

PNR Unacceptable Letter - GLASSIA

Our STN: 125325/0

Kamada, Ltd.

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

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

We have reviewed your submission dated October 2, 2009, 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 conclude that under the Federal Food, Drug, and Cosmetic Act and applicable regulations, your proposed name, APIKAM, is unacceptable.

There is potential for confusion with a currently marketed product, APOKYN (apomorphine). APIKAM is similar to APOKYN in spelling and pronunciation.

You may submit a new proprietary name for FDA consideration or request in writing that your second name, GLASSIA, be reviewed. Any alternate proprietary name(s) should comply with the regulations regarding false, misleading or fanciful names and should not be confused with other medicinal products with orthographic or phonological similarities.

If you have any questions, please contact 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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