

**Attachment One**

**PALO-99-03**

Clinical & Statistical Study Report: Volume 1.117, page 1

Synopsis: Volume 1.117, page 4

Protocol: Volume 1.118, page 5

List of Investigators: Volume 1.119, page 1

Related Publications: Volume 1.120, page 138

**Palo-99-04**

Clinical & Statistical Study Report: Volume 1.135, page 1

Synopsis: Volume 1.135, page 4

Protocol: Volume 1.136, page 4

List of Investigators: Volume 1.136, page 257

Related Publications: Volume 1.137, page 404

**Palo-99-05**

Clinical & Statistical Study Report: Volume 1.156, page 1

Synopsis: Volume 1.156, page 4

Protocol: Volume 1.157, page 5

List of Investigators: Volume 1.158, page 1

Related Publications: Volume 1.160, page 146

cc:

Draft: BKS/November 1, 2002

Final: BKS/November 1, 2002

Filename: reviews/Palonosetron Admin Review.doc

ADMINISTRATIVE REVIEW

-----  
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  
11/1/02 03:52:38 PM  
CSO

Redacted 14

pages of trade

secret and/or

confidential

commercial

information

\*\*\*\*\*  
\*\*\* TX REPORT \*\*\*  
\*\*\*\*\*

TRANSMISSION OK

TX/RX NO 2509  
CONNECTION TEL 915123479375  
CONNECTION ID  
ST. TIME 07/25 08:58  
USAGE T 02'20  
PGS. SENT 16  
RESULT OK



Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Drug Evaluation III

---

**FACSIMILE TRANSMITTAL SHEET**

---

**DATE: July 25, 2003****To:** Craig Lehmann (US Agent)**From:** Brian Strongin**Company:** Helsinn Healthcare SADivision of Gastrointestinal & Coagulation  
Drug Products**Fax number:** (512) 347-9375**Fax number:** (301) 443-9285**Phone number:** (512) 347-1755**Phone number:** (301) 827-7473**Subject:** Approval Letter for NDA 21-372. Enjoy!**Total no. of pages including cover:** 16**Comments:****Document to be mailed:**☐ YES☒ NO

THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED  
AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED  
FROM DISCLOSURE UNDER APPLICABLE LAW.

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.