

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

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