March 10, 2015

Information Request for BLA 125518 (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.

Regarding Amgen communication dated March 5, 2015 (Sequence No. 0022, module 1.11.3) which eliminates the step of providing sample (b) (4) and instead proposes to simultaneously send the questionnaire and a list of "acceptable swabs" (assumed to be available at a primary HCP's office) for sample collection.

- Please clarify who makes the determination for qPCR testing of a suspected lesion, how is that decision is made, and what amount of time is expended to complete this assessment? How is this box ("is qPCR testing required") on the flow diagram initiated, and can you confirm that the lack of a "No" arrow is intentional.
- Please clarify the means by which the sample will be transported to the Amgen central laboratory for qPCR assay?
- Please define: (b) (4) and (b) (4) in your flow chart

Figure 1. Process for Capturing Unintended Exposure in PM Setting