

Information Request Email - GLASSIA, May 25, 2010

From: Ward- Peralta, Cherie
Sent: Tuesday, May 25, 2010 4:26 PM
To: '-----(b)(4)-----'
Subject: FW: STN 125325 - Information Request
Hello -(b)(4)-

This email is regarding your submission, STN 125325/0 that was submitted to the Agency on May 29, 2009 as a biologics license application for Alpha-1 Proteinase Inhibitor (Human). In order to facilitate the review of the BLA, FDA requests the following additional information:

1. You have used two HBV NAT assay methods (------(b)(4)-----) for plasma testing. Please specify which method was used for
------(b)(4)-----

2. Please revise the dates within Table 1-1 for the Submission of the final report for the Immunogenicity Safety and the BAL studies as it currently shows this to be complete two days prior to the completion of the studies (last patient out).
3. Please revise the letter to include the milestone dates and the explicit commitment to also conduct and report to FDA the results of the stage 2 adequately-powered clinical trial using 1 or more clinically meaningful endpoints of which the design specifics of that trial will be contingent on the results of the stage 1 study and available scientific information.

4. Please revise the title of your PMC study as recommend:

A Phase IV, randomized, double-blind, multicenter study exploring potential adverse events associated with particulates, immunogenicity and viral safety following the use of Kamada's Intravenous, Human A1PI vs. Another Commercial, A1PI in Alpha-1 Antitrypsin Deficient Patients.

We would appreciate receiving a response to this information request by May 27, 2010. Please contact me if you have any questions.

Sincerely,

Cherie Ward-Peralta, M.S. Regulatory Project Manager
HFM-380 FDA/CBER
Office of Blood Research and Review
Division of Blood Applications

Page Last Updated: 05/24/2016

Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).

Language Assistance Available: [Español](#) | [繁體中文](#) | [Tiếng Việt](#) | [한국어](#) | [Tagalog](#) | [Русский](#) | [ةيبرعلا](#) | [Kreyòl Ayisyen](#) | [Français](#) | [Polski](#) | [Português](#) | [Italiano](#) | [Deutsch](#) | [日本語](#) | [عسراف](#) | [English](#)