



NDA 021348/S-15

SUPPLEMENT APPROVAL

Actelion Pharmaceuticals, Ltd.
Attention: Lori A. Palmer
Director, US Drug Regulatory Affairs
1820 Chapel Avenue West
Cherry Hill, New Jersey 08002

Dear Ms. Palmer:¹

Please refer to your supplemental new drug application (sNDA) dated May 24, 2019, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zavesca (miglustat)

This "Changes Being Effected" supplemental new drug application provides for revised package labeling to implement "Tallman" lettering on the carton and foil blister pack.

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.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to the submitted carton and immediate container labels, except with the revisions listed above, 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 – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3)*. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 021348/S-15**". Approval of this submission by FDA is not required before the labeling is used.

If you have any questions, call Jenny Doan, Regulatory Project Manager, at (301) 796-1023.

¹ 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>.

Sincerely,

{See appended electronic signature page}

Dragos Roman, M.D.
Acting Director
Division of Gastroenterology and Inborn Errors
Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Carton and Container Labeling

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/

DRAGOS G ROMAN
06/26/2019 02:47:50 PM