

From: [Wagner, Leslie](#)
To: krissy.carrington@sanofipasteur.com
Cc: [Wagner, Leslie](#); [Chattopadhyay, Rana](#)
Subject: Information Request: BL 125563 (CRL - Question 1)
Date: Friday, August 17, 2018 1:37:00 PM
Attachments: [image001.png](#)

Dear Ms. Carrington,

Regarding your Response to the Complete Response Letter (CRL) dated 02 November 2015 for BL 125563, we have the following information request:

We have reviewed your response to CBER comment 1 and do not agree that sufficient product release data are available, generated using the proposed pertussis potency test with the revised mouse age and weight criteria, to support the change to the potency limits proposed for this product. Please revise the potency limits to coincide with the limits set for Quadracel®.

Values must be (b) (4) to:

(b) (4)

Please respond to this email to confirm receipt, and submit your response to the comments listed above through the formal eCTD gateway by COB August 31, 2018.

Please do not hesitate to contact me should you have any further questions.

Best regards,
Leslie

Leslie Wagner

Chemist

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