

RECORD OF TELEPHONE CONVERSATION

Submission Information

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

Telecon Details

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

Telecon Body:

Colleen Sweeney, R.N., M.S.
Captain, USPHS
Primary Reviewer, RRB-1
FDA/CBER/OVRP/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

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