BLA 125476/S-027

APPROVAL LETTER

Takeda Pharmaceuticals U.S.A., Inc.
Attention: Mayuresh Gadre
Senior Manager, Global Regulatory Affairs Development
40 Landsdowne Street
Cambridge, MA 02139

Dear Mr. Gadre:

Please refer to your Supplemental Biologics License Application (sBLA) dated and received November 9, 2018, submitted under section 351(a) of the Public Health Service Act for Entyvio (vedolizumab) injection.

This "Changes Being Effected in 30 days" Supplemental Biologics License Application provides for the addition of [redacted] (b) (4) as an additional testing site for the product-specific host cell protein (HCP) ELISA for vedolizumab drug substance lot release testing.

APPROVAL

We have completed our review of this supplemental biologics license application. This supplement is approved.

This information will be included in your biologics license application file.

If you have any questions, call Andrew Shiber, Regulatory Business Process Manager, at (301) 796 - 4798.

Sincerely,

{See appended electronic signature page}

Kathleen A. Clouse, Ph.D.
Director
Division of Biotechnology Review and Research I
Office of Biotechnology Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Kathleen Clouse Strebel

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