



Our STN: BL 125694/0

PROPRIETARY NAME ACCEPTABLE

November 2, 2018

AveXis, Inc.
Attention: James L'Italien, PhD
Senior Vice President, Chief of Regulatory and Quality Officer
2275 Half Day Road, Suite 200
Bannockburn, IL 60015

Dear Dr. L'Italien:

We have reviewed your September 28, 2018, submission to your Biologics License Application (BLA) for onasemnogene abeparvovec, requesting a proprietary name review for ZOLGENSMA.

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, the name ZOLGENSMA is acceptable.

If you have any questions, please contact the Regulatory Project Manager, Candace Jarvis, at (240) 402-8315.

Sincerely,

Ramani Sista, PhD, RAC, CQA
Director
Division of Regulatory Project Management
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research