DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20852-1448

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

February 6, 2013

Dear Dr. Greenfeder:

We have received your biologics license application (BLA) submitted under section 351 of the Public Health Service Act for the following biological product:

Our Submission Tracking Number (STN): BL 125473/0

Biological Product: Timothy Grass (*Phleum pretense*)

Indication: For the treatment of diagnosed Timothy and related grass pollen induced allergic rhinitis, with or without conjunctivitis in adults and children 5 years of age and older.

Date of Supplement: January 25, 2013

Date of Receipt: January 25, 2013

First Action Due Date: January 25, 2014

US License Number: 1893

We will notify you within 60 days of the receipt date if the application is sufficiently complete to permit a substantive review.

Please submit all future correspondence, supporting data, or labeling relating to this application, citing the above STN number. Send all correspondence to the following address:

Marion Gruber, Ph.D.
Director
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research
Food and Drug Administration
Suite 200N, HFM-99
1401 Rockville Pike
Rockville, MD 20852-1448

Applicants who sent applications via the Food and Drug Administration Electronic Submissions Gateway (ESG) should continue to use those procedures. The ESG is an Agency-wide solution for accepting electronic regulatory submissions that enables the secure submission of regulatory information for review. Instructions for setting up an ESG account can be found at http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm

CBER strongly encourages the use of secure email. Secure email makes use of encryption during transmission and the messages are decrypted upon receipt using the certificate. To establish secure email, please follow the instructions in *SOPP 8119: Use of Email for Regulatory Communications,* Appendix 1 or Appendix 2.

CBER may communicate with you via non-secure email if you provide written authorization to do so. Authorization is file specific; please submit new authorization for each file and/or submission you hold with CBER.

Please note that CBER will only use email in place of telephone communications for general discussions, to relay regulatory issues and to request information. CBER will not provide copies of letters or meeting minutes by email and will not usually accept regulatory submissions via email.

If you have any questions, please contact LCDR Juan Lacayo and Rana Chattopadhyay Ph.D., Regulatory Project Managers, at (301) 796-2640.

Sincerely yours,

Paul G. Richman, Ph.D.
Chief
Regulatory Review Branch 1
Division of Vaccines and
Related Products Applications
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research