

From: [Jarvis, Candace](#)
To: [James L'Italien, PhD \(jlitalien@avexis.com\)](#)
Cc: [Nancy Boman](#); [Jarvis, Candace](#); [Byrnes, Andrew](#)
Subject: BLA 125694/0| AveXis, Inc.| Suffix Review
Date: Thursday, January 24, 2019 2:19:53 PM
Attachments: [image002.png](#)

Good afternoon Dr. L'Italien,
Please refer to your BLA Application received on October 1, 2018.

Your sixth proposed suffix meets the criteria set forth in Guidance for Industry – Nonproprietary Naming of Biological Products. Thus, we find the proper name, onasemnogene abeparvovec – xioi, conditionally acceptable for your proposed product. Should your 351(a) BLA be approved during this review cycle, onasemnogene abeparvovec – xioi, will be the proper name designated in the license and you should revise your proposed labels and labeling accordingly. However, please be advised that if your application receives a complete response, the acceptability of your proposed suffix will be re-evaluated when you respond to the deficiencies. If we find your proposed proper name unacceptable upon our reevaluation at that time, we will inform you of our finding. Please let me know if you have any questions.

Please confirm receipt.

Regards,

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