

From: Sweeney, Colleen
Sent: Monday, June 06, 2016 3:27 PM
To: Margaretten, Nadine (nadine_margaretten@merck.com)
Cc: Steele, Matthew; Khurana, Taruna
Subject: RE: STN: 125592 Advice/Information Request

Dear Dr. Margaretten,

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

1. We acknowledge your June 1, 2016, submission that contained an analysis of the primary endpoint of Total Combined Rhinitis Score (TCRS) during the last 8 weeks of treatment from North American subjects (Study P001). Please calculate the 95% confidence interval of the difference in the TCRS of the treatment relative to placebo for both the Full Analysis set and the Per Protocol Analysis set for each of the following groups:
 - a. Subjects 12 through < 18 years of age.
 - b. Subjects 18 through 65 years of age.
 - c. Subjects > 65 years of age.
2. We acknowledge your March 9, 2016, e-mail correspondence confirming that you will submit a safety update report (SUR) summary of available postmarketing data through April 9, 2016. Please provide an estimated date for the submission of these data.
3. In section 1.3.5.3 of your February 7, 2016, submission, you request 12-year biologics data exclusivity for MK-8237 (House Dust Mites Allergen Extract) in accordance with criteria set forth in the Public Health Service (PHS) Act section 351(a). Please be aware that we are deferring this discussion and request pending a decision to approve your BLA.

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

Thank you,

*Colleen Sweeney R.N., M.S.
Captain, USPHS
Division of Vaccines & Related Product Applications
Office of Vaccines Research & Review Center for Biologics Evaluation & Research
US Food & Drug Administration
10903 New Hampshire Ave Silver Spring, MD 20993 - 0002. Tel: +1 301 796 2640
E- Fax: +1 301 402 0004; Fax: +1 301 827 3075
E. Mail: colleen.sweeney@fda.hhs.gov*

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.