**August Consulting**

515 Capital of Texas Highway
Suite 150
Austin, Texas 78746
Tel: 512.347.1755
Fax: 512.347.9375

May 1, 2013

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Donna Griebel, MD, Director
Food and Drug Administration
Division of Gastroenterology and Inborn Error Products
Center for Drug Evaluation and Research
5901-B Ammendale Road
Beltsville, MD 20705-1266

**Re: NDA 21-372**
**Palonosetron HCl Intravenous Injection, 0.25 mg (Aloxi™)**
**General Correspondence**
**Subject: RESPONSE TO PREA NON-COMPLIANCE LETTER (CINV)**
**Sponsor: Helsinn Healthcare SA**

Dear Dr. Griebel:

This letter responds to FDA's PREA non-compliance letter dated April 11, 2013, for NDA 21-372 which was FDA-approved July 25, 2003. Included below are the reason for delayed submission of the pediatric assessment and a request for deferral extension.

As you know, the initial I.V. palonosetron CINV pediatric assessment study was completed in 2006, was intended to fulfill the NDA 21-372 PREA requirement, and the study report was submitted to the IND as FDA requested. However, during subsequent interactions with FDA regarding the pediatric program it was determined worthwhile to perform an additional pediatric safety and efficacy trial to determine the appropriate dose for each applicable pediatric age group. Therefore an additional safety and efficacy trial was performed which extended beyond the PREA deferral date.

Helsinn plans to submit the pediatric assessment study reports to the NDA by the end of this year and therefore requests pediatric assessment deferral extension to December 31, 2013.

As requested in your letter, a copy of this letter is also being submitted to the IND under which the pediatric assessment studies were performed.

Please call me at 512-347-1755 if you wish additional information.

Best Regards,

Craig Lehmann, Pharm.D.
Authorized Representative for the NDA – Pediatric Program

Cy: (1) FDA
Attention: Dr. Lynne Yao
10903 New Hampshire Avenue
Building #22, Room #6406
Silver Spring, MD 20993

(2) Dr. Paolo Villa Santa, Manager, Regulatory Affairs, and Dr. Dario Ceriani, Director, Regulatory Affairs, Helsinn Healthcare SA