

Clinical Pharmacology/Biopharmaceutics Review

BPCA Summary Review

PRODUCT (Generic Name):	Aripiprazole
PRODUCT (Brand Name):	Abilify
DOSAGE FORM:	Tablets
DOSAGE STRENGTHS:	10mg, 20mg, 30 mg,
NDA:	21436/S-017
NDA TYPE:	Supplement for Schizophrenia in children and adolescents in response to FDA Pediatric Written Request Letter
SUBMISSION DATE:	March 23, 2007
SPONSOR:	Otsuka
OND DIVISION:	Psychiatry

EXECUTIVE SUMMARY

Aripiprazole is currently indicated in the treatment of acute schizophrenia in adults. In a previous study conducted in children and adolescents with conduct disorder, doses up to 15 mg QD were well tolerated. However, the safety and tolerability of doses higher than 15 mg had not been determined in children and adolescents. Results from the current dose escalation multiple dose study indicates that doses up to 30 mg/day are safe and tolerated in children and adolescents .

This sNDA includes a dose escalation multiple dose study to final targeted doses of 20 mg, 25 mg and 30 mg of aripiprazole.

The overall conclusion from the pharmacokinetic studies in adolescents and children was:

- The pharmacokinetics are linear in children and adolescents from 20mg to 30 mg.

RECOMMENDATION

From a Clinical Pharmacology/Biopharmaceutics perspective this sNDA is acceptable with the labeling changes suggested by the reviewer.

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/s/

Andre Jackson

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