

From: [Jarvis, Candace](#)
To: [James L'Italien, PhD \(jlitalien@avexis.com\)](#)
Cc: [Nancy Boman](#); [Jarvis, Candace](#); [Kong, Hyesuk](#); [Byrnes, Andrew](#)
Subject: BLA 125694/0 | AveXis, Inc | Information Request 29 (PLEASE RESPOND BY January 22,2019)
Date: Thursday, January 17, 2019 2:07:25 PM
Attachments: [image013.png](#) **Importance:** High

Good afternoon Dr. L'Italien,

We have the following request for information regarding BLA 125694/0. Please respond by COB January 22, 2019. If you are unable to meet this deadline, please let us know as soon as possible so that we can negotiate a new date.

Please submit the (b) (4) method qualification assay results for the (b) (4) to show the test samples meet their qualification acceptance criteria according to (b) (4).

Please confirm receipt.

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.