

# 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 Allergenics Extract
<b>Trans-BLA Group:</b>	No

## Telecon Details

<b>Telecon Date/Time</b>	02-FEB-2017 05:09 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>	No
<b>Communication Categories</b>	IR - Information Request AD - Advice
<b>Related STNs</b>	None
<b>Related PMCs</b>	None
<b>Telecon Summary</b>	Comments on PMCs received 02/01/2017
<b>FDA Participants</b>	Matt Steele
<b>Applicant Participants</b>	Nadine Margaretten

### Telecon Body:

**From:** Steele, Matthew  
**Sent:** Thursday, February 02, 2017 12:52 PM  
**To:** nadine\_margaretten@merck.com  
**Cc:** Sweeney, Colleen; Khurana, Taruna  
**Subject:** STN 125592

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Dear Nadine,

We have the following comments regarding the PMCs submitted on February 1, 2016, to your BLA:

- 1) We are concerned that the studies will be considered complete after 3 years have elapsed, regardless of patient accrual. We recommend that each study have a specific target enrollment, which is powered to answer the clinical question being addressed.
- 2) In the limitations section of study #2 (EHR-based study) you state: "The reliability for EHR data to capture subsequent exposures and outcomes (which may occur across various care settings with different EHRs) has not been established." Please explain why you do not consider the EHR data reliable beyond one week. If EHR data are considered reliable beyond one week, please comment on whether a single, EHR-based study may be preferable to the two studies that you have proposed.
- 3) While we agree with your proposal to collect data on hypersensitivity reactions in these patients, we also believe that it is important to better characterize the rate of EoE following the use of this product. If a claims-based study is performed, please calculate the power of the claims-based study to assess the rate of EoE. In addition, if a claims-based study is performed, you will need to validate that the claims data in the database you use are sufficiently predictive for the clinical events of interest.

If you would like to schedule a teleconference to discuss any of these items, please send me your availability as soon as possible.