

Information Request for BLA 125518/0 (original application) OncoVEX^{GM-CSF} (Talimogene Laherparepvec) genetically-modified herpes simplex virus type 1 (HSV-1) as oncolytic immunotherapy for the treatment of unresected melanoma - Sterility and Bacterial Endotoxin Test (BET).

1. Please provide the qualification report for the sterility test of OncoVEX^{GM-CSF} demonstrating that the test was qualified in accordance with (b) (4) to confirm the product matrix for the final container drug product is suitable for the intended test method. Please include the (b) (4) conditions and conformance lot numbers.
2. Please provide the bacterial endotoxin test qualification report demonstrating that the final container drug product matrix for OncoVEX^{GM-CSF} is suitable for the intended test method (in accordance with (b) (4) to include maximal valid (b) (4), tested (b) (4), positive product control percent recoveries, lot numbers, selected testing (b) (4) and endotoxin test results.