

Davidson, Mark

From: Davidson, Mark
Sent: Monday, March 20, 2017 11:13 AM
To: 'Rizwana Sproule'
Subject: RE: BLA 125643-YESCARTA- DMPQ Information Request

Dear Dr. Sproule,

We have the following request for information:

1. Please provide the address and FEI (FDA Establishment Identifier) number of the (b) (4), the manufacturer of the (b) (4) Vector.
2. Does (b) (4) manufacture the (b) (4) Vector under a contract with Kite Pharma Inc.?

Thank You

Mark L. Davidson, RHIA
Regulatory Project Manager
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From: Rizwana Sproule [<mailto:RSproule@KitePharma.com>]
Sent: Thursday, March 02, 2017 11:50 AM
To: Davidson, Mark
Cc: Alex Babayan; Nadia Agopyan
Subject: RE: Receipt of final module for BLA 125643-YESCARTA

Dear Mark

Hope you are doing well. We plan on submitting the final modules by 31 March 2017. The CMC module may be submitted slightly earlier but I will notify you when we make the submissions.

Hope you have a great day.

Regards

Rizwana

Rizwana F Sproule, Ph.D.
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From: Davidson, Mark [<mailto:Mark.Davidson@fda.hhs.gov>]
Sent: Thursday, March 2, 2017 8:06 AM
To: Rizwana Sproule <RSproule@KitePharma.com>
Subject: Receipt of final module for BLA 125643-YESCARTA
Importance: High

Dear Dr. Sproule,

Can you please confirm when you think the final module will be submitted to the FDA to complete the rolling BLA?

Thanks

Mark L. Davidson, RHIA
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