

From: Jarvis, Candace
Sent: Tuesday, May 21, 2019 5:45 PM
To: James L'Italien, PhD (jlitalien@avexis.com)
Cc: Nancy Boman; Byrnes, Andrew; Jarvis, Candace; Kong, Hyesuk
Subject: 125694/0| AveXis, Inc|)Post Marketing Commitment #4 Request (Please Respond by May 22, 2019

Importance: High

Hello Dr L'Italien,

CBER will need AveXis to implement a (b) (4) compliant Bioburden test. Please see the following draft PMC language. If this language is acceptable, we will also need you to respond by email and submit it as an amendment to the BLA immediately.

AveXis agrees to revise the Bioburden Determination operating procedure (SOP-085) to be compliance with (b) (4), including (b) (4) on (b) (4) (b) (4). AveXis agrees to implement the revised SOP-085 for all bioburden tests and to provide the revised SOP-085 by July 1, 2019.

Please respond to this request by noon May 22, 2019.

Please acknowledge receipt.

Regards,

Candace N. Jarvis
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Center for Biologics Evaluation and Research
Office of Tissues and Advanced Therapies
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