

**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

**Lorraine D. Wood, MS, MLS(ASCP)<sup>CM</sup>**

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**THIS MESSAGE**