

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 Allergenic Extract
Trans-BLA Group:	No

Telecon Details

Telecon Date/Time	25-MAY-2016 10:22 AM
Author	STEELE, MATTHEW
EDR	No
Post to Web	Yes
Outside Phone Number	
FDA Originated?	Yes
Communication Categories	IR - Information Request
Related STNs	None
Related PMCs	None
Telecon Summary	Requests for revisions to ISS and ISE.
FDA Participants	Matthew Steele. Colleen Sweeny. Taruna Khurana
Applicant Participants	Nadine Margaretten

Telecon Body:

From: Steele, Matthew
Sent: Wednesday, May 25, 2016 10:22 AM
To: 'Margaretten, Nadine'
Cc: Sweeney, Colleen; Khurana, Taruna
Subject: Additional Information Requests for STN 125592

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1. Please revise your Integrated Summary of Safety (ISS) to include all studies conducted using the 12DU dose. We note that you have summarized safety data for various combinations of studies, but not all of the studies together.
2. Please revise your ISS and integrated summary of efficacy (ISE) to include all studies using 12DU dose, analyzed by subgroups including adults 18-65 years old, adults over 65 years as well as race, ethnicity and sex.

Please do not hesitate to contact us with any questions.

Matthew Steele, PhD
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Primary Reviewer and RPM
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