From: Jarvis, Candace
Sent: Thursday, March 11, 2021 12:37 PM
To: Lokuta, Mary
Cc: Bauer, Steven; Sherafat-Kazemzadeh, Rosa; Xu, Lei (CBER); Brony, Michael
Subject: RE: [EXTERNAL] RE: BLA 125730.0| Stratatech Corp | Final Labeling,

Importance: High

Good afternoon Mary,

I hope you are well.

Thank you for providing notification of Stratatech's most recent submission received on March 9,
2021. We have the following comments.

We do not accept the change for adding the patent website link in both the PI and the Patient
Information sheet. This will need to be removed. We do, accept the corrected formatting, updated
phone number, and the addition of the license number and part number.

We refer you to 21 CFR 610.62 regarding the carton labeling. As stated previously, 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. We have reviewed your justification and the label examples
provided and do not agree with the justification proposed. The examples cited in your justification are for
a class of biologics that have been grandfathered in and cannot be compared to your product. The label
as proposed for your product does not comply with regulation. Therefore, we disagree and reiterate our
reference to 21 CFR 610.62.

Please confirm receipt.

Thank you,
Candace

New - COVID-19 CBER Regulated Biologics

DRPM, Achieving Regulatory Excellence!

From: Lokuta, Mary <Mary.Lokuta@mnk.com>
Sent: Tuesday, March 09, 2021 3:29 PM
To: Jarvis, Candace <Candace.Jarvis@fda.hhs.gov>
Cc: Bauer, Steven <Steven.Bauer@fda.hhs.gov>; Sherafat-Kazemzadeh, Rosa <Rosa.Sherafat-
Kazemzadeh@fda.hhs.gov>; Xu, Lei (CBER) <Lei.Xu2@fda.hhs.gov>; Brony, Michael <Michael.Brony@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: BLA 125730.0| Stratatech Corp | Final Labeling,

Greetings Candace
I wanted to let you know that Sequence #0042 was received through the gateway earlier today. This
included
* Removal of the stylized logo from the draft patient information sheet.
* A justification to maintain the logo on the package carton based on FDA guidance documents,
regulatory precedent, and legal best practices.
Additionally, while the review team finalizes the UNII code, we also submitted the draft package insert
with the previously identified minor updates to correct formatting, update phone number, and to add
the license number, part number, and patent statement.
Please let me know if you have any questions and stay well!
Best regards
Mary

Mary A. Lokuta, PhD | Director of Regulatory Affairs

Stratatech - A Mallinckrodt Company
510 Charmany Drive, Suite 150 | Madison, WI 53719
Office: 608 441-2750 | Direct: 608 441-8358 | Fax: 608 441-2757
mary.lokuta@mnk.com | www.mallinckrodt.com

From: Jarvis, Candace <Candace.Jarvis@fda.hhs.gov>
Sent: Thursday, March 4, 2021 1:46 PM
To: Lokuta, Mary <Mary.Lokuta@mnk.com>
Cc: Bauer, Steven <Steven.Bauer@fda.hhs.gov>; Sherafat-Kazemzadeh, Rosa <Rosa.Sherafat-
Kazemzadeh@fda.hhs.gov>; Xu, Lei (CBER) <Lei.Xu2@fda.hhs.gov>; Brony, Michael <Michael.Brony@fda.hhs.gov>
Subject: Re: [EXTERNAL] RE: BLA 125730.0| Stratatech Corp | Final Labeling,

Hi Mary,
Thank you for your email we will discuss internally and get back to you as soon as possible.

Get Outlook for iOS

From: Lokuta, Mary <Mary.Lokuta@mnk.com>
Sent: Thursday, March 4, 2021 1:49:41 PM
To: Jarvis, Candace <Candace.Jarvis@fda.hhs.gov>
Cc: Bauer, Steven <Steven.Bauer@fda.hhs.gov>; Sherafat-Kazemzadeh, Rosa <Rosa.Sherafat-
Kazemzadeh@fda.hhs.gov>; Xu, Lei (CBER) <Lei.Xu2@fda.hhs.gov>; Brony, Michael <Michael.Brony@fda.hhs.gov>
Subject: [EXTERNAL] RE: BLA 125730.0| Stratatech Corp | Final Labeling,

Greetings Candace
I am acknowledging receipt of this email and have a few questions around it.
First, I was in the process of emailing you that in the current draft of the USPI we had noticed:
* a few minor typos (two extra spaces)

*	a formatting issue (table shifted to the left)
*	and one addition we would like to make at line 454 to include a link to the website containing
the current list of patents (“for a list of patents, see https://www.mallinckrodt.com/patents/”)

Would it be acceptable to incorporate these four edits in the submission of the final version as discussed
below?

Additionally, I had reached out previously around the need for the UNII code. This code will be
necessary to complete the SPL information for the submission of the final USPI. Has the UNII code been
determined? If so, can that be provided so that the USPI may be submitted?

Best regards,
Mary

Mary A. Lokuta, PhD | Director of Regulatory Affairs
Stratatech - A Mallinckrodt Company
510 Charmany Drive, Suite 150 | Madison, WI 53719
Office: 608 441-2750 | Direct: 608 441-8358 | Fax: 608 441-2757
mary.lokuta@mnk.com | www.mallinckrodt.com

From: Jarvis, Candace <Candace.Jarvis@fda.hhs.gov>
Sent: Thursday, March 4, 2021 11:31 AM
To: Lokuta, Mary <Mary.Lokuta@mnk.com>
Cc: Bauer, Steven <Steven.Bauer@fda.hhs.gov>; Jarvis, Candace <Candace.Jarvis@fda.hhs.gov>;
Sherafat-Kazemzadeh, Rosa <Rosa.Sherafat-Kazemzadeh@fda.hhs.gov>; Xu, Lei (CBER) <Lei.Xu2@fda.hhs.gov>; Brony, Michael <Michael.Brony@fda.hhs.gov>
Subject: [EXTERNAL] 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

Center for Biologics Evaluation and Research
Office of Tissues and Advanced Therapies
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Bldg. 71, RM 5248
Silver Spring, MD 20993-0002
Tel: 240-402-8315
Fax: 301.595.1303
candace.jarvis@fda.hhs.gov

DRPM, Achieving Regulatory Excellence!