

From: Sweeney, Colleen
Sent: Friday, April 01, 2016 4:05 PM
To: Margaretten, Nadine (nadine_margaretten@merck.com)
Subject: RE: STN 125592/0 Information Request

Dear Dr. Margaretten:

We have the following requests for additional information regarding your BLA:

1. Please provide Standard Operating Procedures (SOPs) for all of the release tests described in Sections 3.2.S.4.2 and 3.2.P.5.2 - Analytical Procedures.
2. The Clinical Study Report (CSR) provided for clinical study P001 (Section 5.3.5.1) lists the clinical supplies dispensed to subjects as manufacturing lot numbers; (b) (4) . The placebo lots are indicated as (b) (4) (pages 4 and 5 of 637). Please indicate the section of Module 3 that contains the product information regarding the above listed drug product and placebo batches used in study P001.
3. Section 3.2.R (Regional Information) contains drug substance batch records written in Danish. Please provide executed batch records for the commercial scale drug substance batches in English.
4. Please provide the Microsoft Word version of the proposed labeling text in Section 1.14.1.3 as stated in your cover letter for this submission.

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

5. Please be aware that the Proper Name for your product is, "House Dust Mite (*Dermatophagoides pteronyssinus* and *Dermatophagoides farinae*) Allergen Extract."

Thank you.

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