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: 31-Mar-2014 02:13 PM Initiated by FDA? Yes

Telephone Number:

Communication Categorie(s): 1. Information Request

Author: JENNIFER BRIDGEWATER

Telecon Summary: IR regarding CMC PMCs by e-mail

FDA Participants: Jennifer Bridgewater, Rana Chattopadhyay, Taruna Khurana, Jon Daugherty

Non-FDA Participants: Scott Greenfeder

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

Telecon Body:
From: Bridgewater, Jennifer
Sent: Monday, March 31, 2014 2:13 PM
To: scott.greenfeder@merck.com
Cc: Khurana, Taruna; Bridgewater, Jennifer; Chattopadhyay, Rana; Daugherty, Jon
Subject: Graste IR
Importance: High

Hello Scott –

Taruna and I had the following comments regarding potential CMC PMC's you submitted to your BLA. If we have a clear understanding of the actions you will take and this has been specified in your BLA; then a PMC may not be needed. We understand you have to consult with you DS and DP manufacturing sites to confirm. But please get back to us as quickly as possible on the following:

Your proposed PMCs and our responses:

1. (b)(4)

Please send us a clear statement from ALK Abello that (b)(4) studies will be initiated (b)(4) then a PMC will not be required.

2. To test one commercial batch of the DP each year for stability for long term storage (36 months) at 25°C ± (b)(4) °C/(b)(4) .

As you are aware, stability testing of one commercial batch of the DP is required under the 211 cGMP regulations and such is not required as a PMC. Please provide us with a statement that ALK-Abello is aware of this US regulatory requirement.

3. To align the wash and dilution buffers per current FDA-ELISA procedure for testing potency of tablet in BAU after completion of validation using (b)(4) different batches (b)(4) times each on (b)(4) .

Changing the wash and dilution buffers after performing validation studies is a reportable change. The level of change (PAS, CBE30 for example) will be determined based on what change you actually make. Please speak with ALK Abello and send us a statement that you will contact CBER upon completion of your study so that we can discuss what type of regulatory submission will be required.

4. (b)(4)

Please send us a statement that (b)(4) study will be performed. Please note that the status of this study will be examined during your next routine inspection.

If you could send a brief amendment to your file that acknowledges the above 4 issues; then no formal PMCs be required for this BLA.

Thanks

Jennifer