

From: [Jarvis, Candace](#)
To: [James L'Italien, PhD \(jlitalien@avexis.com\)](#)
Cc: [Nancy Boman](#); [Jarvis, Candace](#); [Whatley, Angela](#); [Byrnes, Andrew](#)
Subject: BLA 125694/0 | AveXis, Inc | Information 41 \ (PLEASE RESPOND BY 3/15/19
Date: Wednesday, March 13, 2019 9:41:33 AM **Attachments:**
[image013.png](#)

Good morning Dr. L'Italien,

We have the following information request from our CMC division regarding BLA 125694. Please respond no later than March 15, 2019.

Please send the SOP with the written procedures for the receipt, identification, quarantine, storage, handling, sampling, testing, release, and approval or rejection of materials. Please send this information by 3/15/2019.

Please acknowledge 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.