First Committee Meeting Summary for BN080041/0 Memorandum - Intersol, September 17, 2008

INTEROFFICE MEMORANDUM

TO: BN080041/0 FILE

FROM: HEATHER ERDMAN, RPM

CBER/ OBRR/ DBA/RPMB

SUBJECT FIRST COMMITTEE MEETING SUMMARY FOR BN080041/0

SPONSOR: FENWAL, INC.

PRODUCT: INTERSOL SOLUTION

MTG DATE: 17 SEP 2008

MTG ATTENDEES:

RPM: HEATHER ERDMAN **PRESENT**

SL/CHAIRPERSON SALIM HADDAD **PRESENT**

DMPQ: PETE AMIN **PRESENT**

DMPQ: RANDA MELHAM **PRESENT**

PHARM/TOX: JARO VOSTAL **ABSENT**

STATISTICS: PAUL HSHIEH **ABSENT**

CMC (CHEMISTRY): YING WANG (CDER) **ASSIGEND AFTER THE MEETING**

Heather introduced the submission and discussed the review clock, various meetings required, the team selected and the procedures for managing an original NDA submission, since these submissions are not routinely received in this office.

Salim Haddad discussed the contents of the submission and the reviewers' responsibilities for each of these sections. This included but was not limited to: CMC data, CDER will review the chemistry portion and DMPQ will review the manufacturing controls; labeling information located in volume 5 which may still require a limited consult from DBA later in the review; and statistical data, which is contained within the 3-4 volumes of the clinical study data. Paul Hshieh explained that he needed to request for the raw data (i.e. MS Excel or SAS) to allow for him to readily analyze the data. Heather will place this request.

Salim also explained that we will need to request for an inspection since this is a new solution for platelet storage and even though the manufacturing facility has manufactured similar solutions, it is not clear whether there are unique requirements for this solution. Heather is to verify the procedure for making this request for inspection. Heather will also follow-up with Nisha Jain's assessment of PLR requirements; the last we heard from Nisha she was still considering whether this applied. Randa explained that she and Pete are to look at the sterility component of the submission and that she noticed that some manufacturing requirements were not included in the submission (i.e. description of facility and HVAC system), although she was unsure whether they are required in an NDA submission. She was to look into this. (Post meeting Randa determined that the information that she was looking for was not expected to be included in an NDA submission therefore the request was retracted).