

From: Allard, Crystal
Sent: Friday, June 18, 2010 12:53 PM
To: '-----(b)(4)-----'; 'dudun@kamada.com'; 'RuthW@kamada.com'
Cc: Ward- Peralta, Cherie
Subject: RE: Information Request - 125325/0

Hello -(b)(4)-, David, and Ruth,

This email is regarding your submission, STN 125325/0 that was submitted to the Agency on June 1, 2009, as a biologics license application for Alpha-1-Proteinase Inhibitor (Human). In order to facilitate the review of the BLA, FDA requests the following additional information:

In your June 2, 2010 response (Amendment 26), you have detailed the procedures to be followed for ----(b)(4)--- of the drug product in the case of a technical failure. However, you have not provided adequate data for actual lots that have been ---(b)(4)-- in order to support such a procedure. Therefore, we recommend that you withdraw that provision from the BLA. Subsequent to approval, you may wish to submit a proposal for --(b)(4)-- under a prior approval supplement (PAS) that contains data to support such a change.

Please respond to this information request via eCTD sequence as part of the amendment in which you respond to the information requested earlier today (June 18, 2010) and the June 11, 2010 PI comments.

Please feel free to contact me or Cherie with any questions or concerns.

Thanks!

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