

RECORD OF TELEPHONE CONVERSATION

Submission Information

Application Type	BLA
STN	125592/0.0
Review Office	OVRR
Applicant	Merck Sharp & Dohme Corp. / Lic. # 0002
Product	House Dust Mites Allergenics Extract
Trans-BLA Group:	No

Telecon Details

Telecon Date/Time	02-FEB-2017 05:09 PM
Author	STEELE, MATTHEW
EDR	No
Post to Web	Yes
Outside Phone Number	
FDA Originated?	No
Communication Categories	IR - Information Request AD - Advice
Related STNs	None
Related PMCs	None
Telecon Summary	Comments on PMCs received 02/01/2017
FDA Participants	Matt Steele
Applicant Participants	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.