



Our STN: BL 125592/0

BLA FILING NOTIFICATION

Merck Sharp & Dohme Corp.
Attention: Nadine Margaretten, Ph.D
1 Merck Drive
P.O. Box 100
Whitehouse Station, NJ 08889-0100

Dear Dr. Margaretten:

This letter is in regard to your biologics license application (BLA) submitted under section 351 of the Public Health Service Act.

We have completed an initial review of your application dated February 9, 2016, for House Dust Mite (*Dermatophagoides pteronyssinus* and *Dermatophagoides farinae*) Allergen Extract to determine its acceptability for filing. Under 21 CFR 601.2(a) we have filed your application today. The review classification for this application is Standard. Therefore, the review goal date is February 8, 2017. This acknowledgment of filing does not mean that we have issued a license nor does it represent any evaluation of the adequacy of the data submitted.

At this time, we have not identified any potential review issues. Our filing review is only a preliminary review, and deficiencies may be identified during substantive review of your application. Following a review of the application, we shall advise you in writing of any action we have taken and request additional information if needed.

If you have any questions, please contact the Regulatory Project Managers, Captain Colleen Sweeney or Dr. Matthew Steele, 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