FACSIMILE TRANSMISSION RECORD
Division of Blood Applications
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To: Cheryl Chamberlain Roscher, Fenwal, Inc.
FAX No. 847-550-2960
Telephone No. 847-550-7909
Date: 20-Jul-2009

This Fax is regarding **BN080041** that was received by the agency on 04-Aug-2008 as an original NDA for your InterSol Solution and specifically the resubmission that was received by the agency on 12-Jun-2009. The reviewers have the following comments:

1. You state that there are ---(b)(4)----- WFI loops at the Maricao facility. Please clarify whether they are hot or cold loops? If cold loops, please elaborate on the sanitization of the loops.
2. Have you mapped autoclave -(b)(4)- for hot and cold spots during the initial qualification of the vessel (i.e. empty chamber?). Please present data.
3. What is the frequency of requalifying vessel -(b)(4)-, loads, and cycle parameters?
4. You state that vessel -(b)(4)- is the only qualified vessel for InterSol, yet you validate the sterilization process of InterSol in -(b)(4)- different vessels. Please clarify.
5. For Protocol 17913, the Heat Distribution Data Table (p 19/279), you report for Study -b(4)-1227 that the maximum temperature delta is -(b)(4)-, however the highest temperature is -(b)(4)- and the lowest temperature reported is -(b)(4)-which result in a difference of 4.3. Please clarify.
6. Traditionally, BIs and TCs are placed in the -(b)(4)----------. Have you ever during your—(b)(4)-- validation, re-qualification, or routine cycles, placed probes next to the -(b)(4)-? Please explain.
7. Please list the tests (other than -(b)(4)-) and acceptance criteria (critical process parameters) needed to release the InterSol Loads.
8. Please list the common isolates identified at the Maricao facility; and how frequently you monitor and evaluate (re-assess) the bioburden at the Maricao facility.

Information provided by: Transmitted by H. Erdman Date _____
NOTE: This transmission is from a Xerox 7020 telecopier. If you do not receive a legible document, or do not receive all of the pages, please telephone us immediately at the voice number above.

9. You state that finished unsterilized units from the -(b)(4)---- of every batch are sampled for -------(b)(4)--------. Finished unsterilized units from the -(b)(4)- of each batch are sampled for ----------(b)(4)----------. Please clarify the number of units tested from the --b(4)-----and b(4) of every batch.

Please provide a response at your earliest convenience, preferably by COB Friday 31-Jul-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 _____