

From: Fisher, Adriane
Sent: Wednesday, October 6, 2021 12:25 PM
To: Kevin Healy
Subject: Information Request PI #51 | STN 125685/0 | Allogeneic Processed Thymus Tissue | Due Date by COB Wednesday, October 6, 2021
Attachments: BLA 125685/0 | allogeneic processed thymus tissue-agdc - Labeling Section 508 Compliance; Working Version_BLA 125685.0 Draft Label_Annotated_Enzyvant 06Oct2021.docx
Importance: High

Dear Dr. Healy:

We are reviewing your April 9, 2021 biologics license application for Allogeneic Processed Thymus Tissue for the immune reconstitution of patients with congenital athymia. We determined that the following information is necessary to continue our review please see PI attachment.

Please make sure your tables/figures are 508 compliant. See email attachment sent to you on Thursday, September 23, 2021.

Please note: Please accept all changes and comments that you agree with and leave only the ones you disagree, with justification for your disagreement. Please make all your new changes/additions/deletions in track so we can identify what was modified. The PI when you send it back should be the next version of the document.

The review of this submission is on-going, and issues may be added, expanded upon, or modified as we continue to review this submission.

Due to the interest of time, please submit your response to this information request as an amendment to this file by COB Wednesday, October 6, 2021 referencing the date of this request. Please include both a red-line strike out and clean copy of the revised package insert in WORD format. If you anticipate you will not be able to respond by this date, please contact us immediately so a new response date can be identified.

The action due date for this file is October 8, 2021. Please acknowledge receipt.

Sincerely,

Adriane Fisher, MPH, MBA
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New - COVID-19 CBER Regulated Biologics