



BLA 125476/S-038
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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 applications (sBLAs), dated and received December 18, 2020 and February 12, 2021, and your amendments, submitted under section 351(a) of the Public Health Service Act for Entyvio (vedolizumab) for injection.

These Prior Approval supplemental biologics applications provide for the following updates to the Prescribing Information (PI):

- Sections 6.2 Immunogenicity and 12.3 Clinical Pharmacology to revise the immunogenicity results from studies C13006 and C13007 using an updated assay method
- Section 6.3 Postmarketing Experience to add “acute pancreatitis”
- Section 8.2 Lactation to add the results of a milk-only lactation study conducted as a postmarketing commitment

APPROVAL & LABELING

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling with minor editorial revision to update the revision date and reflected in the enclosed 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

FDA.gov,¹ 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 Effectuated” (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*.²

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 Effectuated” (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(s), 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).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved BLA (in 21 CFR 600.80 and in 21 CFR 600.81).

If you have any questions, contact Kelly Richards, Senior Regulatory Health Project Manager, at (240) 402-4276 or email at kelly.richards@fda.hhs.gov

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Deputy Director for Safety
Division of Gastroenterology
Office of Immunology and Inflammation
Center for Drug Evaluation and Research

¹ <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

² We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

BLA 125476/S-038

BLA 125476/S-039

Page 3

ENCLOSURE(S):

- Content of Labeling
 - Prescribing Information
 - Medication Guide

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

JOYCE A KORVICK
08/17/2021 04:40:07 PM