

Immunogenicity Assay Development Memo - GLASSIA, March 22, 2010

Food and Drug Administration
Center for Biologics Evaluation and Research
Memorandum
Date: 3/22/10
From: Jennifer L. Reed, Ph.D.; CBER/OBRR/DH/LPD
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To: File 125325

Through: Dorothy Scott, M.D.; CBER/OBRR/DH/LPD; HFM-345; 301-827-3016
Cc: Cherie Ward-Peralta; OBRR/DBA/RPMB; HFM-380; 301-827-9170
Subject: Immunogenicity Assay Development
Product: Alpha-1 Proteinase Inhibitor (Human) intravenous for chronic augmentation and maintenance therapy in individuals A1PI deficiency and emphysema
Submission Date: December 28, 2009
Manufacturer: Kamada, Ltd.

Recommendation:

The following letter-ready comments may be faxed to the Sponsor:
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.

Page Last Updated: 09/25/2013

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