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-Mar-2014 04:52 AM Initiated by FDA? Yes

Telephone Number:

Communication Categorie(s): 1. Information Request

Author: RANA CHATTOPADHYAY

Telecon Summary: Information Request, CMC

FDA Participants: Rana Chattopadhyay, Juan Lacayo

Non-FDA Participants: Scott Greenfeder

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

Telecon Body:
From: Chattopadhyay, Rana
Sent: Thursday, March 06, 2014 4:52 PM
To: Greenfeder, Scott (scott.greenfeder@merck.com)
Cc: Lacayo, Juan
Subject: STN 125473: Information Request (IR)

Dear Scott
We have reviewed your responses to our CMC information request that you submitted on October 23, 2013 as an amendment to your BLA. We have the following additional questions based on your responses. Please submit your complete response to this Information Request (IR) as an amendment to your BLA, STN 125473:
CMC IR#4 - (b)(4) testing of (b)(4) - In table 1 of your response you indicate that in 2013 (b) (4) pollen lots were tested for (b)(4) . Please provide the test results for these (b) (4) pollen lots.
CMC IR#19 - Expiration dating of (b)(4) - You indicate that the (b)(4) and is regarded as having shelf life for the duration of its use. Your response is not sufficient. Normally, (b)(4) and references are assigned an expiration date based on supportive testing data. Please indicate the shelf life assigned to your current (b)(4) based on your experience with the previous (b)(4) and any supportive analytical tests. Please provide data supporting the shelf life of your (b)(4) . In addition, please indicate if the (b)(4) is tested on stability.

CMC IR#39 - Alignment of FDA competition ELISA - You indicate that the revised ELISA will be implemented after the completion of validation using (b)(4) different batches (b)(4) each on (b)(4) different plates. Please submit a draft Post Marketing Commitment by email for our review and comment. In your PMC you should specify your proposal for the validation, a time frame for collection of data on these lots, and a time frame for submission of the data for our review.

CMC IR#41 - Absence of specified organism testing for the post approval stability program – We request that you consider adding the absence of specified organism test to your future on-going stability protocols. You responded that the "results obtained from the stability program demonstrated that the formulation of the freeze dried tablet does not support microbial growth, showing that acceptable microbial quality has been demonstrated up to 36 months. As absence of specified microorganisms is confirmed at release, the presence of specified organisms is not expected to change over time. Therefore, the applicant proposes to perform only the Microbial Enumeration test (b)(4) in accordance with (b)(4) for the post-approval stability program." We do not agree with your proposal at this time. Please include the absence of specified microorganisms test at Time Zero and at the end of your shelf-life study.