

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	27-SEP-2016 01:20 PM
Author	KHURANA, TARUNA
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 BLA (b) (4) and PPQ lots
FDA Participants	Matthew Steele; Colleen Sweeney; Taruna Khurana
Applicant Participants	Nadine Margaretten

Telecon Body:

From: Khurana, Taruna
Sent: Tuesday, September 27, 2016 1:20 PM
To: nadine_margaretten@merck.com

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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)

Center for Biologics Evaluation and Research

Office of Vaccines Research and Review

U.S. Food and Drug Administration

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Taruna.khurana@fda.hhs.gov

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