

From: Sweeney, Colleen [<mailto:Colleen.Sweeney@fda.hhs.gov>]

Sent: Wednesday, January 25, 2017 8:44 PM

To: Margaretten, Nadine

Cc: Steele, Matthew; Khurana, Taruna

Subject: Re: Information Request regarding

Dear Dr. Margaretten:

As discussed today, we note that your Pharmacovigilance Action Plan for Specific Safety Concerns makes reference to a proposed Post Marketing Study entitled, "Post-Market Claims and EMR Based Study of Serious Allergic Reactions and Eosinophilic Esophagitis in Marketed Use of MK-8237 in the United States." This study is analogous to, and intends to use the existing database currently utilized for post marketing studies of GRASTEK and RAWITEK.

Please explicitly state if this is a Post Marketing Commitment Study. If so, please indicate if you intend to submit further information including a timeline for protocol submission, study completion, and study report submission.

Please submit this information as an amendment to STN 125592/0.

Thank you.

Captain Colleen Sweeney R.N., M.S., USPHS

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