

Fax Transmission Record - GLASSIA, February 2, 2010

FACSIMILE TRANSMISSION RECORD

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

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

Date: February 2, 2010

This Fax conveys our comments to your biological license application submitted on May 29, 2009 for STN 125325/0 for Alpha-1 Proteinase Inhibitor (Human).

Immunogenicity Assay Development:

1. Use of a -----(b)(4)-----, is a good choice as a positive control. However your calculation of sensitivity for the positive control assumes all of the antibody in the positive control is directed against A1PI. -----(b)(4)-----

2. -----(b)(4)-----

3. In this assay it appears that -----(b)(4)-----
- to provide the basis of an improvised standard curve. What is the efficiency of immobilization of your ---(b)(4)-- standard curve? If unknown, the assignment of antibody concentration based on the standard curve is not valid, and the assignment of sensitivity values based on the standard curve is also invalid.

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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