

# RECORD OF TELEPHONE CONVERSATION

## Submission Information

<b>Application Type</b>	BLA
<b>STN</b>	125592/0.0
<b>Review Office</b>	OVRR
<b>Applicant</b>	Merck Sharp & Dohme Corp. / Lic. # 0002
<b>Product</b>	House Dust Mites Allergenic Extract
<b>Trans-BLA Group:</b>	No

## Telecon Details

<b>Telecon Date/Time</b>	25-MAY-2016 10:22 AM
<b>Author</b>	STEELE, MATTHEW
<b>EDR</b>	No
<b>Post to Web</b>	Yes
<b>Outside Phone Number</b>	
<b>FDA Originated?</b>	Yes
<b>Communication Categories</b>	IR - Information Request
<b>Related STNs</b>	None
<b>Related PMCs</b>	None
<b>Telecon Summary</b>	Requests for revisions to ISS and ISE.
<b>FDA Participants</b>	Matthew Steele. Colleen Sweeny. Taruna Khurana
<b>Applicant Participants</b>	Nadine Margaretten

### Telecon Body:

**From:** Steele, Matthew

**Sent:** Wednesday, May 25, 2016 10:22 AM

**To:** 'Margaretten, Nadine'

**Cc:** Sweeney, Colleen; Khurana, Taruna

**Subject:** Additional Information Requests for STN 125592

## **RECORD OF TELEPHONE CONVERSATION**

1. Please revise your Integrated Summary of Safety (ISS) to include all studies conducted using the 12DU dose. We note that you have summarized safety data for various combinations of studies, but not all of the studies together.
2. Please revise your ISS and integrated summary of efficacy (ISE) to include all studies using 12DU dose, analyzed by subgroups including adults 18-65 years old, adults over 65 years as well as race, ethnicity and sex.

Please do not hesitate to contact us with any questions.

Matthew Steele, PhD  
LCDR, US Public Health Service  
Primary Reviewer and RPM  
FDA/CBER/OVRR/DVRPA  
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