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:	March 25, 2015 at 2 p.m. Initiated by FDA? Yes
Telephone Number:	(b)(4)
Communication Category:	1. Advice
Drafted:	Edward Thompson
Revised:	Chava Kimchi-Sarfaty

Telecon Summary: Discussion regarding (b)(4) lot qualification SOP

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

Non-FDA Participants:
Cangene Corporation
Allison Kennedy, Manger, Regulatory Affairs
Evelyn Van der Hart, Sr. Manager, R & D Process Development
Shelly Buhay, Bioanalytical Specialist
Derek Toth, Sr. Director, Bioanalytical & Quality Sciences
Laura Saward, Vice President Winnipeg R & D
Poly Shinkarik, Manager, Project Management
Lori Soluk, Specialist, QA Validation
Steve McGregor, Director Regulatory Affairs

Telecon Body:
FDA requested the conference to discuss the (b)(4) qualification SOP and proposed revisions.

FDA requested the following modifications to be included in the SOP for the qualification of (b)(4) lots used for the bench (lab) scale (b)(4). The current version of the SOP (RAW-065-01.6) is not complete.
1. FDA requested to add (b)(4) testing to the analysis panel.
2. FDA requested to add language to provide guidance and improve the clarity of criteria for release.
3. FDA requested to add the test methods for:
- (b)(4)

4. FDA requested to (b)(4)

Cangene will have the additional data available in the (b)(4) process.

Cangene will submit the agreed upon changes to the FDA as an amendment to the application to satisfy the CR letter issued in 2014 by Friday (3/27/15).