

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: 06-Jan-2014 03:13 PM Initiated by FDA? Yes

Telephone Number:

Communication Category(ies): 1. Information Request

Author: RANA CHATTOPADHYAY

Telecon Summary: IR regarding pediatrics age stratification of PMC study

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, January 06, 2014 5:13 PM

To: Greenfeder, Scott (scott.greenfeder@merck.com)

Subject: STN 125473.0: Information Request (IR)

Dear Scott

Happy New Year.

We have an Information Request regarding your BLA 125473.0 on Timothy Grass pollen allergen extract sublingual immunotherapy. Under the post marketing studies of your product, it is mentioned that 8500 subjects were included, most of whom are adults. We need to know exactly how many children, 5-17 years of age, participated in those studies. Also, from your large database of spontaneous reports, what percentage of prescriptions were to children aged 5-11 years and 12-17 years? Is there any instance where children less than five years of age are prescribed?

We will appreciate if you can send the response to this IR by e-mail as soon as possible followed by submitting it as an amendment to your BLA 125473.0.

Regards.

Rana