

From: Ballica, Rabia
To: ["Steve McGregor"](#)
Cc: [Trout, Deborah](#); [Renshaw, Carolyn](#); [Eltermann, John](#)
Subject: RE: BLA STN 125426--Validation of CCIT for (b)(4) Syringes
Date: Thursday, May 29, 2014 4:03:00 PM

Hi Steve,

Thanks for your quick response following our discussion in this morning. Timeline is acceptable, but try to submit the validation report (including validation protocol and results) by the end of June, because action due date for your BLA is July 29th.

You also asked me this morning whether you needed to transfer your validated CCIT method to (b)(4). The answer is yes, because (b)(4) needs to use a validated CCIT method for the (b)(4) pre-filled syringes.

Please also remember submitting all those e-mail submissions in an amendment to your BLA file.

Let me know if you have any questions.

Thanks

Rabia

From: Steve McGregor [mailto:smcgregor@ebsi.com]
Sent: Thursday, May 29, 2014 3:09 PM
To: Ballica, Rabia
Cc: Trout, Deborah
Subject: BLA STN 125426--Validation of CCIT for (b)(4) Syringes

Dear Rabia,

In follow up to our telephone discussion of May 29, 2014 concerning the CCI testing for the (b)(4) Diluent Syringes, we have conducted an internal review of the activities and timelines to see if we could expedite the validation of the CCI test.

In our May 20th response to the IR for the CCIT validation (BLA eCTD sequence 0028) we committed to submitting the results of the CCIT validation as a Post Marketing Commitment on or before September 30th, 2014. Upon further discussions with the 3rd party vendor responsible for generating suitable positive control syringes ((b)(4)) and our internal validation group, we intend to bring the CCIT of syringes in-house and commit to completing the CCIT validation, and to make the data available to the BLA, on or before the end of the week of July 4th, 2014.

Please confirm that this timeline is acceptable or let me know if you require any additional information. Upon receipt of your feedback we will submit an amendment to the BLA to document these new timelines and retract the request for a PMC for the CCIT validation.

Kind regards

Steve

Steve McGregor
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