by the physicians who make the diagnosis, and not by blood centers. Blood centers will only have the information if provided by, and as a consequence of, a SARS diagnosis by a physician. The physician should do the reporting, based upon his/her first-hand knowledge of the individual with SARS. This is the usual public health approach to a disease in the community.

Thank you for your consideration of the above points.

Sincerely,

Paul Holland

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PVH/gel – 99.03
c-Sally Morgan-Gannon