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HELSINN HEALTHCARE SA

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Robert L. Justice, MD, Director
Division of Gastrointestinal and Coagulation Drug Products
HFD-180
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Pazzallo, September 26, 2002
DCE/lbal

Re: **NDA 21-372**
Palonosetron Hydrochloride Intravenous Injection, 0.25 mg
Original Submission

Dear Dr. Justice:

In accordance with 21 CFR 314.50, we are pleased to submit this original New Drug Application for Palonosetron Hydrochloride Intravenous Injection, 0.25 mg, for the prevention of acute and delayed nausea and vomiting associated with initial and repeated courses of emetogenic cancer chemotherapy, including highly emetogenic chemotherapy.

FDA acknowledged receipt of the user fee for this NDA on September 16, 2002. The user fee identification number is 4391.

As agreed during the pre-NDA meeting and in subsequent communications, the entire NDA is submitted in hard copy with the exception of Section 11, Case Report Tabulations, which is submitted electronically in the archival copy. To facilitate review, the following electronic files on compact disks (CDs) are attached.

- Proposed labeling in Word 97 (CD #1)
- NDA Summary, Section 3.0, in Word 97 (CD #1)
- Case Report Tabulations (PDF files), Section 11.0 (CD #2; CD #3)
- ISS database, SAS transport version 5 files (CD #4)
- ISE database, SAS transport version 5 files (CD #4)
- Rat (PALO-98-03) carcinogenicity study datafiles (CD #5)
- Mouse (PALO-99-18) carcinogenicity study datafiles (CD #6)
- Drug product stability data, including SAS transport version 5 files (CD #7)

Both drug substance and drug product manufacturing establishments are ready for pre-approval inspection at this time as described in the establishment information attached to the Form FDA 356h.

Consistent with discussion at the pre-NDA meeting, 18-month drug product stability data from the RP Scherer West, Inc., dba SP Pharmaceuticals manufacturing site is planned for submission during review in the March 2003 timeframe.

A letter appointing Dr. Craig Lehmann, August Consulting, as Authorized Representative for this NDA is attached to this cover letter. Dr. Lehmann is also cited on the Form FDA 356h in this capacity. Please contact him at 512-347-1755, fax 512-347-9375, regarding all matters pertaining to this NDA.

Patent information is also attached in this letter.

Please contact me at our corporate headquarters in Lugano, Switzerland, if I can be of assistance. My phone number is 011-41-91-985-2121.

Sincerely,

HELSINN HEALTHCARE SA

Dario Ceriani, M. Chem. Pharm.
Senior Manager Regulatory Affairs

Cy: Dr. Craig Lehmann Authorized Representative for the NDA (August Consulting)
Mr. Franco DeVecchi Sr., Authorized US Corporate Representative (VPCI Inc.)

Atch.: Letter appointing Dr. Lehmann as Authorized Representative for the NDA
Electronic files on CD with inventory (Archival copy only)
Patent Information