

From: [Jarvis, Candace](#)
To: [James L'Italien, PhD \(jlitalien@avexis.com\)](#)
Cc: [Nancy Boman](#); [Byrnes, Andrew](#); [Saini, Sonny](#); [Jarvis, Candace](#)
Subject: BLA 125694/0 | AveXis, Inc | Information Request 37 (PLEASE RESPOND BY MARCH 4, 2019)
Date: Monday, February 25, 2019 8:56:19 AM **Attachments:**
[image001.png](#)

Good morning Dr. L'Italien,

We have the following request for information regarding BLA 125694. Please respond by March 4, 2019. Please let us know asap if there will be a delay in providing a response to this request.

Please provide by March 4th updated vial label artwork in section 1.14 of the BLA to include the new color for the 5.5 mL vial labels. Please also provide evidence that the purple and grey label colors are distinguishable.

Please acknowledge receipt of this email.

Regards,

Candace N. Jarvis
Regulatory Project Manager
Center for Biologics Evaluation and Research
Office of Tissues and Advanced Therapies
U.S. Food and Drug Administration
Tel: 240-402-8315
candace.jarvis@fda.hhs.gov



THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender immediately by e-mail or phone.