

**From:** Melendez, Crystal  
**To:** [Sophia Siu](#)  
**Cc:** [Fisher, Adriane \(Adriane.Fisher@fda.hhs.gov\)](#)  
**Bcc:** [Price, Graeme](#)  
**Subject:** 125703.0\_Kite Pharma, Inc.\_Advice for REMS  
**Date:** Wednesday, June 24, 2020 3:35:00 PM  
**Attachments:** [image001.png](#)

Hello Sophia,

*The Yescarta and Tecartus REMS is currently under review. Please submit to the Yescarta BLA the most recent Yescarta and Tecartus REMS document and supporting documents (submitted June 19, 2020) as well as the appended materials. Please submit both versions with tracked changes and clean version of all materials to the Yescarta STN 125643 as a major REMS modification. Please ensure all submitted REMS materials are consistent with REMS document submitted June 19, 2020.*

*The applicant submitted the following request for advice:*

***Following initial approval of the combined YESCARTA and TECARTUS REMS Program, Kite proposes submission of a final close-out REMS assessment for the YESCARTA REMS Program capturing the reporting period from the end of the last assessment report (19 August 2019) through the day prior to initial approval of the new combined YESCARTA and TECARTUS REMS Program. Thereafter, per the proposed combined YESCARTA and TECARTUS REMS assessment timetable (REMS Document, Section IV), Kite will submit REMS Assessments to the FDA at 6 months, 12 months, and annually thereafter from the date of the initial approval of the YESCARTA and TECARTUS REMS Program.***

***Does the Agency agree with Kite's proposal to complete a final close-out YESCARTA REMS Assessment Report following approval of the YESCARTA and TECARTUS REMS Program?***

*FDA Response:*

*This plan is acceptable. Should Tecartus be approved, please submit, within 90 days, the final closeout*

*REMS assessment capturing data as you have described.*

*Please acknowledge receipt.*

*Thank you,*

**Crystal Melendez, MT, RN, BSN**

*Regulatory Project Manager*

**U.S. Food and Drug Administration**

**Center for Biologics Evaluation and Research**

**Office of Tissues and Advanced Therapies**

10903 New Hampshire Avenue

Silver Spring, MD 20993

Bldg. 71, 4268

Tel: 240-402-8348

Wk cell: 240-772-6272

[crystal.melendez@fda.hhs.gov](mailto:crystal.melendez@fda.hhs.gov)

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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent