

From: Sista, Ramani V  
Sent: Monday, February 09, 2015 1:59 PM  
To: Heather Pratt (heather@macopharmausa.com)  
Subject: NDA 125552 - Requesting clarification

Importance: High

Hi Heather,  
Please provide the following information by COB February 18, 2015:

1. Regarding the (b) (4), please clarify if the (b) (4) is sterile.
  2. Please provide your sterility testing results for the (b) (4) and product.
  3. Please provide your test method and qualification/validation for sterility testing of the (b) (4). In addition, please include (b) (4) results for inoculums used in the qualification of sterility testing of the (b) (4).
- Thanks,  
Ramani

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