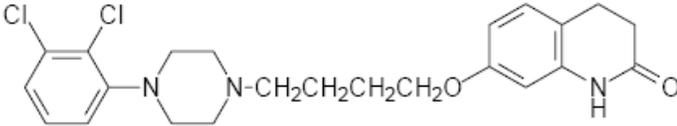


**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
21-436/S-018

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW #1		1. ORGANIZATION ONDQA/DPE/Branch VII		2. NDA NUMBER 21-436	
3. NAME AND ADDRESS OF APPLICANT (<i>City and State</i>) Otsuka America Pharmaceutical, Inc. 2440 Research Blvd. Rockville, MD 20850				4. AF NUMBER	
				5. SUPPLEMENT (S) NUMBER(S) DATES(S)	
6. NAME OF DRUG Abilify®		7. NONPROPRIETARY NAME Aripiprazole		SE1-018	5-16-2007
8. SUPPLEMENT PROVIDES FOR: Treatment of (b) (4).				9. AMENDMENTS DATES	
10. PHARMACOLOGICAL CATEGORY Schizophrenia		11. HOW DISPENSED RX <input checked="" type="checkbox"/> OTC		12. RELATED IND/sNDA/DMF 21-713/S-013 (8-28-2007) 21-729/S-005 (8-28-2007) 21-866/S-005 (8-28-2007)	
13. DOSAGE FORM(S) Tablets (21-436) Oral Solution (21-713) Orally Disintegrating Tablet (21-729) Injection (21-866)		14. POTENCY 2 mg, 5 mg, 10 mg, 15 mg, 20 mg & 30 mg 1 mg/mL (50 mL, 150 mL & 480 mL bottles) 10 mg, 15 mg, 20 mg & 30 mg 9.75 mg/1.3 mL			
15. CHEMICAL NAME, STRUCTURE, MOLECULAR FORMULA AND MOLECULAR WEIGHT: 7-[4-[4-(2,3-dichlorophenyl)-1-piperazinyl]butoxy]-3,4-dihydrocarbostyryl C ₂₃ H ₂₇ Cl ₂ N ₃ O ₂ 448.39					
				16. RECORDS AND REPORTS CURRENT YES_ NO REVIEWED YES_ NO	
17. COMMENTS This bundled efficacy supplement provides for the use of Abilify in the treatment of (b) (4). The applicant has not provided any new CMC information other than some minor editorial changes to how supplied section of the labeling. The applicant has submitted a claim for categorical exclusion from filing an environmental assessment document under 21 CFR 25.31 (b); the expected introduction concentration (EIC) of the substance at the point of entry into the aquatic environment will be below 1 part per billion. The applicant's claim is found to be acceptable.					
18. CONCLUSIONS AND RECOMMENDATIONS Provided information is found to be adequate. This supplement and others in this bundle are recommended for approval from the standpoint of chemistry, manufacturing and controls.					
19. REVIEWER					
NAME Nallaperumal Chidambaram, Ph.D.		SIGNATURE			DATE COMPLETED 10-15-2007
DISTRIBUTION	ORIGINAL NDA	DIVISION FILE	Reviewer: N. Chidambaram Ph.D.	CSO: W. Bender HFD-130	Branch Chief: James Vidra Ph.D.

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

/s/

Nallaperumal Chidambaram
10/15/2007 04:30:42 PM
CHEMIST

Jim Vidra
10/16/2007 03:09:53 PM
CHEMIST