

Fax Transmission Record - GLASSIA, July 16, 2009

FACSIMILE TRANSMISSION RECORD

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

Date: July 16, 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 July 27, 2009 to facilitate the review of your application.

Clinical

1. Please redo and resubmit your adverse events (AE) datasets to include fields for:
 - o Randomized treatment group
 - o Product given during the most recent infusion
 - o Date and start and ending time of most recent infusion
 - o Date and start time of AE
 - o Hours elapsed since the end of the most recent infusion (use a value of zero if the AE began during the infusion).

Please include only treatment-emergent AEs in the revised datasets.

2. Your define.pdf data definition table for the raw data sets is inadequate in that it does not provide complete and unambiguous definitions of all data fields. Please submit revised definition tables by the date mentioned above to correct this deficiency.
3. Neither your raw data nor your analysis datasets appear to contain raw data for the primary endpoint analytes, antigenic and functional A1-PI from individual sampling time points for either the pivotal trial or the single-dose PK/safety study. Please submit these by the date mentioned above. PK data from each sampling time should be submitted for each subject.
4. A spot check of your raw datasets indicates that they are inadequate in that, when right mouse clicking on the field names, the column information dialog box does not provide any additional definition beyond just repeating the field name. The column information for the analysis datasets also appears to be inadequate. For example, "Treatment Number" values of "1" and "2" are not defined and "MAAT" (mean aat) does not indicate over which weeks trough levels are averaged for this derived variable in dataset "AATP1ITT." Please re-do and resubmit your datasets by the date mentioned above to correct this deficiency.

5. It does not appear that you have submitted any SAS export files for the single dose PK/safety study. Please submit adequate SAS export files for this study by the date mentioned above.

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

Page Last Updated: 06/02/2016

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