

# Additional Information Request Email to be added to the Fax - GLASSIA, March 19, 2010

From: Ward- Peralta, Cherie

Sent: Friday, March 19, 2010 11:21 AM

To: '-----(b)(4)-----'

Subject: STN 125325 - Additional information request to be added to the fax sent on March 18, 2010

Hello -(b)(4)-

I would like to include this additional comment to the faxed information request sent yesterday, March 18, 2010 regarding your biologics license application submitted on May 29, 2009 for STN 125325/0 for Alpha-1 Proteinase Inhibitor (Human).

We have a preliminary comment with respect to the submitted (15 Mar 2010) outline for "A Phase IV, Randomized, Placebo-Controlled, Double-Blind, Multicenter Study investigating the Safety and Efficacy

of Kamada-API I.V. vs placebo and another (higher) dose of Kamada API I.V by Weekly Administration in Alpha-1 Antitrypsin Deficient Patients with emphysema:" The proposed duration of 12 months is not adequate to meet the study objectives with respect to the proposed primary endpoint of HRCT lung density change. You need to propose an appropriate longer timeframe of study drug administration and evaluation if they want to use HRCT as the primary endpoint.

Please provide a response to this information request by April 1, 2010 to facilitate the review of your application. If you have additional questions, please contact me.

Thanks

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