

Fax Transmission Record - GLASSIA, September 9, 2009

FACSIMILE TRANSMISSION RECORD

Division of Blood Applications

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

Date: September 9, 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 September 30, 2009 to facilitate the review of your application.

PK

1. The time points within the PK plasma concentration-time data in the PKLABDAT are shown in fixed numbers like 0.1, 0.2 etc. Please submit the real time points at which blood samples were drawn by updating the PKLABDAT file with real time points rather than decimal time points.

Please contact me if you have any questions.

Sincerely,

Cherie Ward-Peralta

Regulatory Project Manager

DBA/OBRR/CBER/FDA

Tel: (301) 827-9170

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