

From: Khurana, Taruna
Sent: Tuesday, January 10, 2017 11:30 AM
To: Margaretten, Nadine
Cc: Sweeney, Colleen; Steele, Matthew
Subject: RE: BLA STN 125592 HDM SLIT _Microbial test Clarification

Dear Nadine,

We have the following request for information;

Please confirm that the 12 DU (b) (4) used to qualify the bioburden test and the test for absence of specified microorganisms has same formulation and manufacturing process as the House Dust Mite product reviewed under this BLA.

Thank you

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Biologist (Regulatory)

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