

From: Morris, Nevitt
To: paul.gil@sparktx.com; jim.wang@sparktx.com
Cc: Morris, Nevitt
Subject: BLA 125610 Information Request Shipping Validation 9.20.17
Date: Wednesday, September 20, 2017 4:52:57 PM
Attachments:
(File Attachment comment)
image001.png

Hi Jim and Paul:

Please response to the following Information Request by next Wednesday, September 27, 2017 COB.

CMC telecon on September 19, 2017

FDA Comments:

We agree with the shipping validation plan sent by e-mail on September 15, 2017 to Nevitt Morris, with the following modifications:

1.

Please provide addition details in the validation study reports regarding how the drug product is packaged and handled at (b) (4). It would be very helpful if you could please provide pictures (or photographs) of the packaging configuration(s) that occur at (b) (4) (e.g., the placement of product and diluent vials in a tray, the tray in the carton, and the carton in the sealed pouch). Please provide pictures of the packed drug product in the shipping container.

2.

We understand that you have proposed 3 shipments for the Drug Product and Diluent shipping validation. Please confirm that you will separate each of the shipments by at least one day.

3.

Please provide justification for not including your validated potency test (i.e., (b) (4) potency assay) as part of the testing plan for Drug Product shipping validation.

4.

You said at the telecon that you plan to submit a complete shipping validation report in November. Please provide us a date when the shipping validation data will be submitted to the BLA.
Thanks and please acknowledge this email Information Request.

Nevitt

Nevitt Morris

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