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
SIGNATURES

Andre Jackson__________________________
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

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

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