DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-436 / S-016
NDA 21-713 / S-010
NDA 21-729 / S-002
NDA 21-866 / S-003 / S-002

Otsuka Maryland Research Institute, Inc.
Attention: Kusuma Mallikaarjun, Ph.D.
2440 Research Boulevard
Rockville, MD 20850

Dear Dr. Mallikaarjun:

Please refer to your supplemental new drug applications dated November 14, 2006, received November 15, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Abilify (aripiprazole) Tablets, DISCMELT, Oral Solution, and Injection for Intramuscular Use.

These "Changes Being Effected" supplemental new drug applications provide for the addition of the terms oropharyngeal spasm, grand mal seizure and jaundice under the **Other Events Observed During the Postmarketing evaluation of Aripiprazole** subsection of the **ADVERSE REACTIONS** section of Abilify labeling.

We have completed our review of these supplemental new drug applications and they are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on November 14, 2006 (copy attached).

Please note that the final printed labeling included with your additional supplemental application (NDA 21-866 / S-002) submitted on November 3, 2006 (amended on November 17, 2006) has been superseded by these applications. Although it will not be reviewed, it will be retained in our files.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, email CAPT Steven D. Hardeman, R.Ph., Chief, Project Management Staff at Steven.Hardeman@FDA.HHS.GOV.

Sincerely,

{See appended electronic signature page}

Thomas Laughren, M.D.
Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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

/s/

Thomas Laughren
9/25/2007 03:30:43 PM