

# 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>	14-SEP-2016 03:17 PM
<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 additional information on historical tox data
<b>FDA Participants</b>	Matthew Steele; Colleen Sweeney; Taruna Khurana
<b>Applicant Participants</b>	Nadine Margaretten

### Telecon Body:

**From:** Steele, Matthew  
**Sent:** Wednesday, September 14, 2016 4:22 PM  
**To:** nadine\_margaretten@merck.com  
**Cc:** Khurana, Taruna; Sweeney, Colleen  
**Subject:** STN 125592/0 Information Request

## **RECORD OF TELEPHONE CONVERSATION**

Hi Nadine, as a follow-up to the historical control tox data you submitted last week, we have the following request for additional information:

“Without identifying the specific products tested, please provide the following information on each of the six studies conducted at the testing facility that were used to generate the late resorption historical control data. You may distinguish the studies by numerical or alphabetical order.

Please provide the following by study: route of administration, general nature of the product tested such as vaccine, allergenic product, drug or other if possible and frequency of dosing.”

Matthew Steele, PhD  
LCDR, US Public Health Service  
Team Leader, RRB-1  
FDA/CBER/OVRR/DVRPA  
Phone: (301)796-2640  
Fax: (301)402-0004

**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 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 received this document in error, please immediately notify the sender by e-mail or phone.