



FACSIMILE TRANSMISSION RECORD
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To: Cheryl Chamberlain Roscher, Fenwal, Inc.
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Date: 11-Feb-2009

This Fax is regarding **BN080041** that was received by the agency on 04-Aug-2008 as an original NDA for your InterSol Solution. The reviewers have the following comments:

1. Provide a list of batches of your drug product (Intersol Platelet Additive Solution) used in pre-clinical and clinical studies along with release test results and stability test results (if available).
2. Provide justification with data for your proposed specifications of Intersol Platelet Additive Solution at release and during stability.

Please provide a response at your earliest convenience, preferably by COB Monday 16-Feb-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

Information provided by: Transmitted by H. Erdman Date _____

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Thank you.

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