

From: Bridgewater, Jennifer

Sent: Sunday, June 12, 2016 8:33 PM

To: 'Godshall, Colleen E.'

Cc: Margaretten, Nadine; Bollen, MA (Mirko); Bridgewater, Jennifer

Subject: RE: BLA 125592:(b) (4) Method Transfer to CBER

Dear Colleen –

Thank you for your email reminder. I sincerely apologize for the delay. We propose a meeting on June 23, 2016 from 10 – 11 am. An alternate date is June 20, 2016 from 10 -11 am. Please note that the primary information necessary for the (b) (4) method transfer lies in documentation and sharing of your standards, controls, and critical reagents. We request that you please provide the following information with respect to the method transfer in an amendment to your BLA. If previously provided in the BLA or IND, please specify location.

- Your current method, including any optimization protocols, worksheets used, tablet dissolution procedures, and any other additional information necessary for performance of the assay
- A detailed description of all standards, controls, and reagents used in performance of the assay, including commercial source (if applicable) and method of preparation
- Information on all equipment used including relevant settings and controls
- (b) (4) type/source
- Your method of analyzing results, including any programs used
- Your complete method validation study and report

With respect to your previous questions; we have the following preliminary responses:

1. We recommend a formal transfer, which includes a protocol and report.

We have not determined this type of transfer will be performed.

2. Would CBER allow representatives from (b) (4) to come to the laboratory, and provide face to face training?

We do not anticipate a need for representatives from (b) (4) for face to face training.

3. Material logistics
 - a. Critical reagents -
 - b. Transfer material. The control sample is suitable for the transfer, but process validation batches are available for the transfer.

We will discuss the preferred sample for transfer during the meeting. The address for submission of critical reagents will be provided when required.

4. Timing for the transfer (establish milestones and target dates)

If your critical reagents and transfer material are not readily available at any time during the review process; please advise. Milestones and target dates will be discussed during the teleconference.

Thank you,

Jennifer

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