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: 25-Feb-2014 01:05 PM Initiated by FDA? Yes

Telephone Number:

Communication Categorie(s): 1. Information Request

Author: RANA CHATTOPADHYAY

Telecon Summary: Information Request on ALK GRASTEK validation strategy

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: Tuesday, February 25, 2014 1:05 PM
To: Greenfeder, Scott (scott.greenfeder@merck.com)
Cc: Lacayo, Juan
Subject: Information Request (IR): STN 125473

Dear Scott
Regarding the ALK GRASTEK validation strategy noted in your memo dated February 9, 2014; please clarify if this strategy (i.e., (b)(4)) was prospectively defined in a process validation protocol. If your protocol does not clearly identify this strategy please provide a protocol for retrospectively validating the process. Please note that batches selected for retrospective validation should be representative of all batches made during the review period, including any batches that failed to meet specifications, and should be sufficient in number to demonstrate process consistency. Retained samples can be tested to obtain data to retrospectively validate the process.

In addition, please note that the purpose of our teleconference on February 11, 2014 was to obtain additional information on your approach for the GRASTEK DS and DP conformance lots. The acceptability of your approach for GRASTEK (for example, (b)(4)) still has to be determined. Our determination on acceptability of your approach will be based on your responses to the questions raised during the teleconference as well as the above question.

Regards.

Rana