

From: [Jarvis, Candace](#)

To: [James L'Italien, PhD \(jlitalien@avexis.com\)](#)

Cc: [Nancy Boman](#); [Byrnes, Andrew](#); [Whatley, Angela](#); [Jarvis, Candace](#)

Subject: BLA 125694/0| AveXis, Inc| Information Request 62 (Please Respond by May 10, 2019)

Date: Tuesday, May 07, 2019 9:08:47 PM

Attachments: [image002.png](#)

Candace N. Jarvis
-S

Original Message

File: 1014 x gnd-by-Candace N. Jarvis - S

On: Tue, 05/07/2019 09:08:47 PM

From: Pw@x - 0-2482 352030000 100 1 - 1 20080600014

File: Candace N. Jarvis - S

Date: 2019 05 10 10:55:58 -04:00

Good evening Dr L'Italien,

1. We note you have not provided the executed report which demonstrates that you have control over the labeling of the frozen DP. Please provide report 1121-validation of labeling for the DP referenced during the teleconference with FDA on May 2 2019, or additional data which demonstrates this process is validated and under control.
2. Regarding the carton artwork submitted on May 2, 2019 in submission number 75, we do not agree with the statement “Infuse within (b) (4) days of receipt or prior to expiry.” Please change this to “Must use within (b) (4) days of receipt” or “Infuse within (b) (4) days of receipt” and submit the revised carton artwork.
3. Please confirm that DP vials will not be distributed if they have less than (b) (4) days of shelf life remaining.
4. According to SOP-330, vector reference standard lots are monitored at least (b) (4) for long-term stability per an approved stability protocol. Please provide this stability protocol.

Please acknowledge receipt of this email.

Candace N. Jarvis
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