Informal Teleconference Summary

Application type and number:	BLA 125661.0
Product name:	JIVI (Recombinant B-domain deleted human coagulation factor VIII conjugated with polyethylene glycol (PEG) (BAY 94-9027))
Proposed Indication:	Control and prevention of bleeding episodes and for surgical & long-term prophylaxis in patients with hemophilia A
Applicant:	Bayer Healthcare, LLC
Meeting date & time:	March 9, 2018 [1:00PM – 1:30PM]
Committee Chair:	Zuben Sauna, PhD
RPM:	Candace Jarvis Kay Owosela
Purpose:	To get clarification about Information Request #18 regarding updating three bleeding events.

FDA Participants

Lin Huo, PhD, OBE/DB/TEB
Candace Jarvis, OTAT/DRPM
Megha Kaushal, MD, OTAT/DCEPT/CHB
Kay Owosela, MSc. OTAT/DRPM

Bayer Participants

Jim Cassaday, Data Management
Monika Maas Enriquez, Clinical
Alex Frumin, Data Management
Jasmine Kang, Labelling
Chi Li, Regulatory
Lisa Michaels, Clinical
Michelle Meng, Regulatory
Kapil Saxena, Clinical
Rene Walsch, Study Management
Maria Wang, Statistics

Discussion Summary:

1) In replacement of updating the database, Bayer agreed to provide validated and updated primary and secondary efficacy results including the three bleeding events manually.
2) FDA also agreed to postpone the due date for this information request from Wednesday, March 14, 2018 to Monday, March 19, 2018.