

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
21-372/S008/S010

MEDICAL REVIEW(S)

**Division of Gastroenterology Products
Clinical Review**

Application Type NDA 21-372/S008, (b) (4) S010
Submission Date 3 June 2007

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Drug Aloxi® Palonosetron
Therapeutic Class 5HT³ Receptor Antagonist

Applicant Helsinn Healthcare SA
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515 Capital of Texas Highway
Austin, Texas 78746

Priority Designation S
Formulation Intravenous
Dosing Regimen 0.075 mg

Indication(s) Post operative nausea and
vomiting (PONV):

(b) (4)

Intended Population Adults

Reviewer Dr. Nancy F. Snow
Medical Officer
HFD-180

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