

CLINICAL PHARMACOLOGY FILING MEMO

Division of Hematology
Office of Blood Review & Research

STN 125325/0

Sponsor: Kamada Ltd

Product: Alpha -1 proteinase inhibitor

Indication: Chronic replacement therapy in congenital API deficiency

Reviewer: Iftekhar Mahmood, Ph. D.

RPM: CHERIE WARD-PERALTA

Submission Date: June 1, 2009

Through: Mahmood Farshid, Ph. D.

Date: July 31, 2009

The preliminary review of the information for clinical pharmacology provided in the submission STN 125325/0 indicates that the application is fileable.

Please send the following comment to the sponsor.

Please provide the elapsed time (the time blood samples were taken to measure plasma concentrations) after drug administration for PK study under the PKTP column within the PKLABDAT data set.

APPROVED

By Iftekhar Mahmood, Ph.D. at 9:40 am, Jul 31, 2009

Iftekhar Mahmood, Ph. D.
Senior Clinical Pharmacology Reviewer
Division of Hematology
Office of Blood Review & Research

APPROVED

By Farshid Mahmood at 9:46 am, Jul 31, 2009

Mahmood Farshid Ph. D.
Deputy Division Director, Division of Hematology
Office of Blood Review & Research