

From: Ward- Peralta, Cherie
Sent: Wednesday, June 23, 2010 1:31 PM
To: '-----(b)(4)-----'
Subject: Information Request - 125325/0 - Respond by June 24, 2010

Attachments: 125325 Lot Release protocol GLASSIA (2).doc

Hello ----(b)(4)----,

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:

1. Please withdraw your request for ----(b)(4)----. To have this operation approved, please submit a post-licensure PAS with the necessary process validation studies containing at least 6 months of stability data under normal and accelerated conditions.
2. Please update your lot release protocol according to the attached file and resubmit the protocol.



125325 Lot Release
protocol GL...

Please respond to this information request via eCTD sequence as an amendment on June 24, 2010.

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

Sincerely

Cherie Ward-Peralta, M.S.

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