



MEMORANDUM

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Biologics Evaluation and Research

To: 125506/0

From: Pratibha Rana

Through: Mikhail Ovanesov

Subject: First Committee Meeting Summary

Date of the Meeting: August 2, 2013

Attendees: Mikhail Ovanesov, Erica Giordano, Carla Jordan, Loan Nguyen, Ze Peng, Boris Zaslavsky, Faith Barash, Yideng Liang, Timothy Lee, Randa Melhem, Anne Pilaro, Michael Wyatt, Karen Campbell, Pratibha Rana (Absent: Nisha Jain and Iftekhar Mahmood ; they updated the status via SL and RPM)

Summary:

1. We verified that all the sections of the application are present and consistent with the Table of Contents (TOC). All the disciplines were able to find the relevant sections and could open the files.

SL, Mikhail conveyed Dr. Nisha Jain's message that the clinical section is present.

Mahmood Iftekhar notified RPM after meeting that the PK studies are present as well.

2. No further consultants are needed at this time; all appropriate consult reviewers have been notified.
3. All review committee members are assigned as appropriate.
4. All review committee members have a clear understanding of their review responsibilities.
5. All review committee members have received the appropriate documents or electronic links.
6. We discussed about an AC meeting is likely but will be discussed further in the future meetings.

7. We confirmed the review schedule and all future meeting dates were sent to the review committee.
8. We confirmed that there are no potential issues found during the early review, including identification of data sets submitted incorrectly, use of data standards, problems encountered opening data tables, or absent datasets at this time.
9. We confirmed that pre-approval inspections may be necessary.
10. We will be identifying BIMO sites requiring inspection before the filing meeting.

END.