

# Fax Transmission Record - GLASSIA, October 23, 2009

## FACSIMILE TRANSMISSION RECORD

Division of Blood Applications

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

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

Date: October 23, 2009

This Fax conveys our request for additional information regarding your biological license application submitted on May 29, 2009 for STN 125325/0 for Alpha-1 Proteinase Inhibitor (Human). Please submit your responses by November 9, 2009 unless stated differently within the requests below to facilitate the review of your application.

### Clinical

1. Please submit an analysis of the subjects in each treatment group who had the onset of their adverse event (AE) during or within 24 hours of the end of an infusion of study product. For cases in which the time of onset of the AE was not captured, assume that all AEs that began on either the day of an infusion or the day following an infusion occurred within 24 hours of the end of an infusion. Present these data (a) only for the initial 12 weeks parallel portion of the study, by treatment group and (b) for the entire duration of study, by actual treatment.
2. Your study report for this study states on p 7 "Two subjects were withdrawn due to AEs, one subject (ID No. -----(b)(6)-----) for pulmonary emboli (Prolastin®) and one subject with urticaria (Kamada-API). The raw dataset for serious adverse events (SAEs) in study -(b)(4)- API 002 ("SERIOU18") lists 6 SAEs (4 unique AE terms) reported for 4 subjects, all in "GROUP" "API." GROUP is defined as "Static value of API for every subject." Please provide the field name in this dataset that indicates to which randomization treatment group each subject belongs.
3. Why were 2 subjects with AAT phenotype MZ enrolled in study -(b)(4)- API 002, given that this phenotype normally is not associated with serum A1-PI levels < ~ 17 microM?

### CMC

4. Please provide samples of the conformance lots (3 samples per lot) to the Product Release Branch, and reference this submission number.
5. In order to allow sufficient time for the review of immunogenicity data, please provide these data by January 1, 2010.

### Administrative

6. Currently, -----(b)(4)-----  
----- is your designated US Agent. However, if you desire that other

individuals in -(b)(4)- represent you (Kamada), please submit a Letter of Authorization for either: 1) other named individuals in -(b)(4)-; or 2) any individual employed by -(b)(4)-, as the designated US Agent.

Please contact me if you have any questions.

Sincerely,

Cherie Ward-Peralta

Regulatory Project Manager

DBA/OBRR/CBER/FDA

Tel: (301) 827-9170

<https://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/FractionatedPlasmaProducts/default.htm>

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