DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-348/S-005

Actelion Clinical Research, Inc.
Attention: Jennifer Dohanish
Regulatory Affairs Associate
1820 Chapel Avenue West
Suite 300
Cherry Hill, NJ 08002

Dear Ms. Dohanish:

Please refer to your supplemental new drug application dated February 23, 2007, received March 1, 2007, submitted under section 505(b)/pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Zavesca® (miglustat) 100 mg Capsules.

We acknowledge receipt of your submissions dated May 2, 2007, June 19, 2007, August 22, 2007, September 12, 2007, September 14, 2007, and February 19, 2008.

This "Changes Being Effected" supplemental new drug application proposes the following changes: labeling revisions to the Description section, Carcinogenesis, Mutagenesis, and Impairment of Fertility section, Warnings (Peripheral Neuropathy subsection) section, Precautions (Diarrhea and Weight Loss subsection) section, and Adverse Reactions section of the package insert.

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

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted) February 19, 2008.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-348/S-005**." Approval of this submission by FDA is not required before the labeling is used.

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 Shelia Lianos, Regulatory Project Manager, at (301) 796-4147.

Sincerely,

*{See appended electronic signature page}*

Joyce Korvick, M.D., M.P.H.
Deputy Director
Division of Gastroenterology Products
Office of Drug Evaluation III
Center For Drug Evaluation & Research

Enclosure

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

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/s/
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Joyce Korvick
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