

(System Info - 257789 CHATTOPADHYAY RANA 12/06/2013 11:52:46
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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: 06-Dec-2013 11:36 AM Initiated by FDA? Yes

Telephone Number: 732-594-1021

Communication Categorie(s): 1. Information Request

Author: RANA CHATTOPADHYAY

Telecon Summary: Request for sample e-diary card and subject comment card

FDA Participants: Rana Chattopadhyay

Non-FDA Participants: Scott Greenfeder

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

Telecon Body:

The sponsor has been requested to send as soon as possible, by e-mail, sample copies of e-diary card and subject comment card for each of the clinical studies under STN 125473.0, followed by officially submitting those documents as an amendment to the BLA.