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To: Cheryl Chamberlain Roscher, Fenwal, Inc.
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Date: 28-Jul-2009

This Fax is regarding **BN080041** that was received by the agency on Aug 4, 2008 as an original NDA for your InterSol Solution and specifically the resubmission that was received by the agency on Jun, 12, 2009. The reviewers have the following comments on Fenwal's May 12, 2009 response to the 'Clinical and Statistics' section of the BN080041 Complete Response letter, dated April 6, 2009:

Item 18a:
The point estimate of the --b(4)---------- in the FCRP-0303 study was 1.25% and the point estimates of the --b(4)---------- in FCRP-0106 varied between 4% and 6.9%.

1. Please indicate whether the --b(4)---------- used during the procedures in FCRP-0303 differed from that in FCRP-0106.

2. Please indicate whether the Amicus device has been modified between the FCRP-0303 and the FCRP-0106 studies that may explain the ---b(4)---------- point estimate.

Item 18b:
You had indicated in your February 12, 2009, communication to FDA, page 3 of 28, item 1b that for both amendments 1 and 2 platelet products were found acceptable --b(4)----------overnight. However in your response to item 1b of the May 12, 2009, document you indicate that the AMICUS Operator's manual recommends a rest of only 2 to 4 hours after collection and that any additional rest period would vary depending on the blood centers' standard operating procedures.

Thus the AMICUS Operator's manual instructions do not reflect the findings of your study. The observed --b(4)---------- at 2 to 4 hours post collection would evidently be higher than the calculated rates of 6.9%, 5.05%, and 4%.

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Therefore we recommend that the rest period in the operator's manual reflects the number of hours of rest in your study that was required for the --b(4)---------- for platelets stored in PAS III and in plasma.

Items 19a and 19b:

1. FDA recommends that labeling of a potential approval of your drug includes mention of the in vitro parameter results for the PAS III solution which exceeded the 20% difference compared to the control.

2. In our January 23, 2009, communication we indicated that the acceptance criteria should be based on the lower limit of a two-sided 95% confidence interval. For the evaluation of in vitro parameters, the two-sided 95% confidence interval should be computed based on the hypotheses formulation (Test-0.8*Control). Please comment.

Item 20a:

1. FDA recommends that labeling of a potential approval of your drug includes mention of the in vitro parameter results for the irradiated products stored in PAS III solution which exceeded the 20% difference compared to the non irradiated control.

2. In our January 23, 2009, communication we indicated that the acceptance criteria should be based on the lower limit of a two-sided 95% confidence interval. For the evaluation of in vitro parameters, the two-sided 95% confidence interval should be computed based on the hypotheses formulation (Test-0.8*Control). Please comment.

Item 20b:

The range of platelet yield of the products that underwent irradiation was concentrated between 2.5×10^6/product to 3.5×10^6/product. Therefore we recommend that labeling reflects these findings. However you may conduct additional testing at either or both sides of this range to expand a future indication of your product.

Item 20c:

We recommend that labeling reflects the accurate conditions and results of testing.

Item 21.a.i: Growth Kinetics Study Comparing Storage in Plasma and PAS III:

To verify the results of growth curve analysis, please provide the following information:

1. The data which is ready to be analyzed immediately without further data manipulation. The data should include all necessary parameters.

2. All SAS programs which were used (a) to generate all the results of the growth curve analysis and (b) to do all the hypotheses testing.

Post marketing evaluation
In anticipation of a potential approval of your application FDA may discuss with you modalities for the conduct of a postmarketing evaluation.

Please provide a response at your earliest convenience, preferably by COB Tues Aug 11, 2009. 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
Regulatory Project Manager
FDA/CBER/DBA/OBRR/RPMB

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