

From: [Jarvis, Candace](#)
To: [James L'Italien, PhD \(jlitalien@avexis.com\)](#)
Cc: [Nancy Boman](#); [Thompson, Deborah](#); [Singer, Mike](#); [Xu, Lei \(CBER\)](#); [Niu, Manette](#); [Byrnes, Andrew](#); [Jarvis, Candace](#)
Subject: BLA 125694/0 |AveXis, Inc| Information Request 60 (PLEASE RESPOND BY MAY 6, 2019)
Date: Wednesday, May 01, 2019 10:09:32 PM
Attachments: [image002.png](#)
Importance: High

Good evening Dr L'Italien,

We have the following information request regarding BLA 125694. Please respond no later than COB on May 6, 2019.

Further information is requested regarding the CL-303 Efficacy and Safety Update. Two treatment-related TEAEs of diastolic hypertension were reported. Please provide information regarding the subject study ID numbers, dates of onset of the events (i.e., study day), description of any related signs or symptoms, assessment of the clinical significance, description of any relevant cardiac laboratory/ECG/echocardiogram findings for the subjects, any treatment provided for the diastolic hypertension, status of diastolic hypertension (i.e., resolved or ongoing), and rationale for the events being considered treatment-related. Please respond by Monday, May 6, 2019.

Please confirm receipt.

Regards,

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