BLA 125476/S-046

SUPPLEMENT APPROVAL

Takeda Pharmaceuticals U.S.A., Inc.
Attention: Steffen Creaser, PhD
Associate Director, Global Regulatory Affairs Development, GI
40 Landsdowne Street
Cambridge, MA 02139

Dear Dr. Creaser:

Please refer to your supplemental biologics license application (sBLA) dated and received April 29, 2022, and your amendments, submitted under section 351(a) of the Public Health Service Act for Entyvio (vedolizumab) for injection.

This Prior Approval sBLA provides for updates to the label to include 0.9% Sodium Chloride Injection, USP, and Lactated Ringer's Injection, USP, as alternatives to Sterile Water for Injection (SWFI) for reconstitution of Entyvio.

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling text for the Prescribing Information and Medication Guide and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements.

Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As* at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this BLA, including pending "Changes Being Effected" (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR

601.12(f)] in Microsoft Word format that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

CARTON AND CONTAINER LABELS

Submit final printed carton and container labels that are identical to the enclosed carton and container labeling and carton and container labeling submitted on June 6, 2022 as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved BLA 125476/S-046.**" Approval of this submission by FDA is not required before the labeling is used.

If you have any questions, call Anh-Thy Ly, Regulatory Business Process Manager, at (240) 402 - 1001.

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

Enclosures:

Content of Labeling
Carton and Container Labeling

Kathleen
Clouse Strebel

Digitally signed by Kathleen Clouse Strebel
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