FACSIMILE TRANSMISSION RECORD
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To: Cheryl Chamberlain Roscher, Fenwal, Inc.
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Date: 18-Sep-2009

This Fax is regarding **BN080041** that was received by the agency on Aug 4, 2008, as an original NDA for your InterSol Solution. During interactive review, we received a response from Fenwal dated September 17, 2009. Based on our review of the response, we are requesting the following information:

1. **Proposed Text of the Labeling for the Drug----Annotated**
   a. Table 1:
      For platelet count per unit we believe it would be more accurate to use 1.5-4.7 x 1011 to specify the range rather than > 1.5-4.7 x 1011.
   b. In vitro assessment at Day 5 (Table 2)
      In our January 23 2009, April 6 2009, and September 8, 2009 communications to you FDA had commented on the disproportionate increase in LDH release in InterSol platelets over the 5-day storage compared to control. Therefore we recommend you add in the LDH row the values on Day 1 for both test and control platelets. Alternately, you can add a row to the table on the LDH release rate (per day and per platelet) in InterSol platelets vs. plasma platelets. While of unknown clinical significance at this point, this finding may reveal itself to be clinically relevant with the market use of the InterSol stored platelets.
   c. Labeling of Irradiated products in the Clinical Studies section
      i. Based on our August 31, 2009 teleconference discussion it was mutually agreed that no reference would be made to a statistical comparison between test and control. Therefore we recommend that you remove the statement "None of the in vitro parameters tested was significantly different between irradiated and non-irradiated except for the extent of shape change".
      ii. Platelet yield range: the platelet yield range that you propose correspond to the day 1 data. However since the claim of your NDA is for a 5-day storage and since Table 3 include Day 5 data it would be more appropriate to list the yield range of the day 5 product. We propose the following statement: "At end of storage on day 5 the

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platelet yields of the irradiated products were concentrated between 2.5 x 1011 and 3.5 x 1011 and included one product < 2.5 x 1011 and 2 products > 3.5 x 1011."

2. **Draft Instructions for Use for InterSol Solution**
   a. Table 1
      For platelet count per unit we believe it would be more accurate to use 1.5-4.7 x 1011 to specify the range rather than > 1.5-4.7 x 1011.
   b. Contraindications
      We recommend you state that there are no known contraindications associated with the use of InterSol…(the word 'known' added).
   c. Warning and Precautions
      In the labeling that you submitted on May 12, 2009 the Draft Instructions for Use had the added statement: "Discard unused or partially used InterSol solution". We recommend you maintain this statement.
   d. Adverse Reactions
      We recommend you replace the last sentence with the sentence you had originally in the submission i.e. InterSol is not expected to cause adverse events other than those normally associated with platelet transfusion.
   e. Clinical studies
      i. Based on our August 31, 2009 teleconference discussion it was mutually agreed that no reference would be made to a statistical comparison between test and control. Therefore we recommend that you remove the statement "None of the in vitro parameters tested was significantly different between irradiated and non-irradiated except for the extent of shape change".
      ii. Platelet yield range: the platelet yield range that you propose correspond to the day 1 data. However since the claim of your NDA is for a 5-day storage and since Table 3 include Day 5 data it would be more appropriate to list the yield range of the day 5 product. We propose the following statement: "At end of storage on day 5 the platelet yields of the irradiated products were concentrated between 2.5 x 1011 and 3.5 x 1011 and included one product < 2.5 x 1011 and 2 products > 3.5 x 1011.".
      iii. Table 2: In our January 23 2009, April 6 2009, and September 8, 2009 communications to you FDA had commented on the disproportionate increase in LDH release in InterSol platelets over the 5-day storage compared to control. Therefore we recommend you add in the LDH row the values on Day 1 for both test and control platelets. Alternately, you can add a row to the table on the LDH release rate (per day and per platelet) in InterSol platelets vs. plasma platelets. While of unknown clinical significance at this point, this finding may reveal itself to be clinically relevant with the market use of the InterSol stored platelets.
   f. Additional comments
      The Draft Instructions for Use from May 12, 2009 included sections on Drug abuse/dependence and on Overdosage. We recommend you maintain these sections

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3. **Other issues discussed in the August 31, 2009**
   Waiting period for ---------(b)(4)---------- after collection
   It was mutually agreed that a statement would be added in the Operator's manual to inform the user that a period of up to **--(b)(4)-** might be required for any present **---------(b)(4)----------** .

Please provide a response at your earliest convenience. 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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