

Clinical Pharmacology/Biopharmaceutics Review

PRODUCT (Generic Name):	Aripiprazole
PRODUCT (Brand Name):	Abilify
DOSAGE FORM:	Tablets
DOSAGE STRENGTHS:	2MG; 5MG 10MG; 15MG; 20MG; 30MG;
NDA:	21436/S017
NDA TYPE:	Labelling
SUBMISSION DATE:	March 23, 2007
SPONSOR:	Otsuka
REVIEWER	Andre Jackson

REVIEW OF LABELLING

OVERALL LABEL COMMENT:

THE LABEL PRESENTED IN THIS REVIEW IS THE FIRM'S PROPOSED PLR FORMAT WITH REVIEWER COMMENTS, INSERTIONS, AND DELETIONS. INCLUSION OF THE INSERTIONS AND DELETIONS WOULD MAKE THIS LABEL ACCEPTABLE TO OCP

(b) (4)

10 Page(s) of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page



SIGNATURES

Andre Jackson _____

Reviewer, Psychopharmacological Drug Section, DCP I
Office of Clinical Pharmacology and Biopharmaceutics

RD/FTinitialized by Raman Baweja, Ph.D._____

Team Leader, Psychiatry Drug Section, DCP I
Office of Clinical Pharmacology
cc: NDA 21-436/S017, HFD-860(Mehta, Baweja, Jackson)
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/s/

Andre Jackson
9/10/2007 10:44:08 AM
BIOPHARMACEUTICS

Raman Baweja
9/10/2007 11:59:58 AM
BIOPHARMACEUTICS