



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-372/S-002

Helsinn Healthcare SA.
Attention: Ms. Carol Anding – (US Agent-MGI Pharma, Inc.)
5775 West Old Shakopee Road, Suite 1000
Bloomington, MN 55437

Dear Ms. Anding:

Please refer to your supplemental new drug application dated April 14, 2004, received April 16, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Aloxi™ (palonosetron hydrochloride) Injection, 0.25 mg/5 mL.

We acknowledge receipt of your submissions dated January 5, January 31, and June 24, 2005.

We also acknowledge the June 28, 2005 teleconference between you and the Division and your June 28, 2005 submission containing the agreed-upon final Patient Package Insert (PPI) text incorporating the agreed upon changes in your June 24, 2005 submission, and the additional revision discussed in the June 28, 2005 teleconference.

Your submission of January 5, 2005 constituted a complete response to our October 15, 2004 action letter.

This supplemental new drug application provides for the addition of a PPI to the labeling.

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 enclosed labeling text for the draft patient package insert (identified as "28 JUNE 2005 FINAL VERSION"), submitted June 28, 2005.

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 21-372/S-002**". Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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, Pharm.D., Regulatory Project Manager, at (301) 827-1250.

Sincerely,

{See appended electronic signature page}

Brian E. Harvey, M.D., Ph.D.
Director
Division of Gastrointestinal and Coagulation Drug 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
7/5/05 04:55:37 PM
for Dr. Brian E Harvey