RECORD OF TELEPHONE CONVERSATION

Submission Type:	BLA Original Submission ID: 125426/0
Office:	OBRR
Product:	Coagulation Factor IX (Recombinant)
Applicant:	Cangene Corporation (Emergent BioSolutions, MB)
Telecon Date / Time:	February 20, 2015/ 1:30 p.m. Initiated by FDA? Yes
Telephone Number:	(b)(4)
Communication Category:	1. Advice
Drafted:	Edward Thompson
Revised:	Chava Kimchi-Sarfaty
	Nobuko Katagiri

Telecon Summary: to present the deficiencies in Cangene's response regarding the (b)(4)

FDA Participants:
Chava Kimchi-Sarfaty, PhD, Research Chemist, OBRR/DHRR/LH
Nobuko Katagiri, PhD, Research Biologist, OBRR/DHRR/LH
Edward Thompson, OBRR/IO

Non-FDA Participants:
Cangene Corporation
Laura Saward, PhD, Vice President, Winnipeg R & D
Derek Toth, Director, Bioanalytical & Quality Sciences
Shelly Buhay, Bioanalytical Specialist
Evelyn Van der Hart, Sr. Manager, R & D Process Development
Christine Hall, PhD, Director, Clinical Research
Matthew Cromie, Sr. Manager, Clinical Research
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Steve McGregor, Director, Regulatory Affairs
Deanne Sutherland, Specialist, Regulatory Affairs

Telecon Body:
CMC Reviewer, Chava Kimchi-Sarfaty requested a teleconference with Emergent BioSolutions (formerly Cangene), to discuss the (b)(4)

FDA discussed the 483 deficiencies that led to the issuance of the CR letter issued in July 2014. Partial assessment was provided earlier by Cangene was presented in tables and graphs, using also statistical tools that are not acceptable according to CBER statistician.

The FDA requests all raw data without statistical tool. All raw data will be submitted in a table format for the FDA to review. The raw data requested would include characterization and release testing results of (b)(4) drug product of lots that were released and those that were not released, but Cangene has data on them. FDA requested Cangene not to include any statistical analysis with the data table.

FDA discussed other observations of the 483 and Cangene's response:
For observation #2, Cangene provided a partial response to the procedure for invalid data. Cangene did not mention the implementation of specific instructions regarding invalidated assay in the specific SOPs of the assays run at their laboratories or the training that will accompany the changes in the governing documents.
For observation #5, FDA request stability testing and data on expired and open container vials of the product. Although the assessment of the QC laboratory was performed, Cangene did not report on stability tests that were executed such as expiration dates after opening or bench stability during testing. Cangene should explain the rationale why their stability testing will include materials that are kept for longer than (b)(4) at the facility. Moreover it is not clear which reagents are listed as "critical reagent."
FDA reminded Cangene of their request to provide the validation of (b)(4) for the worse case condition and the SOP of qualifying a (b)(4).

Cangene agreed to provide the requested information to the FDA by February 27, 2015.