

**From:** [Wagner, Leslie](#)  
**To:** [krissey.carrington@sanofi-pasteur.com](mailto:krissey.carrington@sanofi-pasteur.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*

**Center for Biologics Evaluation and Research**  
**Office of Vaccines Research and Review**  
**U.S. Food and Drug Administration**  
Tel: 240-402-7456 Cel: 240-447-5540  
[leslie.wagner@fda.hhs.gov](mailto:leslie.wagner@fda.hhs.gov)



THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND

MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.