

From: Khurana, Taruna
Sent: Tuesday, January 24, 2017 1:01 PM
To: nadine_margaretten@merck.com
Cc: Sweeney, Colleen (Colleen.Sweeney@fda.hhs.gov); Steele, Matthew (Matthew.Steele@fda.hhs.gov)
Subject: BLA STN 125592 Proper Name

Dear Nadine,

We have the following comment for the Proper name of your product;

- In amendment 7 submitted on April 7, 2017 you requested that in the proper name of your product the species names to be included in alphabetical order e.g. *D. farinae* and *D. pteronyssinus*. This is acceptable.

The agreed upon proper name for the product is House Dust Mite (*Dermatophagoides farinae* and *Dermatophagoides pteronyssinus*) Allergen Extract.

Please make sure to have consistency in the proper name on the Primary Packaging, Secondary Packaging, US Package Insert, and the Lot Release Protocol.

Let me know if you have any question.

Thank you
Taruna

Taruna Khurana, PhD

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