

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	14-SEP-2016 03:17 PM
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	Request for additional information on historical tox data
FDA Participants	Matthew Steele; Colleen Sweeney; Taruna Khurana
Applicant Participants	Nadine Margaretten

Telecon Body:

From: Steele, Matthew

Sent: Wednesday, September 14, 2016 4:22 PM

To: nadine_margaretten@merck.com

Cc: Khurana, Taruna; Sweeney, Colleen

Subject: STN 125592/0 Information Request

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Hi Nadine, as a follow-up to the historical control tox data you submitted last week, we have the following request for additional information:

“Without identifying the specific products tested, please provide the following information on each of the six studies conducted at the testing facility that were used to generate the late resorption historical control data. You may distinguish the studies by numerical or alphabetical order.

Please provide the following by study: route of administration, general nature of the product tested such as vaccine, allergenic product, drug or other if possible and frequency of dosing.”

Matthew Steele, PhD
LCDR, US Public Health Service
Team Leader, RRB-1
FDA/CBER/OVRR/DVRPA
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