

Dehdashti, Seameen (Jean)

From: Dehdashti, Seameen (Jean)
Sent: Friday, January 04, 2019 9:17 PM
To: 'BDV (Barbara Davies)'
Cc: Dehdashti, Seameen (Jean)
Subject: BLA 125671 - FDA Revised Sections of Draft Prescribing Information
Attachments: BLA125671_Draft.PI.Sections_FDA.Comments_04Jan2019.docx

Dear Barbara,

Attached please find FDA review team revised sections of the draft Prescribing Information (PI) for your review and commenting. Please keep the attached document in "Track Changes", so that any edits you add to the document are captured. If you are in agreement with certain FDA edits, please accept these changes. If you are not in agreement with certain FDA edits, please provide your justification in a comment box to the review team. We would appreciate your review of the current sections by close of business, Tuesday, January 8, 2019. A formal amendment to the BLA is not necessary, please only email me your reviewed/revised document. I will document our communication to the file from FDA side. We will start requesting formal amendments to the BLA, once we start review of the full PI.

Please note that the edits found in the attached document are not considered final, and the labeling review is still ongoing by FDA review team and management. We are sending sections of the PI for your review and commenting earlier than scheduled, so that we can explain our rationale for the requested revisions to certain sections. Additional changes will still occur and will be reflected in the full PI that will be sent, once all FDA review disciplines and management have had the chance to review and complete their edits, projected towards the end of January 2019.

Please confirm receipt of this communication, and do not hesitate to contact me, should you have any questions and/or concerns.

Warm regards,

Jean Dehdashti, MSc, RAC
Regulatory Project Manager

Center for Biologics and Evaluation
Office of Tissues and Advanced Therapies
U.S. Food and Drug Administration

Tel: 240-402-9146

Seameen.Dehdashti@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.