

Information Request for BLA 125518/0 'TALIMOGENE LAHERPAREPVEC'

<Bacterial Endotoxin Testing (BET)>

CBER performed BET by Kinetic Chromogenic method on your preservative-free frozen liquid product for each conformance lot (i.e., (b) (4)) using the (b) (4) sample, as stated in your validation report for drug product (TSOP201.04 Form A). CBER had an issue with the (b) (4) sample (b) (4) and had to (b) (4) the (b) (4) in order to generate valid results. Please provide CBER all inhibition/enhancement method qualification reports including data used in deciding to test your product in a (b) (4) state for your (b) (4) .