



**FACSIMILE TRANSMISSION RECORD**  
**Division of Blood Applications**  
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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:

Please indicate whether the plastics (namely PL 2411---(b)(4)-----) used in the Intersol storage bag have ever been used in a previously approved FDA container.

Please provide a response at your earliest convenience, preferably by COB Friday 13-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

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Information provided by: Transmitted by H. Erdman Date \_\_\_\_\_

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