From: Patel, Manisha
To: Giordano, Erica
Cc: Riggins, Cindy; Ahmed, Narin
Subject: RE: BL 125646 DBSQC Information Request
Date: Tuesday, May 16, 2017 9:20:21 AM
Attachments: image001.png
Sensitivity: Confidential

Dear Erica,
I acknowledge receipt of this request.

Kind regards,
Manisha

From: Giordano, Erica [mailto:Erica.Giordano@fda.hhs.gov]
Sent: Tuesday, May 16, 2017 8:55 AM
To: Patel, Manisha <manisha.patel@novartis.com>
Cc: Riggins, Cindy <cindy.riggins@novartis.com>; Ahmed, Narin <narin.ahmed@novartis.com>
Subject: BL 125646 DBSQC Information Request
Sensitivity: Confidential

Good morning,

Please see the information request below and provide confirmation by May 30, 2017 that you will be repeating the requested studies and please submit the results of the requested repeat studies by June 23, 2017. As usual please submit the information directly in response to this e-mail and follow up by submitting the information as an amendment to the BLA.

For mycoplasma validation study, AE51SP.300200PSQ.BUK:

1. Please clarify if Robustness study was performed using vector (b) (4)
2. CBER finds the Limit of Detection (LOD) study unacceptable since it was performed using only (b) (4) of one mycoplasma species (b) (4) CBER requests LOD study be repeated using (b) (4) method and mycoplasma species in accordance with Detection Limit section of (b) (4) in the presence of vector (b) (4) ;
3. CBER finds the Specificity test unacceptable since:
    a. specificity of primer and probe mix was not evaluated using mycoplasma species listed in (b) (4) in the presence of (b) (4)
    b. it was performed using bacterial genera with close phylogenetic relation to mycoplasma species without the presence of (b) (4) ; and
    c. theoretical assessment of primer/probe sets using database analysis which is not recommended by (b) (4) .

Therefore, CBER requests specificity study be repeated in accordance with (b) (4) in the presence of vector (b) (4) and

4. Please provide a comparability study between the (b) (4) mycoplasma methods in the presence of vector (b) (4) .

Please submit the results of repeat LOD and Specificity tests and comparability study on or before June 23, 2017.

Please confirm receipt of this request.

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