

From: Khurana, Taruna
Sent: Tuesday, October 18, 2016 8:03 AM
To: nadine_margaretten@merck.com
Subject: STN 125592 HDM SLIT- CMC Information Request

Dear Margaretten,

We have the following information request regarding (b) (4);

1. In enclosure 2 submitted in the July 1, 2016 amendment to your BLA we notice DP (b) (4) procedure indicated as "draft". Please clarify if the procedure is draft or final.
2. Please indicate if the (b) (4) assay is completely validated and the validation report submitted on July 1, 2016 is final and not experimental.
3. Please indicate the ICH guidelines used for the validation of (b) (4) procedure.
4. (b) (4) and CU analytical worksheet 18310-11.0 has (b) (4) HDM DP (b) (4). This reference material is made up of IHR batch (b) (4) and IHR (b) (4). Please indicate the date of manufacture of these IHRs and of these two specify Der p and Der f IHR.
5. Please provide the procedure for sample reanalysis used during (b) (4) validation.
6. Please provide a list of all the (b) (4) runs performed in the quality lab for the potency test (b) (4) of the drug product batches with reportable results for both (b) (4). Please include all rejected runs in the list and specify the reason for the rejected runs.

Thank you

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