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RESEARCH**

APPLICATION NUMBER:

208271Orig1s000

MEDICAL REVIEW(S)

CLINICAL REVIEW

Application Type	NDA
Application Number(s)	208,271
Priority or Standard	Standard
Submit Date(s)	6/19/2015
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Original PDUFA Goal Date	4/19/2016
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Division / Office	Division of Gastroenterology and Inborn Errors Products/ Office of Drug Evaluation III
Reviewer Name(s)	Dina J. Zand M.D.
Review Completion Date	June 2, 2016
Established Name	Methylnaltrexone bromide
(Proposed) Trade Name	Relistor®
Therapeutic Class	Peripherally acting mu-opioid receptor antagonist (PAMORA)
Applicant	Salix Pharmaceuticals, Inc
Formulation(s)	Oral Tablet
Dosing Regimen	3 tablets once daily (450 mg/day)
Indication(s)	Opioid-induced constipation in adult patients with chronic non- cancer pain
Intended Population(s)	≥18 years of age

Template Version: [March 6, 2009](#)

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