



**FACSIMILE TRANSMISSION RECORD**  
**Division of Blood Applications**  
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**To:** Cheryl Chamberlain Roscher, Fenwal, Inc.  
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**Date:** 23-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. To address safety and compatibility, please provide any risk assessment or testing data for leachables that was performed.
2. Please provide information about the bioburden of the container or port as well as the acceptance criteria and the action and alert limits for the ---b(4)----- for the container closure.
3. Please expand on the specific uses of the different water sources in relation to product manufacturing and final product. Is WFI used in the processing and manufacturing of InterSol? In particular, please describe any final washing steps for the bags.
4. Please provide the acceptance criteria for non-viable particles, and describe your program for testing non viable particles in the classified and Laminar flow hood areas.
5. Please present documentation to support the -(b)(4)---- limit of -(b)(4)----- for InterSol solution.
6. There is no description or reference to depyrogenation of the container or closure in BB-MF -(b)(4)- section 5 or the NDA submission. Please provide information about the acceptance criteria and validation studies done to ensure the container and closure are depyrogenated.
7. In the maximum load sterilization section (Table 4.2.6-8), please describe the process and parameters. In addition, please explain why for one study (--b(4)--), the minute value is -(b)(4)- (as compared to a value of -(b)(4)- for the other two studies).

Please provide a response at your earliest convenience, preferably by COB Friday 06-Mar-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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Information provided by: Transmitted by H. Erdman Date \_\_\_\_\_

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Thank you.

Number of pages (including cover sheet): **1**