

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	24-JAN-2017 03:45 PM
Author	STEELE, MATTHEW
EDR	No
Post to Web	No
Outside Phone Number	
FDA Originated?	Yes
Communication Categories	LF - Labeling via FAX/e-mail
Related STNs	None
Related PMCs	None
Telecon Summary	First round of labeling comments
FDA Participants	Matthew Steele, Colleen Sweeney, Taruna Khurabna
Applicant Participants	Nadine Margaretten

Telecon Body:

From: Steele, Matthew
Sent: Tuesday, January 24, 2017 3:44 PM
To: nadine_margaretten@merck.com
Cc: Khurana, Taruna; Sweeney, Colleen
Subject: Revised Package Insert, STN 125592

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Dear Nadine, please see the attached PI with our comments and proposed revisions. Please note this document is based on the original version you sent in your initial submission. If at all possible, please let us know by this Friday whether these changes are acceptable, or whether you would like to propose more revisions.

Please let us know if you have any questions or comments.

Matthew Steele, PhD
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FDA/CBER/OVRR/DVRPA
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