From: Riggins, Cindy
To: Giordano, Erica; Patel, Manisha
Cc: Ahmed, Narin
Subject: RE: BL 125646 OCBQ/DBSQC Information Request
Date: Thursday, March 23, 2017 12:52:00 PM
Attachments: 7008911_ANSW_MC_840_6.pdf
Sensitivity: Confidential

Dear Erica,
Attached are the responses to the OCBQ/DBSQC information request received on March 9, 2017. There are a total of 13 documents: one ANSW document and 12 appendices. The ANSW document is attached to this email. The attachments will come in 4 separate emails. We will follow up with a BLA submission through the gateway of these documents.
Take care,
Cindy

From: Giordano, Erica [mailto:Erica.Giordano@fda.hhs.gov]
Sent: Thursday, March 09, 2017 12:34 PM
To: Patel, Manisha
Cc: Riggins, Cindy; Ahmed, Narin
Subject: BL 125646 OCBQ/DBSQC Information Request
Sensitivity: Confidential

Good afternoon,

Please review the information request below and provide a response by noon on March 23, 2017.

Vector Substance and Product
Please provide (b) (4) s qualification for (b) (4) methods for vector substance and vector product, respectively, to include type of media, conformance lot numbers, incubation conditions and duration, and back titration results of positive controls to show suitability of (b) (4) assays for the intended purpose.

Please provide (b) (4) qualification reports for both vector substance and product including the batch numbers tested, maximum valid dilution (MVD), positive product control (PPC) % recoveries and your selected testing dilution.

Please provide (b) (4)
assay (report no: AE51SP.300200PSQ.BUK).

CTL019 Final Product
Please provide endotoxin qualification report for CTL019 Final Product including the batch numbers tested, MVD, PPC % recoveries and your selected testing dilution.

Please provide an estimated timeframe of evaluating (b) (4) sterility test method using in house and slow growing stressed environmental isolates.

CBER expects Limit of Detection (LOD) study be performed on a variety of microorganism

including indicator microorganisms stated in (b) (4) and environmental isolates from manufacturing facility during a validation study. Please provide the rationale for using only four microorganisms for LOD study during evaluation of (b) (4) sterility test method (report number: VR70541-01A).

For mycoplasma validation study," VR68208 (b) (4) A (b) (4) based assay to verify the absence of mycoplasma," please provide:

An estimated timeframe for evaluating of (b) (4) using the (b) (4) assay;
Strain number (b) (4) used in the validation study;
Specificity results of bacterial species, which are the potential cross-detection: (b) (4)
Rationale for performing LOD test on (b) (4) instead of (b) (4)
Results of 1 GC/reaction obtained during the LOD study;
Protocol of comparability study between (b) (4) and (b) (4) methods (cell culture and indicator methods) and back titration results of inoculums used in cell culture and indicator methods obtained during comparability study; and
GC and CFUs for stocks of mycoplasma species used in the validation of mycoplasma study VR68208.

Please confirm receipt of this notification 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