

From: Sweeney, Colleen [<mailto:Colleen.Sweeney@fda.hhs.gov>]
Sent: Wednesday, July 27, 2016 4:49 PM
To: Margaretten, Nadine
Cc: Steele, Matthew; Khurana, Taruna
Subject: RE: STN 125592/0 Clinical Information Request

Dear Dr. Margaretten,

We have the following requests for additional information regarding your biologics license application (BLA):

On Page 172, Section 2.1.5.1.3.2, Summary of Clinical Safety, Potential Cases Evaluated for eosinophilic esophagitis (EoE) in the All Combined Phase II and Phase III Trials, you reference a *Database Review of Corticosteroids* and state, "Approximately 100 cases of corticosteroids, taken in a formulation (inhaled solution or aerosol) that is generally consistent with swallowed administration of a corticosteroid, were reported." Please indicate which of these cases were in the placebo or the treatment group. In addition, please provide information regarding alternative diagnoses or reasons why these subjects may have been prescribed swallowed corticosteroids.

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

Thank you,

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