

**Tilghman, Tracy**

**From:** Lindsey, Kimberly  
**Sent:** Tuesday, September 25, 2012 12:22 PM  
**To:** Tilghman, Tracy  
**Cc:** Ananyeva, Natalya  
**Subject:** FW: Proposed FDA comments for EVARREST telecon regarding PI points of clarification 9.18.2012

**Attachments:** BLA STN 125392 PI clarification points 9.18.202.doc

Tracy

[Please make this part of the administrative file.](#)

Thank you

Kimberly

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**From:** Lindsey, Kimberly  
**Sent:** Wednesday, September 19, 2012 10:39 AM  
**To:** Ananyeva, Natalya  
**Subject:** Proposed FDA comments for EVARREST telecon regarding PI points of clarification 9.18.2012

Hi Natalya,

I discussed the clinical points of clarification with Nisha yesterday afternoon. This draft document summarizes our current thinking on the clinical clarification points. After the telecon, we should make our final edits to the PI and send them to Nisha and Tim as the final part of the SBRA. Once we receive their edits, we can send the annotated PI to Ethicon.



BLA STN 125392 PI  
clarificatio...

Of course, we will take notes during the telecon and our responses may change based on the discussion today.

Thanks,  
Kimberly