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APPLICATION NUMBER:

202107Orig1s000

MEDICAL REVIEW(S)

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CLINICAL REVIEW

Application Type	NDA
Application Number(s)	202107
Priority or Standard	Standard
Submit Date(s)	
Received Date(s)	April 18, 2011
PDUFA Goal Date	February 18, 2012
Division / Office	DMEP
Reviewer Name(s)	Zemskova Marina, MD
Review Completion Date	January 13, 2012
Established Name	Mifepristone
(Proposed) Trade Name	Korlym
Therapeutic Class	
Applicant	Corcept Therapeutics
Formulation(s)	Oral tablets
Dosing Regimen	300-1200 mg once a day
Indication(s)	Endogenous Cushing's syndrome
Intended Population(s)	Adults

Template Version: March 6, 2009

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