

(System Info - 237943 CHATTOPADHYAY RANA 05/30/2013 14:34:13  
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### RECORD OF TELEPHONE CONVERSATION

Submission Type: BLA Submission ID: 125473/0 Office: OVRR

Product: Timothy Grass Pollen Allergen Extract

Applicant: Merck Sharp & Dohme Corp.

Telecon Date/Time: 20-May-2013 05:33 PM Initiated by FDA? Yes

Telephone Number: 7325941021

Communication Category(ies): 1. Advice

Author: RANA CHATTOPADHYAY

Telecon Summary: Advice regarding submission of information supporting the efficacy of MK-7243 against cross-reactive to Timothy Grass.

FDA Participants: Rana Chattopadhyay; Non-FDA Participants: Scott Greenfeder

Trans-BLA Group: No; Related STNs: None; Related PMCs: None

Telecon Body:

**From:** Chattopadhyay, Rana

**Sent:** Monday, May 20, 2013 5:34 PM

**To:** 'Greenfeder, Scott'; Lacayo, Juan

**Cc:** Sweeney, Colleen; Daugherty, Jon

**Subject:** RE: Guidance sought responding to BLA 125473 pre-BLA meeting request

Dear Scott

We would like to review a summary of the information you want to submit before determining its relevance to your BLA/IND. Therefore, we recommend that you may please send me informally by e-mail a summary of the information you want to submit.

Regards.

Rana

**Rana Chattopadhyay, Ph.D.**

*Biologist [Regulatory]*

Division of Vaccines & Related Product Applications

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**From:** Greenfeder, Scott [mailto:[scott.greenfeder@merck.com](mailto:scott.greenfeder@merck.com)]  
**Sent:** Monday, May 20, 2013 10:16 AM  
**To:** Lacayo, Juan; Chattopadhyay, Rana  
**Cc:** Sweeney, Colleen  
**Subject:** Guidance sought responding to BLA 125473 pre-BLA meeting request

Dear Juan/Rana,

In the FDA minutes from the pre-BLA meeting for BLA 125473 the Division requested information supporting the efficacy of MK-7243 against grass cross-reactive to Timothy Grass (Question 1). We have gathered this information and are in the process of drafting the response document. Can you please give me some guidance on how we should submit this response? Should it be submitted to the IND? We believe this should also be part of the BLA, how would you like us to submit this to the BLA?

Thanks for your help,

Regards,  
Scott

**Scott Greenfeder, Ph.D.**

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