

RECORD OF TELEPHONE CONVERSATION

Submission Information

Application Type	BLA
STN	125592/0.0
Review Office	OVRR
Applicant	Merck Sharp & Dohme Corp. / Lic. # 0002
Product	House Dust Mites Allergenics Extract
Trans-BLA Group:	No

Telecon Details

Telecon Date/Time	10-FEB-2017 12:08 PM
Author	STEELE, MATTHEW
EDR	No
Post to Web	Yes
Outside Phone Number	
FDA Originated?	No
Communication Categories	AD - Advice IR - Information Request
Related STNs	None
Related PMCs	None
Telecon Summary	Discussion via e-mail clarifying several requests.
FDA Participants	Matthew Steele, Colleen Sweeny, Taruna Khurana
Applicant Participants	Nadine Margaretten

Telecon Body:

From: Steele, Matthew [<mailto:Matthew.Steele@fda.hhs.gov>]

Sent: Friday, February 10, 2017 4:27 PM

To: Margaretten, Nadine

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Cc: Sweeney, Colleen; Khurana, Taruna

Subject: RE: Another USPI comment/question: STN 125592 Label and Med Guide comments

Nadine, we have the following answers:

- 1 EoE: Of the 2 MK-8237 treated subjects diagnosed with EoE, 1 subject (from P001) was a 13-year-old treated with 12 DU and the other subject (from MT-06) was a 34-year-old treated with 6 DU.

Question to FDA: The AEs currently summarized in section 6 of the USPI are for MK-8237 12 DU and placebo, and for ages 18-65 to align with the indication. Please confirm if the Sponsor should add information in Section 6 on the 2 EoE cases described above, neither of which meet both the age range and dose for the proposed indication.

RESPONSE: We confirm that you should add these cases of EoE to section 6. Because EoE is a rare and serious side effect, any recorded cases should be described.

- 2 (b) (4)

RESPONSE: Your proposed label implies that your product (b) (4)

You have not submitted data to support this claim

(b) (4)

- 3 The sponsor agrees to include the FAS-MI analysis in the table for the primary and secondary endpoints . The sponsor also requests to include some limited prespecified FAS information to allow a like-with-like comparison to the efficacy reported from trial 1 (Table 2) and with other AIT products as this will be helpful to prescribers. Please see the attached rationale. Can you kindly bring this request to the reviewers?

RESPONSE: We agree that the results from the FAS with observation analysis can be presented for information only. Please clearly state in the footnote that the FAS with observation analyses are considered additional analyses.

-Matt

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From: Margaretten, Nadine [mailto:nadine_margaretten@merck.com]

Sent: Friday, February 10, 2017 10:13 AM

To: Steele, Matthew

Cc: Sweeney, Colleen; Khurana, Taruna

Subject: Another USPI comment/question: STN 125592 Label and Med Guide comments

Dear Matt,

I have one more update and request from our labeling team pertaining to the USPI Table 3.

The sponsor agrees to include the FAS-MI analysis in the table for the primary and secondary endpoints . The sponsor also requests to include some limited prespecified FAS information to allow a like-with-like comparison to the efficacy reported from trial 1 (Table 2) and with other AIT products as this will be helpful to prescribers. Please see the attached rationale. Can you kindly bring this request to the reviewers?

Thanks and best regards,
Nadine

From: Steele, Matthew [<mailto:Matthew.Steele@fda.hhs.gov>]

Sent: Thursday, February 09, 2017 5:17 PM

To: Margaretten, Nadine

Cc: Sweeney, Colleen; Khurana, Taruna

Subject: RE: status, USPI revisions: STN 125592 Label and Med Guide comments

Thank you for the update. I will send your comments along.

-Matt

From: Margaretten, Nadine [mailto:nadine_margaretten@merck.com]

Sent: Thursday, February 09, 2017 5:01 PM

To: Steele, Matthew

Cc: Sweeney, Colleen; Khurana, Taruna

Subject: RE: status, USPI revisions: STN 125592 Label and Med Guide comments

Dear Matthew,


We are revising the labeling although we have some questions as noted below. FDA's perspective will help our team to revise the labeling appropriately in a timely manner. Because we need to generate new tables for the USPI, we need a few more days to prepare the labeling.

- 1 USPI Table 1 AEs: we are preparing a new table that will have the solicited AEs listed by the patient friendly terms from the side effect report card, both total, and by severity. We have mapped the patient friendly terms to be included in the table and the MedDRA preferred terms in the database to support the new Table 1. These tables may take 1-2 days to prepare.

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- 2 EoE: Of the 2 MK-8237 treated subjects diagnosed with EoE, 1 subject (from P001) was a 13-year-old treated with 12 DU and the other subject (from MT-06) was a 34-year-old treated with 6 DU.

Question to FDA: The AEs currently summarized in section 6 of the USPI are for MK-8237 12 DU and placebo, and for ages 18-65 to align with the indication. Please confirm if the Sponsor should add information in Section 6 on the 2 EoE cases described above, neither of which meet both the age range and dose for the proposed indication.

- 3 (b) (4)
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Question to FDA: Can you please clarify the reason why FDA has asked us to remove this information?

For your information, today we submitted additional AE tables under the BLA. However, these tables were prepared to support the current USPI Table 1 and hence may not be useful as we are now preparing new tables to list the AE terms in the side effect report card.

Thanks and regards, I would appreciate guidance from FDA on the above questions.
Nadine