

Davidson, Mark

From: Davidson, Mark
Sent: Tuesday, September 26, 2017 1:04 PM
To: Rizwana Sproule (RSproule@KitePharma.com)
Cc: 'Nadia Agopyan'; 'Alex Babayan'
Subject: Kite Pharma 125643 Package Label and CMC IR 9.26.17

Importance: High

Dear Dr. Sproule,

1. Please revise the package label so that it is consistent with 21 CFR 610.62(b). The package label trade name should be all one color, no italics, same typography, and no intervening images (i.e. purple and gold arrow) because the current label presentation adversely affects the prominence of proper name. Please provide a revised sample label by 9/29/17.
2. Please provide the (b) (4) Executed RA038 Summary Report by 9/28/17. RA038 was expected to be completed 9/15/17.

Please provide the package label revision and (b) (4) information ASAP.

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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