

From: Ballica, Rabia
To: ["smcgregor@ebsi.com"](mailto:smcgregor@ebsi.com)
Cc: [Trout, Deborah](#); [Renshaw, Carolyn](#)
Subject: I need additional information
Date: Tuesday, May 27, 2014 7:36:00 PM

Hi Steve,

If I remembered correctly, you mentioned during May 1st teleconference that (b)(4) had been conducting CCIT on the diluent batches shipped from (b)(4) to US, but I cannot locate any test results from (b)(4) in any of your responses. Please provide a summary of results from the CCIT testing performed on those batches by (b)(4). I also need a summary of stability data for only sterility testing at release, expiry and other stability time points (where sterility testing is performed such as month 3 and 9 you mention in the BLA submission).

In addition, could you please verify the following information (that is provided in your BLA submission and its amendments):

- (b)(4) performs only release testing (including sterility and other release tests listed in your BLA submission) on the (b)(4) pre-filled syringes
- (b)(4) does not perform any CCIT on the (b)(4) pre-filled syringes
- (b)(4) (syringe supplier) performs (b)(4) testing on syringes (not on the (b)(4) pre-filled syringes from (b)(4)) before being shipped to (b)(4) for use in diluent manufacturing
- Cangene performs CCIT testing on the (b)(4) pre-filled syringes (on shipped pre-filled syringes by (b)(4))
- (b)(4) performs stability testing on diluent lots (not shipped)

Please provide your response to the items listed above by the end of (b)(4). Let me know if you have any questions.

Thanks

Rabia