Bioresearch Monitoring Inspection Results Memorandum - Intersol, June 22, 2009

MEMORANDUM
DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Biologics Evaluation and Research

DATE June 22, 2009

FROM Janet White, Bioresearch Monitoring Branch, HFM-664
Division of Inspections and Surveillance
Office of Compliance and Biologics Quality

THROUGH Patricia Holobaugh, Bioresearch Monitoring Branch Chief, HFM-664

TO Salim Haddad, Chair, NDA Committee, HFM-335

SUBJECT Bioresearch Monitoring Inspection Results
NDA: BN080041
Sponsor: Fenwal, Inc.
Product: Platelet Additive Solution III (PAS III) – InterSol Solution

SUMMARY STATEMENT
The bioresearch monitoring inspections of three clinical sites did not reveal problems that impact the data submitted in the application.

BACKGROUND
This study was conducted at three clinical sites and inspections of all three clinical investigators were performed in support of this New Drug Application (NDA). The inspections focused on specific questions concerning one study protocol with two amendments and the comparison of information from the NDA to source documents.

Study Site	Site #	Location	Number of Subjects	Form FDA 483 Issued	Inspection Final Classification
The American National Red	01	Philadelphia, Pennsylvania	Amendment 1: 29 Amendment 2: 14	No	NAI

Study Site	Site #	Location	Number of Subjects	Form FDA 483 Issued	Inspection Final Classification
Cross - Penn Jersey Region					
Blood Center of Wisconsin	02	Milwaukee, Wisconsin	Amendment 1: 39 Amendment 2: 14	No	NAI
Yale-New Haven Hospital	03	New Haven, Connecticut	Amendment 1: 33 Amendment 2: 22	Yes	VAI

PROTOCOL: FCRP-0106

STUDY TITLE: **Amendment 1:** Evaluation of PAS III (InterSol Solution) for the Storage of Platelets Up to -(b)(4)-Days
Amendment 2: Evaluation of PAS III (InterSol Solution) for the Storage of Platelets Up to Five Days Including In Vivo Study and Gamma Irradiation

SPONSOR/MONITOR ISSUES

Site 01: At this site, there was documentation showing three protocol deviations for Protocol FCRP-0106, Amendment #1, but these deviations were not included in the submission to the FDA by the sponsor.

Site 02: No sponsor or monitoring issues were noted at this site.

NOTEWORTHY INSPECTIONAL FINDINGS

The inspections at Site 01 and Site 02 revealed no deviations from applicable regulations.

Site 03: There were only a few minor problems noted. Ten of 33 subjects participating in the study were not consented properly. Eight subjects were given the incorrect version of the informed consent document, and two subjects were given a revised version that lacked the additional risk information included in the previous version. Also, the lot number of Platelet Additive Solution III was not recorded at the time of use as required by amendment 1 of the protocol.

BIMO ADMINISTRATIVE FOLLOW-UP

Inspection closeout letters were issued to the clinical investigators at all three of the study sites. Please contact me at (301) 827-6336 if you have any questions about this memo or any aspect of bioresearch monitoring.

_____

Janet White
Consumer Safety Officer

Distribution
cc: