

Dear Ms. Mayer,

In regards to your BLA125563, we have the following comment for you.

In your October 31, 2018 response to information request regarding the (b) (4) test algorithm, you stated that the assessment of (b) (4) using a difference test and coefficients of correlation was developed in (b) (4) following a presentation by (b) (4). While the method was accepted in (b) (4) this does not imply such method is preferred today. (b) (4) states that an (b) (4)

(b) (4) Although we will consider the currently proposed assessment of (b) (4) as acceptable for this submission, as we recognize that you may not have the relevant data to specify an equivalence margin, we strongly recommend that you adopt an equivalence test for future assessment of (b) (4). Please acknowledge.

Could you please send us your response by Monday November 3<sup>rd</sup>? Please feel free to contact me if you have any questions.

Best,  
Girish

**Girish Ramachandran, Ph.D.**  
**Primary Regulatory Reviewer/Regulatory Project Manager**  
**FDA/CBER/OVRR/DVRPA**  
10903 New Hampshire Ave.  
WO71  
Silver Spring, MD 20993-0002  
Phone- 301-796-2640  
FAX-301-595-1124

[Girish.Ramachandran@fda.hhs.gov](mailto:Girish.Ramachandran@fda.hhs.gov)

