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To: Cheryl Chamberlain Roscher, Fenwal, Inc.
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Date: 19-Nov-2009

This Fax is regarding **BN080041** that was received by the agency on 04-Aug-2008, as an original NDA for your InterSol Solution. We received your PMR/PMC proposal on 12-Nov-2009. Based on our review of the proposal, the reviewers have the following comments:

1. **During the Oct 15, 2009 teleconference the main points of discussion were as follows:.**
   a. Adverse events (transfusion reactions): it was agreed that the comparison between test and control products will include the specific type of transfusion reactions (e.g. TRALI, allergic reaction, febrile non hemolytic transfusion reaction, etc…) rather than simply lumping all reactions into a single category of adverse event.
   b. The transfusion reaction rates (for each category) rather than the absolute reaction numbers will be tallied and compared.
   c. FDA emphasized the importance of conducting an active follow-up on all transfused products in the study rather than relying on the passive receipt of transfusion reaction reports from transfusion sites.
   d. FDA also stressed the importance of consistent reporting among the sites.
   e. A complete statistical plan including hypothesis testing will be developed in discussion between FDA and Fenwal. For the ---(b)(4)---------- FDA recommended that the test product does not exceed the control product by 20%.
   f. For the transfusion reaction rate comparison FDA initially recommended at that teleconference that the test product not exceed twice the rate of the control. **Note: please see additional comments below.**
   g. Final protocols need not be submitted prior to the approval; however progress in the discussions is anticipated.
   h. A face-to-face meeting may be held to address pending issues.

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2. **Specific comments to November 12, 2009 proposal**

   a. As discussed in the October 15, 2009 teleconference the comparison in transfusion reactions is expected to be by reaction type.

   b. Upon further internal discussion and considering a) the broad range of transfusion reaction rates reported in the literature and b) the varying clinical significance of different transfusion reaction types, the acceptable margin between test and control products for transfusion reaction rates will be discussed further with Fenwal prior to finalizing the protocol.

   c. It is Fenwal's responsibility to ensure that platelet collection centers and transfusion services are recruited into the studies.

   d. The reporting channels for both PMR and PMC will need to be agreed upon with FDA.

   e. The investigators should ensure a consistency of reporting for transfused outpatients and inpatients.

Please acknowledge that you have received this fax. We appreciate your assistance regarding this matter. If you have any questions, please feel free to contact Heather Erdman at 301.827.6182.

Thanks,
Heather Erdman, RAC, CQPA
Regulatory Project Manager
FDA/CBER/DBA/OBRR/RPMB

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