

Davidson, Mark

From: Davidson, Mark
Sent: Thursday, June 29, 2017 8:48 AM
To: 'Rizwana Sproule'
Cc: 'Nadia Agopyan'; 'Alex Babayan'
Subject: BLA 125643 -YESCARTA® Proprietary Name Acceptance

Importance: High

Dear Dr. Sproule:

We have reviewed your March 31, 2017, submission to your Biologics License Application (BLA) for axicabtagene ciloleucel, requesting a proprietary name review for YESCARTA®.

In consultation with Center for Biologics Evaluation and Research's Advertising and Promotional Labeling Branch (CBER/APLB), we conclude that, under the Federal Food, Drug, and Cosmetic Act and applicable regulations, YESCARTA® is Acceptable.

If you have any questions, please contact the Regulatory Project Manager, Mark L. Davidson at (240) 402-8277.

Sincerely yours,

Mark L. Davidson, RHIA
Regulatory Project Manager
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