

From: Sweeney, Colleen
Sent: Wednesday, June 08, 2016 4:29 PM
To: Margaretten, Nadine (nadine_margaretten@merck.com)
Cc: Steele, Matthew; Khurana, Taruna
Subject: RE: STN 125592 Advice information Request regarding carton and container labels and APAC

Dear Dr. Margaretten,

We have the following advice and requests for additional information regarding your biologics license application (BLA):

1. The following items pertain to your proposed container (blister pack) label:
 - a. Please be aware that all detachable labels must contain the national drug code (NDC), proprietary name, lot and expiration date.
 - b. We do not object with your proposal to abbreviate the genus "*Dermatophagoides*."
 - c. Please revise the position of the trade name to be below the proper name [21 CFR 610.62(a)].
 - d. Please revise the proper name to be as prominent as the trade name [21 CFR 610.62(b)].
 - e. Please be aware that the minimum font size for the proper name is 6 point.

2. The following items pertain to your proposed carton label:
 - a. Please revise the position of the trade name to be below the proper name [21 CFR 610.62(a)].
 - b. Please revise the proper name to be as prominent as the trade name [21 CFR 610.62(b)].
 - c. Please amend the label to include the NDC.
 - d. Please amend the label to include storage or dosage information, or a reference to the package insert.

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

3. Please be aware that there will be no Allergenic Products Advisory Committee (APAC) Meeting summoned to discuss your product submitted under STN 125592/0.

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