

From: Polo, Stephanie
Sent: Wednesday, November 14, 2018 3:56 PM
To: 'Patrick.O'Neil@sanofi.com' <Patrick.O'Neil@sanofi.com>
Cc: Prutzman, Kirk C <Kirk.Prutzman@fda.hhs.gov>; Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>
Subject: STN 125682/0-DENG VAXIA: Proprietary Name Acceptable

Dear Mr. O'Neil,

We have reviewed your August 31, 2018 submission to your Biologics License Application (BLA) for Dengue Tetravalent Vaccine (Live, Attenuated) requesting a proprietary name review for DENG VAXIA.

In consultation with the 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, your proposed proprietary name, DENG VAXIA, is acceptable.

Please confirm receipt of this message and let me know if you have any questions or need additional information.

Best regards,

Stephanie Polo

Primary Reviewer/Regulatory Project Manager

Center for Biologics Evaluation and Research
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