

Valencia, Iliana

From: Wood, Lorraine

Sent: Friday, April 14, 2017 12:35 PM

To: Wolfgang Pieken

Cc: Valencia, Iliana

Subject: Request for Teleconference for BLA 125588 and 125589

Importance: High

Sent on Behalf of Iliana Valencia

Dear. Dr. Pieken,

FDA is requesting a phone conversation regarding your current submissions, BL 125588 (NAT) and BL 125589 (AFIA) and your responses to software and instrumentation questions received on March 20, 2017 and March 23, 2017, respectively. Please include staff with software development, quality systems and risk management expertise with these devices, so we can discuss your responses and establish a plan to resolve outstanding questions efficiently.

Please let me know your availability for the teleconference.

Thanks

Lorraine

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