

PNA Letter - GLASSIA

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration

1401 Rockville Pike

Rockville, MD 20852-1448

Our STN: 125325/0

Kamada Ltd.

Attention: -----(b)(4)-----

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

We reviewed your December 30, 2009 submission to your biologics license application (BLA) for Alpha-1-Proteinase Inhibitor (Human) requesting a proprietary name review.

In consultation with CBER's Advertising and Promotional Labeling Branch (APLB), we concluded that under the Federal Food, Drug, and Cosmetic Act and applicable regulations, your proposed proprietary name, GLASSIA, is acceptable at this time.

We will perform another proprietary name review of GLASSIA closer to the time of the action due date to ensure that we have not approved a conflicting proprietary name for another product in the interim.

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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