

From: Lacayo, Juan
Sent: Monday, October 21, 2013 2:56 PM
To: Greenfeder, Scott
Cc: Chattopadhyay, Rana
Subject: RE: Question re: BLA 125473
10/25/2013

Dear Scott,

Regarding your response dated May 3, 2013 to our request for information dated April 23, 2013. You did not provide sufficient validation data for the (b)(4) assay (IR comment 7) as requested. Please provide method validation to support the use of this assay. Your response should address the following:

1. Does your package have adequate (b) (4) characteristics to test using the (b)(4) method?
2. Is the (b)(4) standardized? Is (b)(4) added to the mixture? If so, to what concentration.
3. What amount of (b)(4) is an operator able to visually see?
4. Are you using a positive control ((b)(4)) and have you challenged the procedure to determine what (b)(4) operators can detect?
5. Do you challenge the method regularly to confirm its ability to detect defects?

Thank you in advance for your timely response,

Juan

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