

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	29-AUG-2016 01:18 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 historical control data for tox study #P120737.
FDA Participants	Matt Steele, Colleen Sweeney, Taruna Khurana
Applicant Participants	Nadine Margaretten

Telecon Body:

From: Steele, Matthew
Sent: Monday, August 29, 2016 1:17 PM
To: nadine_margaretten@merck.com
Cc: Sweeney, Colleen; Khurana, Taruna
Subject: STN 125592 IR

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Hi Nadine, we have the following information request for this BLA:

“Please provide the historical control data for the findings of late resorption (and the % resorption rate) in mice at the testing facility ((b) (4)) when the embryo-fetal development study (study#P120737) was conducted. These data can be compiled from the 5 year period during which the study was performed.”

Matthew Steele, PhD
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