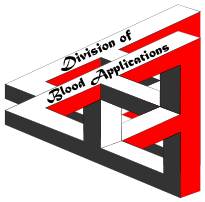

FACSIMILE TRANSMISSION RECORD
Division of Blood Applications
1401 Rockville Pike, Suite 400N, HFM-380
Rockville, Maryland 20852-1448

FAX (301) 827-2857
TEL (301) 827-3524

To: Cheryl Chamberlain Roscher, Fenwal, Inc.
FAX No. 847-550-2960
Telephone No. 847-550-7909
Date: 12-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. A teleconference was held on Aug 11, 2009, and upon rereading the Jul 30, 2009, document pertaining to Safety Reports for Platelet Additive Solutions, we are requesting a clarification on the "complaints" reporting system.

In attachment 3 of the July 30, 2009, document you include tables that list complaints "presenting a hazard that could have lead to an adverse event and have come to Fenwal's attention". The fact that you report zero complaints for InterSol, does that mean that:

1) You received no complaints at all from your customers on the usage and performance of platelets stored in InterSol, or

2) You did receive complaint reports but Fenwal Europe determined that they are either (i) unrelated to platelet transfusion, or (ii) related but not serious or unexpected, or (iii) do not meet the criteria listed under bullet 3 on page 7 of attachment 1 of the July 30, 2009, document

In case you did receive complaint reports, please provide them to FDA along with your assessment at the time of those reports.

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 _____
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.