CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-372/S008/S010

MEDICAL REVIEW(S)

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Division of Gastroenterology Products
Clinical Review

Application Type	NDA 21-372/S008, (b) (4) S010
Submission Date	3 June 2007
PDUFA Goal Date	3 March 2008
Drug	Aloxi® Palonosetron
Therapeutic Class	$5HT^3$ Receptor Antagonist
Applicant	Helsinn Healthcare SA
Regulatory Contact	Dr. Craig Lehmann August Consulting, Inc 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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