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APPLICATION NUMBER:

204427Orig1s000

<u>MEDICAL REVIEW(S)</u>

CLINICAL REVIEW

Application Type	NDA
Application Number	204,427
Priority or Standard	Standard
Submit Date	July 29, 2013
Received Date	July 29, 2013
PDUFA Goal Date	July 29, 2014
Division / Office	DDDP
Reviewer Name	Milena Lolic, M.D., M.S.
Review Completion Date	March 11, 2014
Established Name	Tavaborole solution 5%
Trade Name	Kerydin
Therapeutic Class	Oxaborole antifungal
Applicant	Anacor Pharmaceuticals Inc.
Formulation	Solution
Dosing Regimen	Daily for 48 weeks
Indication	Onychomycosis
Intended Population	Adults

Clinical Review
Milena Lolic, MD, MS
NDA 204,427
Kerydin (tavaborole) Topical Solution, 5%

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