

(System Info - 248050 CHATTOPADHYAY RANA 09/11/2013 10:18:55  
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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: 11-Sep-2013 10:10 AM Initiated by FDA? Yes

Telephone Number: 732-594-1021

Communication Category(ies): 1. Advice

Author: RANA CHATTOPADHYAY

Telecon Summary: E-mail response to Merck's question about proposed proper name of the product

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:

Dear Scott

On March 22, 2013, we sent you a letter stating that in our initial review we found the proposed proper name, GRASTEK, for your product under STN 125473.0 acceptable. However, we will make a final decision on acceptability of the proper name close to the action due date for your BLA, STN 125473.0. Therefore, you have been granted provisional approval for 'GRASTEK' as your product name under STN 125473.0 and CBER plans to use that in the forthcoming APAC.

Dr. Juan Lacayo will respond to your question about ISE submission

We are working on the IRs and will send them to you as soon as we finalize them.

Regards.

Rana

From: Greenfeder, Scott [mailto:scott.greenfeder@merck.com]

Sent: Monday, September 09, 2013 2:01 PM

To: Lacayo, Juan

Cc: Chattopadhyay, Rana

Subject: Question regarding use of proposed tradename for MK-7243

Hi Juan, Rana

I hope this finds you well.

We noted in the FR for the BLA 125473 APAC that the product was referenced as "GRASTEK". We have been putting together our background information for the APAC and presentation using MK-7243 as GRASTEK has not been fully approved. Can you clarify whether it is FDA's intent to use GRASTEK in background documents and at the FDA presentation? We are flexible and would like to refer to the product in a manner consistent with FDA in order to avoid confusion to the APAC members and others.

Two other minor catch up items.

I had sent an email last week or so that we would be supplying the ISE tables. These are on track to submit in the next few weeks. Is this timing OK?

In the Quality discussion we had August 7th reference was made to IRs that were forthcoming. Do you have any update on these?

Many thanks,

Regards,

Scott