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Date: September 8, 2009

This Fax is regarding **BN080041** that was received by the agency on Aug 4, 2008 as an original NDA for your InterSol Solution and specifically the information request fax was received by the agency on September, 3, 2009. In response to Fenwal's September 3, 2009 inquiry, FDA's rationale for requesting a post marketing monitoring of -(b)(4)------ and adverse event rate of AMICUS apheresis platelets stored in 65% InterSol/35% plasma is based on the following:

1) Certain in vitro parameters of the test platelets, essentially CD 62 at day 5 and LDH release over the 5-day storage, have shown differences with the control that may be meaningful in term of the safety of the product, related respectively to the activation of platelets and potential release of inner granule contents such as cytokines.
2) The increase in CD62, reflecting an increased activation of the platelets, along with the --(b)(4)---------- of the collected products, may indicate an activated state of the platelet post transfusion leading to adverse events in the recipient.
3) An --b(4)---------- rate in the collected product may lead to unnecessary wastage of a valuable product impacting availability.
4) Lack of market safety data on the use of InterSol as a stand-alone configuration (i.e. separate from its use in Intercept platelets) in the markets where InterSol has been commercialized. Fenwal 'zero complaint' report dated August 13 2009 pertain to complaints and adverse events related to the *malfunction* of the device or *inadequacy of labeling or instructions* rather than a tracking of reactions associated with the transfusion of the product.
5) After its potential approval, InterSol will be the first platelet additive solution to be used in the U.S. market.

Internal discussions within FDA are currently in progress to determine whether the post marketing monitoring will be a Post marketing requirement (PMR) or a Post marketing commitment (PMC).

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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