

Memo Filing Meeting Memorandum - Intersol, October 1, 2008

INTEROFFICE MEMORANDUM

TO: BN080041/0 File
FROM: HEATHER ERDMAN, RPM
CBER/ OBRR/ DBA/RPMB
SUBJECT FILING MEETING SUMMARY FOR BN080041/0
SPONSOR: FENWAL, INC.
PRODUCT: INTERSOL SOLUTION
MTG DATE: 01 OCT 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)
PRESENT

Heather reiterated the meeting goal as detailed in the meeting request and provided an update on the e-format of the statistical data; the data has not arrived yet; a voice mail was left for Fenwal regarding status. (Update/ post-meeting: Fenwal explained that the data should arrive on Monday 06Oct08)

Salim sought clarification on what areas of the CMC section (section 4 of the submission) would be covered by which reviewers. It was determined that the DMPQ reviewers (Randa and Pete) would review sections 4.2.5 & 4.2.6 (container closure and sterilization respectively) and Ying will review the remaining sections under section 4 (i.e. sections 4.1, 4.2.1-4.2.4, 4.2.7, 4.3 and 4.4).

Salim, Ying, Randa and Pete each stated that there appears to be no issues with the submission to prevent filing. Data appears to be present; whether it is sustentative to support the claim is to be determined. Paul Hsieh had relayed to Salim before the meeting the same observation.

The following clarifications/ updates were provided:

- Heather and Salim have made the request for inspection
 - Update/ post-meeting: discussions were held with OCBQ
 - The formal inspection request to ORA will take place on ~07Jan09 for anticipated inspection to occur on ~07Mar09 (<60 days after the request)
 - The EIR should be available by the end of March2009.
 - All reviewers' questions/ issues that want to be included in the inspection should be identified by ~05Jan09. These questions should be directed to Salim and Heather; Heather in turn will communicate it to OCBQ.
- Nisha Jain still needs to consider and provide feedback regarding PLR requirements; Heather is to follow-up.
- Ying asked Salim, who was the scientific lead during the IND phase, whether CBER had made any requests for the firm to meet in this NDA submission. Salim replied that there were no special requests made.

Action Items:

- Salim is to meet with Jaro to get his assessment of his portion of the review (Update/ post-meeting: no filing issues observed; proceed with Filing letter)
- Heather is to issue a Filing Letter, after Salim's discussion with Jaro (Update/ post-meeting: completed)
- Heather is to ascertain whether an APLB reviewer will be required to join the team
- Heather is to share with the team the anticipated inspection date as soon as possible (Update/ post-meeting: completed, note above: ~mid Mar 2008; issues identified by 05Jan09)
- Heather is to provide Ying access to the electronic version of the submission. (Update/ post-meeting: An ERIC ticket has been created to allow shared access to a network drive)