

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

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