

MAA Letter - GLASSIA

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Our STN: BL 125325/0
Kamada Ltd.
Attention: -----(b)(4)-----

Dear ----(b)(4)-----:

We received your March 11, 2010 amendment to your biologics license application (BLA), submitted under section 351 of the Public Health Service Act (42 U.S.C. 262), for Alpha-1-Proteinase Inhibitor (Human) on March 11, 2010.

We consider your submission a major amendment under the reauthorization of the prescription drug user fee program in the Food and Drug Administration Amendments Act of 2007.

Because we received this major amendment within 3 months of the action due date, we will add an additional 3 months to the time by which we should complete our review. Therefore, the action due date is July 1, 2010.

If you have any questions, please contact the Regulatory Project Manager, Cherie Ward-Peralta, at (301) 827-9170.

Sincerely yours,
Basil Golding, M.D.

Director
Division of Hematology
Office of Blood Research and Review
Center for Biologics Evaluation and Research

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