DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-372/S-006

Helsinn Healthcare SA
Attn: Craig Lehmann, Pharm.D.
US Agent, August Consulting
515 Capital of Texas Highway, Suite #150
Austin, TX 78746

Dear Dr. Lehmann:

Please refer to your supplemental new drug application dated July 31, 2006, received August 2, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Aloxi® (palonosetron hydrochloride) 0.25 mg/mL Injection, 5 mL.

We acknowledge receipt of your submissions dated September 14, 26, October 6, and December 18, 2006, May 23, and August 22, 2007.

This supplemental new drug application provides for a change in the dosage and administration section of the ALOXI labeling. You proposed to delete a sentence which prevents repeated dosing within a seven day interval.

We completed our review of this application, as amended and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions indicated in the enclosed labeling.

The following items are the minor and editorial changes made in the attached label:

- "See full prescribing information for ALOXI" – a period was added to this sentence at the top of Highlights.
- "See 17 for PATIENT COUNSELING INFORMATION and FDA-Approved patient labeling," The words "Patient" and "Labeling" are now capitalized.
- A vertical line in the left margin was added to Section 2.1 in the FPI because it's the Recent Major Change.
- In 12.3 under Special Populations, the cross-reference to section 8 was corrected.
- In section 17 in the FULL PRESCRIBING INFORMATION (FPI), under "17 PATIENT COUNSELING INFORMATION," a reference to 17.2 was added to read: "*See FDA-approved Patient Labeling (17.2).*"

Please make the following format corrections to your label:

- The "Use in Specific Populations" header in Highlights has an odd, incomplete dashed line. Please correct this and make it consistent with the others.
- You must add a vertical line at the bottom of page one separating the “CONTENTS” section from the FPI.

These revisions are terms of the approval of this application.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Gastroenterology Products and two copies of both the promotional materials and the package inserts directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Giuseppe Randazzo, Project Manager, at (301) 796-0980.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., MPH
Deputy Director
Division of Gastroenterology Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure (label)

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

8/30/2007 10:18:52 AM