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Internal Memorandum

Date: 1-28-09
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APPROVED
By Jaro Vostal at 2:51 pm, Jul 27, 2009

To: Salim Haddad, MD
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Subject NDA 080041, Nonclinical Pharmacology and Toxicology, InterSol Platelet Additive solution, PAS III.

Background

InterSol Platelet Additive solution, also referred to as Platelet Additive Solution III (PAS III) is a buffered solution that was developed by Fenwal to support storage of S59 pathogen reduced platelets (S59 PRP). S59 psoralen is a chemical additive of a pathogen reduction process developed by Cerus Corporation with support from Fenwal (then Baxter). The S59 pathogen reduced platelets were evaluated in a US Phase III clinical trial in the year 2001 (SPRINT trial). The pathogen reduction process includes re-suspension of platelets collected by apheresis on an AMICUS instrument in a ratio of 35% plasma and 65% PASIII, addition of the S59 to the platelets, illuminating the mixture with UV A light, incubating the illuminated mixture with an absorption device to remove un-reacted S59 and storage of the cells in the plasma additive solution mixture for up to 5 days at room temperature. Fenwal is now proposing using PASIII as a stand alone additive solution for the storage of platelets without pathogen reduction processing.

Leachables from filter Inersol b(4)

During the Compliance Branch inspection of the Fenwal, Maricao, PR manufacturing facility the FDA inspector issued a 483 citation to Fenwal for not having filter validation data for b(4) Filter that was used in the PAS III manufacture. The citation stated that Fenwal failed to follow their own Protocol 30114 section b(4) Specifically the inspector requested data on filter compatibility and filter extractables with the PAS solution. The manufacturer responded by providing extractables data that was generated by the b(4) b(4) Fenwal used this data to support the application of their filter to PAS which is a buffered salt solution. Compliance branch requested an opinion from CDER expert (Edwin Melendez) on using the b(4) data to validate the Fenwal process. CDER expert concurred that this would be an acceptable practice. In addition Compliance Branch requested an opinion of a DFI National Drug Expert (Ms. Rebecca Rodriques). She also concluded that testing performed by b(4) b(4) is adequate to support Fenwal application.

Conclusion
The leachables testing performed by b(4) on the b(4) filter is acceptable to validate Fenwal application of this filter to the manufacture of their PAS solution.