

**From:** Khurana, Taruna  
**Sent:** Thursday, February 02, 2017 9:11 AM  
**To:** nadine\_margaretten@merck.com  
**Cc:** Sweeney, Colleen (Colleen.Sweeney@fda.hhs.gov); Steele, Matthew (Matthew.Steele@fda.hhs.gov)  
**Subject:** STN 125592 HDM SLIT-Drug Substance (b) (4) Clarification

Dear Nadine,

Please clarify what (b) (4) release tests for Der far and Der pte drug substances are performed by (b) (4) and what type of tests are performed by (b) (4) listed as optional for (b) (4) in the submission.

Thank you  
Taruna

**Taruna Khurana, PhD**

*Biologist (Regulatory)*

Center for Biologics Evaluation and Research  
Office of Vaccines Research and Review  
U.S. Food and Drug Administration  
Tel: 301-796-2640  
[Taruna.khurana@fda.hhs.gov](mailto:Taruna.khurana@fda.hhs.gov)

