

From: [Jarvis, Candace](#)
To: [James L'Italien, PhD \(jlitalien@avexis.com\)](#)
Cc: [Nancy Boman](#); [Byrnes, Andrew](#); [Jarvis, Candace](#)
Subject: BLA 125694/0| AveXis, Inc Information Request 38 (PLEASE RESPOND BY MARCH 13, 2019)
Date: Wednesday, March 06, 2019 5:40:48 PM
Attachments: [image002.png](#) **Importance:** High

Good evening Dr. L'Italien,

We have the following request for information regarding BLA 125694/0. Please respond by no later than March 13, 2019.

The draft package insert currently indicates that when the Zolgensma kit is removed from the shipper it will thaw within (b) (4) if refrigerated or within (b) (4) at room temperature. Our current understanding is that you intend the commercial product to be packaged in a kit that may contain up to 9 vials. Please provide data to support thaw times for the 9-vial kit.

Please acknowledge receipt.

Regards,

Candace N. Jarvis
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