Information Request for BLA 125518/0 (original application) Imlygic™ (talimogene laherparepvec; OncoVEX^{GM-CSF}) genetically-modified herpes simplex virus type 1 (HSV-1) encoded with hGM-CSF, as oncolytic immunotherapy for the treatment of injectable regionally or distantly metastatic melanoma.

1. Regarding your Risk Management Plan (module 1.16):

   - Multicenter observational registry Study 20120139 for evaluation of long-term safety data (pages 24 and 33): If it has been submitted in the original BLA, could you clarify where the protocol is located in your application? If it has not been submitted, when can FDA expect to receive the protocol?

   - For the potential risk of Talimogene laherparepvec-mediated (b) (4) response (page 23), you state that an "*assay will be available prior to product launch*." Where is this assay described in your application? If it has not been submitted, when can FDA expect to receive further details of this assay?