

Davidson, Mark

From: Davidson, Mark
Sent: Friday, September 29, 2017 3:37 PM
To: 'Rizwana Sproule'
Cc: 'Nadia Agopyan'; 'Alex Babayan'
Subject: Kite Pharma 125643 YESCARTA PRESCRIBING INFORMATION Label 9.29.17
Attachments: YESCARTA PI Working Version 9-29-17.docx; Attachment to YESCARTA PI Working Version 9-29-17_Group Terms.docx

Hi Dr. Sproule as we discussed earlier today, please try to respond to the PI revisions by Monday, October 2, 2017.

Dear Dr. Sproule,

Please see the attached prescribing Information (PI) label for YESCARTA™ (axicabtagene ciloleucel). This is the second round of comment to the prescribing information label. Please review and if need make any revisions you feel should be incorporated and return the PI back to me by Mon. October 2, 2017, 12:00PM EST. In your return email, let me know if you agree with the recommended changes or you can make revisions with comment. We will continue with this process until we have reached an agreement. Please give me call if you have question(s) or if you would like to discuss in more detail.

Thank You

Mark L. Davidson, RHIA
Regulatory Project Manage
OTAT/CBER/FDA
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Phone: 240-402-8277
Fax:301-595-1303
mark.davidson@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 immediately by e-mail or phone."