



FACSIMILE TRANSMISSION RECORD
Division of Blood Applications
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To: -----(b)(4)-----
From: Kelly Lewis for Cherie Ward-Peralta, OBRR/CBER/FDA
Date: June 11, 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:

1. We agree to the method that you proposed in Amendment 22 for -----(b)(4)-----
----- at release in -----(b)(4)-----
----- . Please define -----(b)(4)----- and set the specification to --(b)(4)--
-----.
2. In your stability studies of the drug product, please include -----(b)(4)-----
----- by -----(b)(4)----- (as a specification) and -----(b)(4)----- (for
information only; -----(b)(4)-----). Please place on stability the first lot of
the product manufactured every year. Please report the results in Annual Reports.
3. Please perform -----(b)(4)----- analysis at the time of lot release with no specifications set
at this time. Please report the results in Annual Reports together with the -----(b)(4)-----
----- . For the -----(b)(4)----- analysis please -
----- (b)(4)-----.
4. Although, you are only responsible for viral testing information related to your product,
please remind -(b)(4)- that they should provide validation data for -----(b)(4)----- to the
relevant BLAs for all their products.

NOTE: This transmission is from a Xerox 7020 telecopier. If you do not receive a legible document, or do not receive all of the pages, please telephone us immediately at the voice number above.

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Thank you.

Number of pages (including cover sheet) 3

Please agree to the following post-marketing commitments and please provide wording for these commitments in a Letter of Post-Marketing Commitments:

(b)(4)-----

(b)(4)-----

(b)(4)-----

(b)(4)-----

(b)(4)-----

(b)(4)-----

11. You will assure that the final study report from -(b)(4)- regarding the validation data for both -----(b)(4)----- procedures used in testing -----(b)(4)----- will be submitted by January 1, 2011 by Kamada to STN 125325 (Final PMC report) or by -(b)(4)- to STN -(b)(4)- with reference to STN 125325. In the latter case, you will also submit a Final PMC Report to STN 125325 notifying about corresponding submission to STN -(b)(4)-. (Please chose the option or use both options if the way of the submission has not been determined yet.)

We would appreciate a response to this information request by June 14, 2010.

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Please contact me if you have any questions.

Sincerely,

Kelly Lewis
Regulatory Project Manager
FDA/CBER/OBRR/DBA
Tel: (301) 827-9427