

From: [Jarvis, Candace](#)
To: [James L'Italien, PhD \(jlitalien@avexis.com\)](#)
Cc: [Nancy Boman](#); [Byrnes, Andrew](#); [Singer, Mike](#); [Xu, Lei \(CBER\)](#)
Subject: BLA 125694/0| AveXis, Inc | Information Request 64 (Please Respond by May 17, 2019)
Date: Tuesday, May 14, 2019 7:37:00 PM **Attachments:**
[image013.png](#)

Good evening Dr. L'Italien,

We have the following request for information regarding BLA 125694/0. Please respond to this IR by May 17, 2019

Please provide the information below:

1. The number of investigators who are sponsor employees (including both full-time and part-time employees).
2. The number of investigators with disclosable financial interests/arrangements.
:
3. If there are investigators with disclosable financial interests/arrangements, please specify the number of investigators in each of the categories listed below. (Please also provide for each such investigator an attachment with details of the disclosable financial interests/arrangements, and steps taken to minimize potential bias. If you are unable to obtain that information for any investigator(s), please provide the reason the information could not be obtained.)
 - a. Number of investigators receiving compensation for conducting the study, where the value could be influenced by the outcome of the study.
 - b. Number of investigators receiving significant payments of other sorts.
 - c. Number of investigators holding proprietary interest in the product tested.
 - d. Number of investigators holding significant equity interest in the sponsor.
4. Please complete and sign Form 3454 and Form 3455.

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5. For Study AVXS-101-CL-303, please provide the number of patients screened, the number excluded from the study, and the reason(s) those patients were excluded.

Please acknowledge receipt.

Regards,

Candace N. Jarvis
Regulatory Project Manager

Center for Biologics Evaluation and Research
Office of Tissues and Advanced Therapies
U.S. Food and Drug Administration

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