

# 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>	24-JUN-2016 11:03 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>	Request for corrected Stats datasets
<b>FDA Participants</b>	Matt Steele Taruna Khurana Colleen Sweeny
<b>Applicant Participants</b>	Nadine Margaretten

### Telecon Body:

**From:** Steele, Matthew  
**Sent:** Friday, June 24, 2016 11:02 AM  
**To:** nadine\_margaretten@merck.com  
**Cc:** Sweeney, Colleen; Khurana, Taruna  
**Subject:** STN 125592/0

## **RECORD OF TELEPHONE CONVERSATION**

Dear Dr. Margaretten,

We have the following comments regarding this BLA:

1. In your submission STN 125592/0, the analysis dataset “adefx.xpt” for study P003 has file size of 0 KB. This data file cannot be properly opened. Please provide the analysis dataset “adefx.xpt” for study P003.
2. The analysis dataset “adefx.xpt” for study P015 (MT-06) does not appear to contain a flag column for Per-Protocol population. Please provide an updated dataset “adefx.xpt” for study P015 with a flag for Per-Protocol population.

We respectfully request that you provide the information within two weeks.

Matthew Steele, PhD  
LCDR, US Public Health Service  
Team Leader, RRB-1  
FDA/CBER/OVRR/DVRPA  
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