

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.

Colleen Sweeney R.N., M.S.
Captain, USPHS
Division of Vaccines & Related Product Applications
Office of Vaccines Research & Review Center for Biologics Evaluation & Research
US Food & Drug Administration
10903 New Hampshire Ave Silver Spring, MD 20993 - 0002. Tel: +1 301 796 2640
E- Fax: +1 301 402 0004; Fax: +1 301 827 3075
E. Mail: colleen.sweeney@fda.hhs.gov

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.