NDA 209279/S-008

SUPPLEMENT APPROVAL

Actelion Pharmaceuticals Ltd
c/o Janssen Research & Development, LLC
Attention: Jenna Giacchi
Associate Director, Regulatory Leader
1820 Chapel Avenue West
Suite 300
Cherry Hill, NJ 08002

Dear Ms. Giacchi:

Please refer to your Supplemental New Drug Application (sNDA) dated June 26, 2020, received June 26, 2020, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Tracleer (bosentan) tablet, for suspension.

We also refer to our approval letter dated July 29, 2021, which contained the following error: Missing Labeling Language

This replacement approval letter incorporates the correction of the error. The effective approval date will remain July 29, 2021, the date of the original approval letter.

This Prior Approval supplemental new drug application provides for a final and complete PAS data package to support the registration of a bisected 32 mg tablet for oral Suspension.

APPROVAL
We have completed our review of this supplemental application, as amended. This supplement is approved.

FULFILLMENT OF POSTMARKETING REQUIREMENT(S)/COMMITMENT(S)
We have received your submission dated June 26, 2020, reporting on the following postmarketing commitment listed in the September 5, 2017 approval letter.

3265-1 Develop and submit CMC information supporting the change to the scoring of the tablet, i.e. changing the tablet from quadrisected to bisected.

We have reviewed your submission and conclude that the above commitment was fulfilled.

This completes all of your postmarketing requirements and postmarketing commitments acknowledged in our September 5, 2017, letter.

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, that is identical to the enclosed labeling 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*.

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).

Sincerely,

{See appended electronic signature page}

Ee Sunn Chia Ph.D.
Director
Division of New Drug Products III
Office of New Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):
Content of Labeling

Ee-Sunn (Joanne) Chia

Digitally signed by Ee-Sunn (Joanne) Chia
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