DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

Our STN: BL 125518/0

MAJOR AMENDMENT ACKNOWLEDGEMENT

DECEMBER 11, 2014

AMGEN, INC.
ATTENTION: MS. KATHLEEN SUGRUE-RICHARDS
BIOVEX INCORPORATED, A WHOLLY-OWNED SUBSIDIARY OF AMGEN INC
ONE AMGEN CENTER DRIVE
THOUSAND OAKS, CA 91320

Dear Ms. Sugrue-Richards:

We received your November 26, 2014 amendment to your biologics license application (BLA) submitted under section 351 of the Public Health Service Act (42 U.S.C. 262) for Talimogene laherparepvec on November 28, 2014.

We consider your submission a major amendment under the reauthorization of the prescription drug user fee program in the *Food and Drug Administration Safety and Innovation Act* of 2012 and will add an additional three months to the time by which we should complete our review. Therefore, the action due date is October 27, 2015.

We will contact you regarding your proposed labeling no later than September 27, 2015. If post marketing study commitments (506B) are required, we will contact you no later than September 27, 2015.

If you have any questions, please contact the Regulatory Project Manager, Mark L. Davidson, at 240-402-8277.

Sincerely yours,

Raj K. Puri, M.D., Ph.D.
Director
Division of Cellular and Gene Therapies
Office of Cellular, Tissue and Gene Therapies
Center for Biologics Evaluation and Research