DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-372/S-005

Helsinn Healthcare SA
Attention: Timothy K Ressler, (US Agent, MGI Pharma, Inc.)
Vice President, Regulatory Affairs
6611 Tributary St
Baltimore, MD 21224

Dear Mr. Ressler:

Please refer to your supplemental new drug application dated February 16, 2006, received February 23, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Aloxi® (palonosetron hydrochloride) Injection, 0.25 mg/mL, 5 mL.

This "Changes Being Effected" supplemental new drug application provides to add a statement to the ADVERSE REACTIONS Section of the Package Insert (PI).

We completed our review of this application. 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 enclosed labeling text for the package insert submitted February 16, 2006.

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 Betsy Scroggs, Regulatory Project Manager, at (301) 796-0991.

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 and Research

Enclosure

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

/s/

Joyce Korvick
8/23/2006 12:59:14 PM