

**Information Request for MACI (STN 125603/0) Regarding Vericel's Response received on 11 October, 2016 for Sterility using (b) (4) Validation testing**

Please provide attachments #1 and #2 for your validation report (GTR-168-03-01-A), which contain MACI batch production records for sample configuration and challenge strain inoculum preparation records for confirmatory (b) (4), respectively.