

**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

**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)



---

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender immediately by e-mail or phone.