

From: Sweeney, Colleen
Sent: Wednesday, February 22, 2017 2:40 PM
To: Margaretten, Nadine (nadine_margaretten@merck.com)
Cc: Khurana, Taruna; Steele, Matthew
Subject: RE: STN 125992/0 Submission of February 17, 2017

Dear Dr. Margaretten:

We note that your February 17, 2017, submission to STN 125592/0 contains a proposed (b) (4) [REDACTED] method to test the next (b) (4) [REDACTED] stability data for one of the out of specification (OOS) *Dermatophagoides farinae* drug substance batches. We remind you of the January 18, 2017, telephone conference discussion in which we explicitly stated that future validation data with release limits must be submitted as a post-approval supplement to your biological license application (BLA). We reiterate this request.

Please be aware that the data submitted in this amendment will not be reviewed. The only amendments you should submit at this time are ones that are in response to our specific requests, i.e. updated package insert (PI) .

We request that you withdraw this submission and resubmit the contents pending post approval.

Thank you.

Colleen Sweeney

Captain Colleen Sweeney R.N., M.S., USPHS

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