

(System Info - 256406 CHATTOPADHYAY RANA 11/19/2013 14:20:55
CHATTOPADHYAYR)

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-Oct-2013 12:06 PM Initiated by FDA? Yes

Telephone Number: 732-594-1021

Communication Category(ies): 1. Other -

Author: RANA CHATTOPADHYAY

Telecon Summary: CBER concurrence with Merck's proposal for (b)(4)
(b)(4) Testing and Comment #34 in amendment, dated 10/22/13

FDA Participants: Juan Lacayo

Non-FDA Participants: Scott Greenfeder

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

Telecon Body:

From: Lacayo, Juan

Sent: Thursday, October 31, 2013 12:05 PM

To: 'Greenfeder, Scott'

Subject: Response regarding (b)(4) testing and CMC IR comment 34 in
Amendment 009 for BLA 125473

Dear Scott,

We have the following responses concerning two different Amendments:

1. We have reviewed the information provided in support of the development of modified (b)(4) parameters (Amendment 008 dated September 20, 2013). You proposed an (b)(4) (b)(4). Based on the data you provided in your development study, these modified values for the (b)(4) test are acceptable to the Agency. We also agree with your proposal to use the (b)(4) method for performing the (b)(4) test for the Timothy grass drug product.

2. In response to comment 34 of our CMC Information Request (IR) dated September 16, 2013, you indicate that you have initiated studies for alignment of the wash and dilution buffers to the current FDA ELISA procedure (PBS containing 0.05% Tween-20) used to test the Timothy grass drug product. You provided supportive data regarding the alignment of the wash and dilution buffers in your response to our CMC IR comment 34 in Amendment 009 to your BLA dated October 22, 2013. In your response, you indicate that data obtained from initial comparative studies show no significant difference in the relative potency values as a result of changing the wash and dilution buffer from (b) (4) [REDACTED] PBS containing 0.05% Tween 20. Based on these data, you propose to change the wash and dilution buffer in accordance with the CBER ELISA method for lots after the launch lots. In other words, your launch lots will be tested by ELISA using your wash and dilution buffer and all subsequent lots will be tested by ELISA using CBER's recommended wash and dilution buffer. We agree with your proposal. The best mechanism for reporting this change (PMC or a supplement after BLA approval) will be discussed with you at a later date.

Thanks,
Juan

From: Greenfeder, Scott [mailto:scott.greenfeder@merck.com]
Sent: Friday, September 20, 2013 3:00 PM
To: Lacayo, Juan
Cc: Chattopadhyay, Rana
Subject: Response regarding (b)(4) [REDACTED] testing for BLA 125473

Dear Juan,

Today we submitted our response regarding the request of 18 June 2013 to perform (b)(4) [REDACTED] testing of drug product for BLA 125473. This includes proposed specifications and limits. I am including a copy of this response for your records. We respectfully request response to this proposal as quickly as possible since concurrence with these specifications is critical to our ongoing manufacturing effort.

Thank you for your help,

Regards,
Scott