RECORD OF TELEPHONE CONVERSATION

Submission Type: BLA Submission ID: 125426/0 Office: OBRR

Product:
Coagulation Factor IX (Recombinant)

Applicant:
Cangene Corporation

Telecon Date/Time: 29-Jul-2014 03:30 PM Initiated by FDA? Yes

Telephone Number: (b) (4) Access code: (b) (4)

Communication Categorie(s):
1. Other - Rationale for Complete Response Letter

Author: LT THOMAS J. MARUNA, USPHS, MSc, MLS(ASCP)^{CM}

Telecon Summary:
To provide the FDA's rationale for issuing a Complete Response to this original application.

FDA Participants:
Chava Kimchi-Sarfaty, CMC Reviewer
Nisha Jain, Chief, Clinical Review Branch
Thomas J. Maruna, Regulatory Project Manager (acting on behalf of Edward Thompson)

Non-FDA Participants:
Allison Kennedy – Manager, Regulatory Affairs
Steve McGregor – Director, Regulatory Affairs
Angela Dyer – Director, Regulatory Affairs
Deanne Sutherland – Specialist, Regulatory Affairs
Evelyn Van der Hart – Manager, R & D Process Development
Derek Toth – Director, Bioanalytical & Quality Sciences
Poly Shinkarik – Manager, Program Management
Lori Soluk – Specialist, QA Validation
Jeff Broadfoot – Senior Director, Quality
Laura Saward – Vice President, Winnipeg R & D
Sean Kirk – SVP, Operations, Biosciences Division

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:
CMC Reviewer, Chava Kimchi-Sarfaty requested a teleconference with Emergent BioSolutions (formely Cangene), to discuss the FDA's rationale for issuing a complete response (CR) letter to original biologics license application 125426/0, with the intention of covering the deficiencies outlined in the CR letter.

Emergent BioSolutions indicated that they had not reviewed the letter entirely in advance of the teleconference as it had been received earlier that afternoon; therefore, explicit deficiencies were not discussed. Emergent BioSolutions was informed that any specific issues could be addressed and further discussed through the request for a type-C meeting or teleconference with FDA in advance of providing their formal response to the CR letter.

Cangene expressed the following based upon their cursory review of the CR letter:

1. Many of the deficiencies identified in the CR letter had been addressed in amendments submitted to the BLA during the May – June, 2014 review timeline. The FDA responded that these amendments contained a substantial amount of information and could not be reviewed within the milestone constraints; further, designation of a Major Amendment (MA) was not feasible – Emergent BioSolutions's responses to 483 items could not be provided within sufficient time for review despite the extension granted by a MA. However, those deficiencies that have been responded to in earlier amendments do not have to be resubmitted; Emergent BioSolutions's response should include a cross reference to the amendment intended to address the specified deficiency.

2. Emergent BioSolutions requested clarification concerning the deficiency outlined in comment 1c of the CR letter (i.e. "*Please provide reports on complete characterization of three consecutive lots of rFIX* (b) (4) *Drug Product (DP) manufactured since June 2014*"). Emergent BioSolutions stated that the (b) (4) from the DP; therefore, (b) (4) of the DP should not be necessary. The FDA stated that characterization of (b) (4) DP should be included in the formal response to the CR letter.

3. Emergent BioSolutions inquired about the status of clinical review. The FDA informed Cangene the review clock on the BLA has been stopped pending a formal and complete response to the CR letter; therefore, at this time clinical review is complete and only new information contained in Cangene's response will be reviewed.

4. Emergent BioSolutions requested clarification concerning the class of response that would be considered for the intended resubmission (i.e. Class-1 resubmission [2 month PDUFA goal date] or Class-2 resubmission [6 month PDUFA goal date]). The FDA could not comment on the resubmission class at this time; this designation will be dependent upon the volume and content of the resubmission.

END