

# RECORD OF TELEPHONE CONVERSATION

## Submission Information

<b>Application Type</b>	BLA
<b>STN</b>	125592/0
<b>Review Office</b>	OVRR
<b>Applicant</b>	Merck Sharp & Dohme Corp.
<b>Product</b>	House Dust Mites Allergen Extract
<b>Trans-BLA Group:</b>	No

## Telecon Details

<b>Telecon Date/Time</b>	6-Oct-2016 02:54 PM
<b>Author</b>	Colleen Sweeney
<b>EDR</b>	Yes
<b>Post to Web</b>	No
<b>Outside Phone Number</b>	(732) 594-0373
<b>FDA Originated?</b>	Yes
<b>Communication Categories</b>	Information Request (IR)
<b>Related STNs</b>	None
<b>Related PMCs</b>	None
<b>Telecon Summary</b>	IR regarding clinical data, specifically, Studies P001 and P015
<b>FDA Participants</b>	Colleen Sweeney
<b>Applicant Participants</b>	Nadine Margaretten

### Telecon Body:

Colleen Sweeney, R.N., M.S.  
Captain, USPHS  
Primary Reviewer, RRB-1  
FDA/CBER/OVRR/DVRPA  
Phone: (301)796-2640  
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**From:** Sweeney, Colleen

**Sent:** Thursday, October 06, 2016 2:51 PM

**To:** Margaretten, Nadine (nadine\_margaretten@merck.com); Shenouda, Andro

**Cc:** Steele, Matthew; Khurana, Taruna

**Subject:** FW: MK-8237 BLA 125592/0 Information Requests

Dear Dr. Margaretten,

We have the following requests for additional information regarding your biologics license application (BLA):

The following item pertains to Study P001:

1. Please provide the Baseline Observation Carried Forward using only the Daily Symptom Score (DSS) in subjects < 18 years of age; 18 through 65 years of age; and greater than 65 years of age.

The following item pertains to Study P015:

2. You indicate that the primary efficacy analysis was based on a linear mixed effect model and performed on the full set analysis (FAS) using a multiple imputation strategy for missing data (dataset denoted as FAS-MI). Please provide the percent treatment difference with the 95% confidence interval for the FAS-MI population.
3. Please provide your rationale and/or data to support your claim that this product is not systemically absorbed.
4. Please provide your rationale for seeking licensure in adults 18 through 65 years of age based on your pivotal study which includes 12 years of age and older.

Please submit the above information as an amendment to STN 125592/0.

*Colleen Sweeney R.N., M.S.*

*Captain, USPHS*

*Division of Vaccines & Related Product Applications*

*Office of Vaccines Research & Review Center for Biologics Evaluation & Research*

*US Food & Drug Administration*

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