

From: Jarvis, Candace
Sent: Thursday, March 4, 2021 12:31 PM
To: Lokuta, Mary
Cc: Bauer, Steven; Jarvis, Candace; Sherafat-Kazemzadeh, Rosa; Xu, Lei (CBER); Brony, Michael
Subject: BLA 125730.0| Stratatech Corp | Final Labeling,

Importance: High

Good afternoon Mary,
I hope you are well and are staying safe.

I wanted inform you that the Package Insert is acceptable and request that the final SPL version be in sent in as an amendment to the BLA.

Regarding the carton labels and the “logo” on the Patient information sheet (At the top), the proprietary name is listed first followed by the proper name. Per FDA guidance, the proprietary name and the proper name may not be separated by placement of intervening matter that, in any way, would detract, obfuscate, or de-emphasize the established name of the product, or obscure the relationship between the proprietary name and the proper name. This means that the proper name should be listed first followed by the proprietary name. You will not be able to have the “dot rainbow” above the name StrataGraft. Also the name StrataGraft will need to be capitalized on the Primary carton labels and Patient Information Sheet.

Please note that anytime you use the full product title you should adhere to the guidance listed above. This applies to all package and containers

Once this has been changed and reviewed by FDA, we will then ask the final version be sent in.

Please respond by Tuesday, March 9, 2021 by 12PM EST

Please let me know if you have any questions.
Please confirm receipt.

Thank you,

Candace N. Jarvis
Regulatory Project Manager

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