CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

21-372

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-372

11/7/02

Helsinn Healthcare SA
c/o August Consulting
Attention: Craig Lehmann, Pharm.D.
515 Capital of Texas Highway, Suite 150
Austin, TX 78746

Dear Dr. Lehmann:

We have received your new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Palonosetron Hydrochloride Intravenous Injection, 0.25 mg

Review Priority Classification: (S) Standard

Date of Application: September 26, 2002

Date of Receipt: September 27, 2002

Our Reference Number: NDA 21-372

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, we will file the application on November 26, 2002 in accordance with 21 CFR 314.101(a). If we file the application, the user fee goal date will be July 27, 2003.

Under 21 CFR 314.102(c), you may request an informal conference with this Division (to be held approximately 90 days from the above receipt date) for a brief report on the status of the review but not on the ultimate approvability of the application. Alternatively, you may choose to receive a report by telephone.

Please cite the NDA number listed above at the top of the first page of any communications concerning this application. Address all communications concerning this NDA as follows:

U.S. Postal Service/Courier/Overnight Mail:
Center for Drug Evaluation and Research
Division of Gastrointestinal and Coagulation Drug Products, HFD-180
Attention: Division Document Room, 6B-24
5600 Fishers Lane
Rockville, Maryland 20857

If you have any questions, call me at (301) 827-7310.

Sincerely,

{See appended electronic signature page}

/S/

Brian Strongin, R.Ph., M.B.A.
Regulatory Health Project Manager
Division of Gastrointestinal and
Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

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

/s/

Brian Strongin
11/7/02 01:16:40 PM

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

IND [redacted]

Helsinn Healthcare SA
Attention: Craig Lehmann (US Agent), Pharm.D.
515 Capital of Texas Hwy, Suite #150
Austin, TX 78746

Dear Dr. Lehmann:

Please refer to the meeting between representatives of your firm and FDA on January 30, 2001. The purpose of the meeting was to discuss the production of drug product registration batches for Palonosetron Injection and initiation of the drug product stability program for those batches.

The official minutes of that meeting are enclosed. You are responsible for notifying us of any significant differences in understanding regarding the meeting outcomes.

If you have any questions, call me at (301) 827-7310.

Sincerely,

{See appended electronic signature page}

/S/

Melodi McNeil
Regulatory Health Project Manager
Division of Gastrointestinal & Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure

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