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T910.15: First Committee Meeting Agenda/Summary

Application number: BLA 125612/0
Product name: Human Fibrinogen
Proposed Indication: Treatment of acute bleeding episodes (b) (4) in adult and pediatric patients with congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia
Applicant: Octapharma
Meeting date & time: July 7, 2016, 2:00 pm– 2:30 pm EDT
Committee Chair: Ze Peng, PhD
Meeting Recorder: Lorraine Wood, MS, MLS(ASCP)^{CM}

Attendees:

Discipline	Name [with credentials (not title)]	Attended meeting?
Regulatory Project Manager (RPM)	Lorraine Wood, MS, MLS(ASCP)^{CM}	Y
Chair & CMC reviewer	Ze Peng, PhD	Y
Clinical Reviewer	Victor Baum, MD	Y
Clinical Pharmacology Reviewer	Iftekhar Mahmood, PhD	N
Non-clinical Pharmacology & Toxicology Reviewer	Pending	
OCBQ/DMPQ Reviewer	Randa Melhem, PhD	Y
OCBQ/DMPQ/PRB Reviewer	Jacqueline Glen	N
Statistical Reviewer of non-clinical and clinical data	Shuya (Joshua) Lu, PhD	Y
Postmarketing Safety Epidemiological Reviewer	Faith Barash, MD, MPH	Y
OCBQ/APLB Reviewer	Kristine Khuc, PharmD	Y
OCBQ/BIMO Reviewer	Anthony Hawkins	Y
OCBQ/DBSQC Regulatory Coordinator	Karen Campbell	Y
OCBQ/DBSQC Reviewer	Tao Pan, PhD	Y
OCBQ/DBSQC Reviewer	Grainne Tobin	Y
OCBQ/DBSQC Reviewer	Obinna Echeozo	Y
Consult Reviewer(s)	None	
Other Attendee(s)		
OBRR/DHRR Deputy Director	Mahmood Farshid, PhD	Y
OBRR/DHRR	Michael Kennedy, PhD	Y
OBRR/DHRR/LH Acting Branch Chief	Timothy Lee, PhD	Y
OBRR/DHCR/HPRB Branch Chief	Mitchell Frost, MD	Y
OBRR/RPMS Branch Chief	Iliana Valencia, MS	Y

Discipline	Name [with credentials (not title)]	Attended meeting?
OBE/DB/TEB Team Lead	Renee Rees, PhD	Y

Discussion Summary:

1. *The review committee consists of a reviewer for all appropriate disciplines, except for non-clinical pharmacology/toxicology and for which the reviewer assignment request is still pending. (Request submitted on July 5, 2016).*

2. *This submission is on a standard review schedule, which has a 12-month review timeline.*

3. *This product is categorized as a PDUFA V product.*

4. *Filing meeting date confirmed for July 27, 2016. Tentative schedule of the Mid-Cycle and Late-Cycle meeting was distributed to the review committee on June 23, 2016.*

5. *This submission was not granted orphan designation.*

6. *This submission triggers PREA; the sponsor submitted a request for a deferral.*

7. *An Advisory committee is not indicated for this submission.*

8. *There are no potential issues discovered at this time that will affect the review of this submission.*

9. *Dr. Peng and Dr. Melhem discussed the GMP pre-license inspection issue for this submission, and agreed to waive this inspection at this time.*

10. *Mr. Hawkins from Bioresearch Monitoring (BIMO) Branch stated that there are multiple clinical sites, including two in the United States, and sites in India, the United Kingdom, and Iran. After discussion with Dr. Baum, the sites identified for the BIMO inspection will be in India and the United Kingdom.*

11. *The review committee was reminded that a filing checklist will need to be completed for each appropriate discipline prior to the filing meeting. The regulatory project manager will send the review committee an email reminder to complete the filing checklist and upload it into the SharePoint folder two days prior to the filing meeting.*