

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-JUN-2016 11:03 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	Request for corrected Stats datasets
FDA Participants	Matt Steele Taruna Khurana Colleen Sweeny
Applicant Participants	Nadine Margaretten

Telecon Body:

From: Steele, Matthew
Sent: Friday, June 24, 2016 11:02 AM
To: nadine_margaretten@merck.com
Cc: Sweeney, Colleen; Khurana, Taruna
Subject: STN 125592/0

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Dear Dr. Margaretten,

We have the following comments regarding this BLA:

1. In your submission STN 125592/0, the analysis dataset “adeff.xpt” for study P003 has file size of 0 KB. This data file cannot be properly opened. Please provide the analysis dataset “adeff.xpt” for study P003.
2. The analysis dataset “adeff.xpt” for study P015 (MT-06) does not appear to contain a flag column for Per-Protocol population. Please provide an updated dataset “adeff.xpt” for study P015 with a flag for Per-Protocol population.

We respectfully request that you provide the information within two weeks.

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