

From: [Jarvis, Candace](#)
To: [James L'Italien, PhD \(jlitalien@avexis.com\)](#)
Cc: [Nancy Boman](#); [Byrnes, Andrew](#); [Wang, Wei \(FDA\)](#); [Jarvis, Candace](#); [Glen, Jacqueline](#)
Subject: BLA 125694/0 | AveXis, Inc | Information Request 42 (Please Respond by March 28, 2019)
Date: Thursday, March 14, 2019 9:26:39 PM
Attachments: [image002.png](#) **Importance:** High

Good evening Dr. L'Italien,

We have the following request for additional information regarding BLA 125694. Please respond no later than March 28, 2019.

1. During the pre-license inspection (PLI), we noted that some parts of the filler are (b) (4). Please update the BLA submission Section 3.2.A.1 with information of cleaning and sterilization of (b) (4) parts.
2. In Section 3.2.S.2.2 of STN 125694/0 you stated that the (b) (4) (i.e., the (b) (4) is not re-used). During the PLI we noted that a (b) (4) was mentioned in the Master Batch Record for (b) (4). It was not clear if the (b) (4) Please clarify.
3. Please address the suitability of your Container Closure Integrity Test method (i.e. CCIT by (b) (4)) to detect the potential compromised container closure integrity due to loss of elastic properties of the CL Butyl stopper (material number (b) (4) Gray) during the long term (up to (b) (4) storage at $\leq -60^{\circ}\text{C}$. Information provided should address the potential regaining of elastomeric properties of the stopper and the re-sealing of the container closure system once thawed.

Please confirm receipt.

Regards,

Candace N. Jarvis
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