



**March 12, 2014**

OUR STN: BL# 125518/0

Amgen, Inc.  
Attention: Anne Marie Woodward  
BioVex, Wholly Owned Subsidiary of Amgen  
34 Commerce Way  
Woburn, MA 01801

Dear Ms. Woodward:

We have reviewed your December 13, 2013 request for a proprietary name review for talimogene laherparepvec, included with the first module of your submission of portions of an application (SoPA), for your planned Biologics License Application (BLA) under provision (c) of Section 506 of the Food, Drug, and Cosmetic Act (the Act)(21 U.S.C. 356.

In consultation with CBER's Advertising and Promotional Labeling Branch (APLB) we conclude that under the Federal Food, Drug, and Cosmetic Act and applicable regulations, your proposed proprietary name "IMLYGIC" is acceptable at this time.

You should request another proprietary name review of "IMLYGIC" for further evaluation within 14 days of submitting your biologics license application.

If you have any questions, please contact Mark L. Davidson at (301) 827-6536.

Sincerely yours,

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