

Davidson, Mark

From: Davidson, Mark
Sent: Friday, September 29, 2017 7:49 PM
To: 'Rizwana Sproule'; 'Nadia Agopyan'; 'Alex Babayan'
Subject: BLA 125643 Kite Pharma YESCARTA Risk Evaluation and Mitigation Strategy (REMS) Documents 9.29.17
Attachments: YESCARTA_REMS_doc_20170921_for OCC--occ redline v2.docx;
YESCARTA_REMS_supp_redlined_AMJ_cz 20170929.docx

Dear Dr. Sproule,

Please see the attached Risk Evaluation and Mitigation Strategy (REMS) Documents for YESCARTA™ (axicabtagene ciloleucel). Please review and if need comment on any revisions you feel should be pointed out to the FDA. Please return the REMS documents back to me by Wed. October 4, 2017, 12:00PM EST. Also, please send a formal amendment to the BLA 125643 as you would the PI. 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 a call if you have question(s) or if you would like to discuss in more detail.

Thank You

Mark L. Davidson, RHIA
Regulatory Project Manager
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

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