

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 Allergenics Extract
Trans-BLA Group:	No

Telecon Details

Telecon Date/Time	03-FEB-2017 12:55 PM
Author	STEELE, MATTHEW
EDR	No
Post to Web	No
Outside Phone Number	
FDA Originated?	No
Communication Categories	IR - Information Request
Related STNs	None
Related PMCs	None
Telecon Summary	Request for info on source of SUR data.
FDA Participants	Matthew Steele, Colleen Sweeney, Taruna Khuana
Applicant Participants	Nadine Maragretten

Telecon Body:

From: Steele, Matthew
Sent: Friday, February 03, 2017 12:55 PM
To: nadine_margaretten@merck.com
Cc: Sweeney, Colleen; Khurana, Taruna
Subject: STN 125592

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Hi Nadine, we have the following requests for information:

- 1) Please confirm that the data you to us for the Post-marketing Safety Update Report (SUR) was generated as part of a pharmacovigilance plan with the EU & Japan.
- 2) Please state the specific countries this data was generated in and the number of prescriptions for this product written in each of these countries.

Matthew Steele, PhD
LCDR, US Public Health Service
Team Leader, RRB-1
FDA/CBER/OVRR/DVRPA
Phone: (301)796-2640
Fax: (301)402-0004

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