

Fax Transmission Record - GLASSIA, April 20, 2010

FACSIMILE TRANSMISSION RECORD

Division of Blood Applications

1401 Rockville Pike, Suite 400N, HFM-380

Rockville, Maryland 20852-1448

FAX (301) 827-2857

TEL (301) 827-9170

FAX No. 703-548-7457

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

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

Date: April 20, 2010

This Fax 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:

CMC

1. To aid in the ongoing review of your BLA submission, CBER requests an update on your activities toward refining the immunogenicity assay for Kamada-API. Please include assay development milestones and a working timeline. CBER would like to stress that a sensitive immunogenicity assay remains a high priority for this program.
2. -----(b)(4)-----

3. In your current manufacturing process, bulk drug substance can be stored -----
(b)(4)----- prior to being processed to drug product. Please confirm that you will validate the hold time for drug substance in your comparability protocol that evaluates drug substance manufactured from -----(b)(4)-----.
4. Please confirm that you will establish upper and lower limits for mixing speed, mixing time, and -(b)(4)- contact time during the -----(b)(4)-----
containing -(b)(4)--.

We would appreciate a response to this information request by May 4, 2010.

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

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](#) | [ىسراف](#) | [English](#)