

From: Paul Gil
To: Morris, Nevitt
Cc: Jim Wang
Subject: RE: BLA 125610 SPARK, Information Request DMPQ 9/25/17
Date: Monday, September 25, 2017 1:26:10 PM
Attachments: image002.png

(File Attachment comment)

Hi Nevitt,
I acknowledge receipt of this IR.
Regards,
Paul

From: Morris, Nevitt [mailto:Nevitt.Morris@fda.hhs.gov]
Sent: Monday, September 25, 2017 1:03 PM
To: Jim Wang <jim.wang@sparktx.com>; Paul Gil <Paul.gil@sparktx.com>
Cc: Morris, Nevitt <Nevitt.Morris@fda.hhs.gov>
Subject: BLA 125610 SPARK, Information Request DMPQ 9/25/17
Importance: High

Hi Jim and Paul:

Please respond to the following DMPQ Information Request by October 16, 2017.
Please acknowledge receipt of this email Information Request.

DMPQ IR due October 16, 2017

1.
Please clearly indicate container closure integrity test (CCIT) method (s) used for the drug product and diluent container closure (CC) systems (used for PPQ lot and commercial manufacturing). Please also indicate CCIT conditions along with acceptance criteria for testing. If CCIT method used for CC systems stored at (b) (4) (such as CCIT used for stability studies) is different than that for CC systems stored (b) (4), please ensure that CCI testing conditions and acceptance criteria are indicated for each of the test methods used.

2.
We cannot locate validation report (s) for CCIT method (s) used in the integrity evaluation of the product and diluent CC systems - stored at (b) (4). Please provide those validation reports (including protocol and data). Please ensure that CCIT method validation (s) are conducted with voretigene

neparovec drug product and/or its diluent under appropriate conditions that represent actual manufacturing conditions (such as with CC systems used in PPQ / commercial lot manufacturing and stored at (b) (4) etc.).

3.

Please also compare the (b) (4) values used at (b) (4) filler with the data presented in the (b) (4) (tr-2010-014.pdf which is provided in the submission).

(Unsigned signature field (Click to sign)) Signature field is unsigned

Thanks,

Nevitt

Nevitt Morris

Nevitt
Morris,
RN,
BSN,
BS
Consumer
Safety
Officer
Office
of
Tissues
and
Advanced
Therapies
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