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 an oncolytic immunotherapy indicated for the treatment of injectable regionally or distantly metastatic melanoma.

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

   In the phase 3 clinical trial 005/05, suspected herpetic lesions in patients were *not* routinely tested by qPCR for product versus wild type HSV-1. A contributing reason was that some herpetic lesions crusted over/resolved in the time that elapsed before sample collection could take place. Please provide a detailed strategy that would ensure that eligible individuals (the patient, close contact, or health care provider) in the post-licensure period (whether in postmarketing study 20130193 or identified through the Amgen Global Safety Database) have **rapid and reliable access** to sample collection and laboratory testing of suspected herpetic lesions/manifestations to confirm T-Vec transmission should it occur. Also provide, if available, evidence that validates your proposal.