

# Fax Transmisson Record - GLASSIA, March 18, 2010

## FACSIMILE TRANSMISSION RECORD

Division of Blood Applications

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

From: Cherie Ward-Peralta, OBRR/CBER/FDA

Date: March 18, 2010

This Fax conveys our request for additional information regarding your biologics license application submitted on May 29, 2009 for STN 125325/0 for Alpha-1 Proteinase Inhibitor (Human). Please provide a response to this information request by April 1, 2010 to facilitate the review of your application.

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Please correct your database and the analysis of AEs that began during or within 72 hours of the end of an infusion accordingly.

8. Please correct the erroneous statements in your draft package insert regarding the number of subjects in each randomization group of the pivotal study who completed all 12 infusions during the double-blind portion of the study and all 24 infusions of the entire study. Our analysis shows that

- Four subjects out of 17 randomized to treatment 1 (Prolastin) had fewer than 12 infusions during period 1 (weeks 1-12)
- Three out of 33 subjects randomized to treatment 2 (Kamada A1PI) had fewer than 12 infusions during period 1.
- During period 2 (weeks 13-26), 16 subjects randomized initially to Prolastin had all 12 infusions (of Kamada A1-PI) and 1 had no infusions during period 2.
- During period 2, 8 of 32 subjects initially randomized to Kamada A1-PI had fewer than 12 infusions during period 2, and 1 subject had no infusions during period 2.

Please contact me if you have any questions.

Sincerely,

Cherie Ward-Peralta  
Regulatory Project Manager  
DBA/OBRR/CBER/FDA  
Tel: (301) 827-9170

Page Last Updated: 05/24/2016

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