

From: Sweeney, Colleen
Sent: Friday, November 18, 2016 2:31 PM
To: Margaretten, Nadine (nadine_margaretten@merck.com)
Cc: Steele, Matthew; Khurana, Taruna
Subject: RE:STN 125592/0: Information Request to submit Final Study Report submitted under IND 15015.107 (enclosed) to the BLA

Dear Dr. Margaretten:

We have the following request for additional information regarding your biological license application (BLA):

On April 15, 2015, you submitted the enclosed Final Study Report entitled, "Chromosomal Aberration Test of Allergen Extract (b) (4) Obtained from Two Types of House Dust Mites (*Dermatophagoides pteronyssinus* and *Dermatophagoides farinae*) in Cultured Human Peripheral Blood Lymphocytes," under IND 15015.107.

Please submit this Final Study Report as an amendment to STN 125592/0.

Thank you.

Colleen Sweeney R.N., M.S.

Captain, USPHS

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