

# RECORD OF TELEPHONE CONVERSATION

## Submission Information

<b>Application Type</b>	BLA
<b>STN</b>	125592/0.0
<b>Review Office</b>	OVRR
<b>Applicant</b>	Merck Sharp & Dohme Corp. / Lic. # 0002
<b>Product</b>	House Dust Mites Allergenic Extract
<b>Trans-BLA Group:</b>	No

## Telecon Details

<b>Telecon Date/Time</b>	27-SEP-2016 01:20 PM
<b>Author</b>	KHURANA, TARUNA
<b>EDR</b>	No
<b>Post to Web</b>	Yes
<b>Outside Phone Number</b>	
<b>FDA Originated?</b>	Yes
<b>Communication Categories</b>	IR - Information Request
<b>Related STNs</b>	None
<b>Related PMCs</b>	None
<b>Telecon Summary</b>	Request for additional information on BLA (b) (4) and PPQ lots
<b>FDA Participants</b>	Matthew Steele; Colleen Sweeney; Taruna Khurana
<b>Applicant Participants</b>	Nadine Margaretten

## Telecon Body:

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**From:** Khurana, Taruna  
**Sent:** Tuesday, September 27, 2016 1:20 PM  
**To:** nadine\_margaretten@merck.com

## RECORD OF TELEPHONE CONVERSATION

**Cc:** Steele, Matthew (Matthew.Steele@fda.hhs.gov); Sweeney, Colleen  
**Subject:** RE: STN 125592/0 IR (9.27.16)

Dear Dr. Margaretten,

We have the following information request for the information submitted on September 12, 2016 for MK-8237

1. Please clarify if (b) (4) of MK-8237 is dependent on approval of the BLA. If the BLA did not receive approval on February 8, 2017, when would the (b) (4) 
2. Please specify when commercial batches of this product will be manufactured subsequent to approval.

Thank you

Taruna

**Taruna Khurana, PhD**

*Biologist (Regulatory)*

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