



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 15, 2009. Based on our review of the response, we are requesting the following information:

1. The variable of -(b)(4)- is the time intercept at -(b)(4)- and it should not have a negative value. However, some negative values were found in the provided data set. No negative time values are apparent in the corresponding figure (figure 6). Please clarify how the negative values were generated and how you dealt with the negative time values?
2. The -(b)(4)- is not normally distributed; I suggest the data needs to be log-transformed before doing further analysis.

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

Information provided by: Transmitted by H. Erdman Date _____

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Thank you.

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