Review Update Meeting
STN: 125426/0
Coagulation Factor IX (Recombinant)
Cangene Corporation (Emergent BioSolutions, MB)

January 29. 2015
1:30 a.m. to 3 p.m.
White Oak Building 71
Room 1208/1210

Meeting Agenda:

Review Team Introductions
Chair Person: Dr. Chava Kimchi-Sarfaty
Clinical Reviewer: Dr. Irwin Feuerstein
CMC Product Reviewer: Dr. Katagiri Nobuko
Clinical Pharmacology: Dr. Iftekhar Mahmood
Toxicology Reviewer: Dr. Anne M. Pilaro
Postmarketing Safety Epidemiological Reviewer: Dr. Bethany Baer
Statistical Reviewer: Dr. Chunrong Cheng
DMPQ Reviewer: Rabia Ballica
OCBQDBSQC Representative: Karen Campbell
OCBQ/DBSQCReviewer: Dr. Lokesh Bhattacharyya
OCBQ/DBSQC Reviewer: Hyesuk Kong
Regulatory Project Manager: Edward Thompson

Non-Review Team members
OBRR Director, Dr. Jay Epstein
OBRR Deputy Director, Dr. Ginette Michaud
OBRR Associate Director, Joe Giglio
OBRR Associate Director, Dr. Mark Weinstein
OBRR/DHRR Director, Dr. Basil Golding
OBRR/DHCR Division Director, Dr. Paul Mintz
OBRR/DHCR Deputy Division Director, Dr. Howard Chazin
OBRR/DHRR, Laboratory of Hemostasis Acting Chief, Dr. Timothy Lee
OBRR/DHCR, Clinical Review Branch Chief, Dr. Nisha Jain
OBE/DE Deputy Director, Dr. Christopher Jankosky
OBE/DB Mathematical Statistician Team Lead, Dr. Renee Rees
OCBQ/DBSQC, Laboratory of Analytical Chem. & BRP Chief, Dr. Lokesh Bhattacharyya
OCBQ/DMPQ Director, John Eltermann
OCBQ/DMPQ, Branch I Chief, Carolyn Renshaw
OCBQ/DIS Bioresearch Monitoring Branch Chief, Patricia Holobaugh
OBRR, Regulatory Project Management Chief, Iliana Valencia

Introduction of application, including important dates

Summary Description of Product: Coagulation Factor IX (Recombinant) used to control and the prevention of bleeding episodes and peri-operative management in patients with hemophilia B.

Receipt Date: 4/6/2012
Filing Date: 5/25/2012
1st Mid-Cycle Meeting: 8/30/2012
CR letters issued: 2/1/2013 and 7/29/2014

1. Important Goal Dates

   a. Tentative Review Completion Goal Date according to GRMP (T-minus 14): 4/15/2015

   b. Action Due Date: 4/29/2015

2. Each reviewer is expected to document their review progress and discuss the relevant content of the submission and present an overview.

   a. Identifying any information requests.

   b. Identifying issues that could prevent approval.

   c. Identifying any problems.

   d. Developing a clear plan for addressing any problems.

3. Identification of need for additional input from review team or through additional consults.

4. Ensure PeRC presentation date is scheduled, the PeRC forms have been submitted.(2 weeks before PeRC meeting), and clinical reviewer has addressed waiver/deferral of PREA decision.

5. Determining whether PMCs are needed or REMS issues.
   Dr. Baer commented no PMRs or REMS at this time. Based on Dr. Jain's suggestion, Cangene will be requested to perform a field study to evaluate the ability of clinical laboratories to monitor recovery of their product in patients' plasma (post-infusion monitoring) using their routine assays and reagents.

6. Making any recommendations for review to go to an advisory committee if necessary.
   No BPAC

7. Discuss Pending Lot Release requirements: samples and test protocols submissions and the lot release testing plan.
   Karen Campbell stated lot testing will commence in mid-February for additional two lots manufactured post June 2014.

8. Ensure UNII Code process is initiated.
   RPM submitted request on January 29, 2015

9. Determine NDC assignments to product/packaging
   RPM contacted applicant for NDC assignments. Cangene responded and the NDC assignments with the labels will be submitted by 2/27/2015

10. Determine proper name convention.
    PNR letter has been submitted and another PNR will be performed prior to issuance of the next final action letter.

11. Pending Labeling Issues – Package insert revisions and are Carton/container affected by change.
    Labeling revisions and review are ongoing at this time.

12. Additional Meetings Needed (Labeling, PeRC)
    None required at this time. PeRC is complete. Clinical reviewer expects that future labeling meeting are likely, details to be determined.

Drafted: Edward Thompson
Revised: Chava Kimchi-Sarfaty
Anne M. Pilaro