From:	Riggins, Cindy
To:	Giordano, Erica
Cc:	Ahmed, Narin; Patel, Manisha
Subject:	RE: BL 125646 DBSQC Information Request
Date:	Friday, April 21, 2017 11:18:39 AM
Attachments:	image001.png 7008911_ANSW_MC_840_11 .pdf AQP018 Bioburden (b) (4) Method Qualification - CTL-019 (murine)....pdf TRPT-17-026 Sterility testing of CTL019 (murine) HIV-1 vector in accorda....pdf TRPT-17-025 Qualification report for endotoxin testing of CTL019 (murine....pdf (b) (4) mycoplasma (b) (4) qualification plan.pdf VP68208A (AS5135).pdf
Sensitivity:	Confidential

Dear Erica,
Attached is the response document to the CMC information request received on April 7, 2017 (7008911_ANSW_MC_840_11). There are five associated appendices for these responses so you will receive 6 documents total. We will follow up with a BLA amendment through the gateway of these documents.
Take care,
Cindy

From: Giordano, Erica [mailto:Erica.Giordano@fda.hhs.gov]
Sent: Wednesday, April 19, 2017 10:50 AM
To: Riggins, Cindy; Patel, Manisha
Cc: Ahmed, Narin
Subject: RE: BL 125646 DBSQC Information Request
Sensitivity: Confidential

Hi Cindy,

Thank you for asking. Yes it is acceptable to provide my e-mail address to (b) (4) as a contact to send the SOPs.

Thanks again,
Erica

From: Riggins, Cindy [mailto:cindy.riggins@novartis.com]
Sent: Wednesday, April 19, 2017 10:24 AM
To: Giordano, Erica; Patel, Manisha
Cc: Ahmed, Narin
Subject: RE: BL 125646 DBSQC Information Request
Importance: High
Sensitivity: Confidential

Dear Erica,
Regarding Question 4 below, (b) (4) would like to provide the requested SOPs directly to FDA as they do not provide SOPs to clients except as part of on-site visits or audits. Would this be acceptable and if so, should I provide them your email address as the appropriate contact?

Thank you,
Cindy

From: Giordano, Erica [mailto:Erica.Giordano@fda.hhs.gov]
Sent: Friday, April 07, 2017 9:35 AM
To: Patel, Manisha
Cc: Riggins, Cindy; Ahmed, Narin
Subject: BL 125646 DBSQC Information Request
Sensitivity: Confidential

Good morning,

Please see the information request below and provide a response by noon on April 21, 2017. As usual please provide a response by e-mail and follow up by submitting the information as an official response to the BLA.

Vector Substance and Product

1. Please provide differences between the manufacturing process of (b) (4) vector (used in (b) (4) qualification study) and CTL09 vector substance.

2. Please provide a report for method suitability study for (b) (4) testing using (b) (4) . Please include batch numbers, back titration results and test volume inoculated in the report.

3. According to (b) (4) qualification report (number AQP-008), the positive product control (PPC)% recoveries for vector substance and vector product are (b) (4) and (b) (4), respectively which are on lower and higher end of (b) (4) recovery range. CBER requests re-qualifying (b) (4) method for both vector substance and vector product using a series of dilution below Maximum Valid Dilution (MVD) and choosing a dilution that provides PPC recoveries closest to (b) (4).

4. For (b) (4) validation study, AE51SP.300200PSQ.BUK, please provide (b) (4) protocol no. (b) (4)

CTL019 Final Product

5. For mycoplasma validation study,VR68208 (b) (4)

    a. Please provide the validation protocol for VR68208 (b) (4) including the procedure for DNA extraction from the test samples; and

    b. Please clarify if GC/reaction in Table 12-1 “Summary of limit of detection” is genomic copies per PCR reaction or inoculated copies during DNA extraction.

Please confirm receipt and let me know if you have any questions.

Thank you,

Erica Giordano
Regulatory Project Manager
Center for Biologics Evaluation and Research
Office of Tissues and Advanced Therapies

U.S. Food and Drug Administration
Tel: 240-402-8298
Erica.Giordano@fda.hhs.gov