



FACSIMILE TRANSMISSION RECORD
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To: Cheryl Chamberlain Roscher, Fenwal, Inc.
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Date: 24-Aug-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 Aug 7, 2009. Based on our review of the response, we are requesting the following information:

1. For the data set named pasgrowth2.sas7bda, please answer the following questions:
 - (a) What do variables ---(b)(4)--- and ---(b)(4)-- represent and how were they obtained? Please explain the missing values for variables ----(b)(4)-----
 - (b) Please correct some mistakes for variables Max and T_max. For example, with Bug=-(b)(4)-, Donor=8, Media=PAS Max and T_max are incorrect; please double check the values of these two variables.
2. Please check whether variables -(b)(4)- Max and T_max are all normally distributed.
3. Please indicate which variable is "the end of the lag phase" and how this variable was obtained.
4. Pertaining to Item 18b: Please provide the number and proportion of products, both test and control, for both amendments 1 and 2, which required ----(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

Information provided by: Transmitted by H. Erdman Date _____

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