Summary of Teleconference and e-mail Communications May 27th through 29th 2014

Because both May 1st teleconference and subsequent associated e-mail communications (*refer to May 1st teleconference minutes-uploaded in EDR*) and May 20th amendment submission to the BLA file did not provide any sufficient information to resolve the CCIT* method validation issue of the diluent pre-filled syringes, additional information was requested through an e-mail May 27th (*Refer to Attachment 1*). The firm's response was received May 28th via an e-mail (*Refer to Attachment 2*). The following day in the morning (May 29th), I received a phone call from Steve McGregor (*Director, Regulatory Affairs Biosciences Division, Emergent Biosolutions*). The information in the firm's May 28th e-mail and CCIT validation protocol were discussed. During the discussions, I indicated firmly that the validation study still needed to be completed and associated results needed to be submitted to the BLA file latest by July. In response, the firm decided on the same day of the discussion to conduct an expedited validation study and submit the validation protocol along with its associated data to the BLA file by July 4th (*refer to Attachment 3 and June 3rd amendment submitted to the BLA file*).

*CCIT: Container closure integrity testing

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