NDA 020049/S-034

**SUPPLEMENT APPROVAL**

Takeda Pharmaceuticals U.S.A., Inc.
Attention: Valerie Tews
Senior Manager Regulatory Affairs
40 Landsdowne Street
Cambridge, MA 02139

Dear Ms. Tews:

Please refer to your Supplemental New Drug Application (sNDA) dated and received April 29, 2020, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Pentasa (mesalamine) Extended- Release Capsules.

This Prior Approval supplemental new drug application provides for a revision to the established name for the Pentasa product from mesalamine controlled-release capsules to mesalamine extended-release capsules along with quality information to confirm that the NDA 020049 drug product complies with the requirements within the current USP monograph for the drug product.

## 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.

## CARTON AND CONTAINER LABELS

Submit final printed carton and container labels that are identical to enclosed carton and container labels, 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 "**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 020049/S-034.**" Approval of this submission by FDA is not required before the labeling is used.

## REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Grecia C. Edwards, Regulatory Business Process Manager, at (240) 402 - 1773.

Sincerely,

*{See appended electronic signature page}*

David Lewis, PhD.
Branch Chief, BII
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure:
Carton and Container Labeling

David Lewis

Digitally signed by David Lewis
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