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APPLICATION NUMBER:

207202Orig1s000

CLINICAL REVIEW(S)

Clinical Review
Daniel J. Lee, M.D.
NDA 207202
aripiprazole + MIND1 system (Abilify Mycite)

CLINICAL REVIEW

Application Type	NDA
Application Number(s)	207202
Priority or Standard	Standard
Submit Date(s)	04/21/2017
Received Date(s)	04/21/2017
PDUFA Goal Date	10/21/2017
Division/Office	DPP/ODE1
Reviewer Name(s)	Daniel J. Lee, MD
Review Completion Date	10/26/2017
Established Name	aripiprazole
(Proposed) Trade Name	Abilify Mycite
Applicant	Otsuka Pharmaceutical Development and Commercialization, Inc
Formulation(s)	Oral tablet, 2 mg, 5 mg, 10 mg, 15 mg, 20 mg, 30 mg
Dosing Regimen	once daily
Proposed Indication(s)	(b) (4)
Intended Population(s)	(b) (4)
Recommendation on Regulatory Action	Approve
Recommended Indication(s) (if applicable)	schizophrenia, acute treatment of manic and mixed episodes associated with bipolar I disorder, bipolar I maintenance, and adjunctive treatment of major depression

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