

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

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