

Filing Meeting Minutes, April 17, 2009 - Laviv

Participants

Donald Fink, Atm S. Hoque, Alan Ou, Lisa Stockbridge, John Thomas, Gang Wang, Janet White, Michael Yao, Bo Zhen, Craig Zinderman, Keith Wonnacott, Kimberly Benton, Raj Puri, Stephanie Simek, Mercedes Serabian, Bruce Schneider, Ashok Batra, Patrick Riggins, Agnes Lim, Yao-Yao Zhu, Randa Melhem

1. Administrative – (Lori)

- eRoom update – Lori created a folder in the Regulatory Management Staff eroom for STN 125348 and will make sure that all team members have access to that eroom.
- Briefing Dr. Midthun –Dr. Witten or Steph will provide updates to Dr. Midthun at Office Directors meetings up to the mid-cycle review date when a briefing document will be sent.
- The mid-cycle review is set for August 3rd. Lori requested that all review team members try to keep this date available, and to update their Outlook calendars well in advance with vacation dates that fall around this time.

2. Discussion regarding acceptability for filing – (All)

- Checklists – all review team members received the checklist templates except Randa Melhem who was recently assigned by DMPQ. Lori will send the template to her.
- Refuse to File Deficiencies – **No RTF deficiencies were found for any of the modules. The Review team concurred to recommend filing of the BLA.**
- Review issues – a number of issues were raised that need to be addressed during the review cycle
- Filing letter due May 5th, 2009 – Completed filing templates to be sent to Lori ASAP

3. Advisory committee (OCTGTAC) discussion – (All)

- Areas of concern for Isologen based on examination of CDRH
- Medical Devices Advisory Committee - General and Plastic Surgery Devices Panel meeting November 18-19, 2008
- Committee composition
- It was agreed that the list of panel members for the above CDRH AC meeting could provide some members for the Isologen AC, but that other members with experience in the cell therapy field would also be required.
- Sponsor notification – Not discussed at this time
- FR Notice – Not discussed at this time .

Action Items

- A monthly meeting schedule will be set up to allow for discussions of particular issues that arise during the review cycle. Separate meetings will be arranged to discuss the AC meeting agenda/questions
- Inspections

Timing for DMPQ originally planned to be in late August, but as this will be close to the mid-cycle review phase, it was suggested that the inspection occur in late September to mid-October, before the advisory committee meeting in November.

- Product reviewer credentialing – still to be done