



Our STN: BL **125473/0**

Merck Sharp & Dohme Corp.
Attention Scott Greenfeder, Ph.D.
126 E. Lincoln Avenue
P.O. Box 2000, RY 33-204
Rahway, NJ 07065

Dear Dr. Greenfeder:

We have reviewed your submission dated January 25, 2013, to your Biologics License Application (BLA) for GRASTEK (Standardized Allergenic Extract, Timothy Grass [*Phleum pretense*]) 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 proprietary name, GRASTEK, is acceptable at this time.

We will perform another proprietary name review of GRASTEK 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, Dr. Rana Chattopadhyay at (301)-796-2640.

Sincerely yours,

Wellington Sun, M.D.
Director
Division of Vaccines and
Related Products Applications
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research