

Information Request for MACI (STN 125603/0)

IR in regards to an IR submitted by CBER on 29 June, 2016 and as discussed during a Mid-Cycle Telecon with Vericel on the same day, where CBER requested a (b) (4) sterility limit of detection (LOD) study using (b) (4) in accordance with (b) (4), either (b) (4). During this Telecon, Vericel requested CBER determine which of their known environmental microorganisms should be included in their LOD study.

CBER found (b) (4) mentioned in Validation Reports (GTR-139-03-01 and GTR-168-03-01) and in section 3.2.S.4 Table 4 of the current submission. Out of these environmental microorganisms, CBER requests Vericel perform their LOD study using (b) (4), in addition to the (b) (4). CBER is expecting these results on or before 01 October, 2016.