

Davidson, Mark

From: Davidson, Mark
Sent: Monday, August 14, 2017 2:28 PM
To: 'Rizwana Sproule'
Cc: 'Alex Babayan'; 'Nadia Agopyan'
Subject: Kite Pharma BLA CMC IR 08/14/2017

Importance: High

Dear Dr. Sproule,

We have the following request for CMC information:

1. Please submit available stability data for (b) (4) vector lots (b) (4) (described in Table 1 of Amendment #46). Please also provide a testing schedule for stability studies on these lots.
2. Please describe what method was used for cell viability testing on Patient lots (b) (4), described in Tables 5 and 6 of Amendment #46.
3. Please provide an electronic copy of label on the (b) (4) vector (b) (4).

Please try to respond by August 18, 2017.

Thanks

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