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: 28-Feb-2014 03:20 PM Initiated by FDA? Yes

Telephone Number:

Communication Categorie(s): 1. Information Request

Author: RANA CHATTOPADHYAY

Telecon Summary: Information Request on PMC study

FDA Participants: Rana Chattopadhyay, Juan Lacayo, Jon Daugherty

Non-FDA Participants: Scott Greenfeder

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

Telecon Body:
From: Chattopadhyay, Rana
Sent: Friday, February 28, 2014 3:20 PM
To: Greenfeder, Scott (scott.greenfeder@merck.com)
Cc: Lacayo, Juan; Daugherty, Jon
Subject: STN 125473: Information Request- Postmarketing Commitment (PMC)

Dear Scott
Please submit a protocol synopsis for a postmarketing commitment (PMC) to conduct a Phase 4 safety study of GRASTEK in the population for whom the product would be approved in the US. In your protocol synopsis, we advise you to conduct a study in approximately 10,000 subjects who will receive GRASTEK as indicated and to follow them for the occurrence of local and systemic adverse events (AEs) that result in medical attention (e.g., epinephrine use, hospitalization, and/or an ER visit). However, your proposal may include your own proposed sample size with a provided calculation and a justification that is supported with data. Also, in this study potential risk factors for any AEs that occur should be assessed as secondary objectives based on information obtained in evaluation of events. Such risk factors would include, but not be limited to month of year when event occurs, age, antecedent interruption of therapy, and use of any concomitant medication including allergen immunotherapy.

Please submit your protocol synopsis as an amendment to your BLA, STN 125473.
Regards.
Rana

From: Greenfeder, Scott [mailto:scott.greenfeder@merck.com]
Sent: Monday, March 03, 2014 8:02 AM
To: Chattopadhyay, Rana
Cc: Lacayo, Juan; Daugherty, Jon
Subject: Re: STN 125473: Information Request- Postmarketing Commitment (PMC)

Dear Rana,

Thank you for this request. Do you have proposed timing for Merck to respond? We will need to take some time to design this study and understand how we can accumulate the data CBER is requesting.

Regards, Scott

From: Chattopadhyay, Rana [mailto:Rana.Chattopadhyay@fda.hhs.gov]
Sent: Tuesday, March 04, 2014 11:53 AM
To: Greenfeder, Scott
Cc: Lacayo, Juan; Daugherty, Jon
Subject: RE: STN 125473: Information Request- Postmarketing Commitment (PMC)

Dear Scott:

As you may know, PMCs are part of the approval letter for all BLAs. Therefore, we need your agreed PMCs soon, given the fact that the current target date for a regulatory decision on your BLA 125473 is April 7, 2014.

Rana

From: Greenfeder, Scott [mailto:scott.greenfeder@merck.com]
Sent: Tuesday, March 04, 2014 11:56 AM
To: Chattopadhyay, Rana
Cc: Lacayo, Juan; Daugherty, Jon
Subject: RE: STN 125473: Information Request- Postmarketing Commitment (PMC)

Thank you Rana,

We will work on our response. Will you also want proposed timelines for the PMC with our submission?

Regards,
Scott

From: Chattopadhyay, Rana
Sent: Tuesday, March 04, 2014 12:13 PM
To: 'Greenfeder, Scott'
Cc: Lacayo, Juan; Daugherty, Jon
Subject: RE: STN 125473: Information Request- Postmarketing Commitment (PMC)

Scott:

As per 21CFR601.70(b)(7), you need to submit the schedule for post-marketing study which include the actual or projected dates for submission of the study protocol to FDA, completion of patient accrual, completion of study and submission of the final study report to FDA.

Rana