

From: [Jarvis, Candace](#)
To: [James L'Italien, PhD \(jlitalien@avexis.com\)](#)
Cc: [Nancy Boman](#); [Byrnes, Andrew](#); [Wang, Wei \(FDA\)](#); [Jarvis, Candace](#)
Subject: BLA 125694/0| AveXis, Inc| Information Request 24 (Please Respond by January 18, 2019)
Date: Monday, January 07, 2019 7:56:40 PM
Attachments: [image013.png](#)
Importance: High

Good evening Dr. L'Italien,

We have the following request for information regarding BLA 125694. Please respond by January 18, 2019. If you are unable to respond to this request by the designated timeline, please let us know.

Comments:

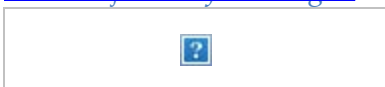
1. Air Flow – In the Air Pressurization Plan (RG0.07A), Air Flow direction was illustrated from the (b) (4) out through PALs (b) (4) and out through PAL (b) (4). However, the air pressures indicate that air flow direction is from PALs (b) (4) into the (b) (4). Air Flow from PAL (b) (4), into the Fill Suite (b) (4) appears to be an issue. Please clarify this information discrepancy. Please clarify if doors of the (b) (4) PALs (b) (4) may be open at a same time.
2. Please clarify if (b) (4) is used. If not, please provide justifications.
3. Based on diagrams provided in Section 3.2.A.1. Facilities and Equipment – Diagrams of STN 125694/0, Cleanroom areas (b) (4) served by (b) (4) seemed to be a (b) (4) manufacturing unit with different controls of Personnel and Material Flows compared with flows in manufacturing cleanroom areas (such as (b) (4)). Please clarify if cleanroom areas served by (b) (4) are used for AVXS-101 (b) (4) DP commercial manufacturing activities.
4. In Section 3.2.A.1. Facilities and Equipment – Diagrams of STN 125694/0, Bookmarks RG0.05, RG0.05A, RG0.05B, RG0.07 and RG0.07A did not match the actual Sheet Numbers of these diagrams. Product Flow information was incomplete. Please update the Section with correct and complete flow diagrams.
5. The AHU serving the PAL (b) (4) was not indicated in Table 4 “Cleanrooms, Environmental Classifications, and AHUs” of section 3.2.A.1 Facilities and Equipment of STN 125694/0.

6. Please indicate the air pressure for the room number (b) (4) –
PAL).

Please acknowledge receipt.

Regards,

Candace N. Jarvis
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