

**From:** Sweeney, Colleen [<mailto:Colleen.Sweeney@fda.hhs.gov>]  
**Sent:** Wednesday, January 26, 2017  
**To:** Margaretten, Nadine  
**Subject:** Re: Acknowledgement of Intention to submit PMC study/s

Dear Dr. Margaretten:

In addition to the discussion of January 25, 2017, regarding your Pharmacovigilance Action Plan for Specific Safety Concerns that 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," we acknowledge your intention to submit further information regarding you Post Marketing Commitment Study/s under this BLA.

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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